#### **Statistical Analysis Plan**

**Study ID: 213362** 

**Official Title of Study:** An Open-Label, Randomized-Sequence, Multicenter, Single-Crossover Study to Assess the Relative Bioavailability and Bioequivalence of Niraparib Tablet Formulation Compared to Niraparib Capsule Formulation in Patients With Advanced Solid Tumors

**NCT ID:** NCT03329001

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## Statistical Analysis Plan

#### AN OPEN-LABEL, RANDOMIZED-SEQUENCE, MULTICENTER, SINGLE-CROSSOVER STUDY TO ASSESS THE RELATIVE BIOAVAILABILITY AND BIOEQUIVALENCE OF NIRAPARIB TABLET FORMULATION COMPARED TO NIRAPARIB CAPSULE FORMULATION IN PATIENTS WITH ADVANCED SOLID TUMORS

GSK/TESARO Protocol Number:	213362/3000-01-004
Protocol Version:	6.0 (Amendment 5)
Compound Number:	GSK 3985771, MK-4827
Study Drug Name:	Niraparib
Phase:	Phase 1
Methodology:	Open-Label, Cross-Over
Sponsor:	TESARO, GSK Company
Analysis Plan Date:	12 July 2023
Analysis Plan Version:	Version 7.0

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## SPONSOR SIGNATURE PAGE

Protocol Title:	AN OPEN-LABEL, RANDOMIZED-SEQUENCE, MULTICENTER, SINGLE-CROSSOVER STUDY TO ASSESS THE RELATIVE BIOAVAILABILITY AND BIOEQUIVALENCE OF NIRAPARIB TABLET FORMULATION COMPARED TO NIRAPARIB CAPSULE FORMULATION IN PATIENTS WITH ADVANCED SOLID TUMORS
Protocol Number:	3000-01-004
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By signing this document, I acknowledge that I have read the document and approve of the planned statistical analyses described herein. I agree that the planned statistical analyses are appropriate for this study, are in accordance with the study objectives, and are consistent with the statistical methodology described in the protocol, clinical development plan, and all applicable regulatory guidance and guidelines.

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# LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
AE(s)	adverse event(s)
AESI	Adverse Events of Special Interest
ALT	alanine aminotransferase
ALP	alkaline phosphatase
AML	Acute Myeloid Leukemia
AST	aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical
AUC	area under the plasma concentration-time curve
BA	bioavailability
BE	bioequivalence
BMI	body mass index
CI	confidence interval
CL/F	apparent total body clearance
C <sub>max</sub>	Maximum observed plasma concentration
CSR	clinical study report
CV	coefficient of variation
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic case report form
EOT	end-of-treatment
FE	food effect
ICF	informed consent form
ICH	International Council for Harmonisation
LLN	lower limit of normal
LS mean	least-squares mean
CCI	
MDRP	Medical Data Review Plan
MDS	Myelodysplastic Syndromes
MedDRA	Medical Dictionary for Regulatory Activities
NCI CTCAE	National Cancer Institute Common Terminology Criteria for Adverse Events
PI	Package Insert
РК	pharmacokinetics
PT	preferred term

Abbreviation	Definition
Q1	first quartile
Q <sub>3</sub>	third quartile
QD	one time per day
SAE	serious adverse event
SAP	statistical analysis plan
SD	standard deviation
SOC	system organ class
t <sub>1/2</sub>	termination elimination half-life
TEAE	treatment-emergent adverse event
t <sub>max</sub>	Time to reach C <sub>max</sub>
US	United States
ULN	upper limit of normal
Vz/F	apparent terminal volume of distribution
WHO	World Health Organization

## 1. Information from the Study Protocol

## 1.1. Introduction and Objectives

#### 1.1.1.Introduction

The approved niraparib drug product is an immediate release hard gelatin capsule dosage form that contains 100 mg of niraparib per capsule. The labelled starting dose for niraparib is 300 mg. Facilitating this dose requires the administration of three 100 mg capsules.

It is the Sponsor's intent to introduce a tablet dosage form that provides the 100 mg, 200 mg and 300 mg dose in single dose strength tablets to reduce the pill burden on the patients.

To this end, the Sponsor has developed a tablet dosage form with the specific intent to provide comparable performance to the approved capsule dosage form. The formulation and manufacturing process of the tablet were selected to produce a tablet with comparable in-vitro performance to the capsule.

This study is an open-label Phase 1 study to evaluate the relative bioavailability (BA) and bioequivalence (BE) of niraparib administered as a tablet formulation compared to the reference capsule formulation manufactured by the same process as currently marketed in the United States. Specifically, a 300 mg niraparib tablet will be compared to three (3) niraparib capsules ( $3 \times 100$  mg). In addition, this study will evaluate the effect of a high-fat meal on the pharmacokinetics (PK) of the niraparib 300 mg tablet formulation (Stage 3). The Extension Phase of this study is to enable patients enrolled in the study to continue to receive treatment with niraparib if they are tolerating it and, in the Investigator's opinion, may receive benefit.

#### 1.1.2. Study Objectives

The primary objectives of this study are as follows:

- Stage 1: To obtain preliminary assessment of the relative bioavailability of 300 mg niraparib administered as a tablet versus capsule formulation and to estimate the intra-subject variability of niraparib PK
- Stage 2: To evaluate if the tablet formulation  $(1 \times 300 \text{ mg})$  of niraparib is bioequivalent to the capsule formulation  $(3 \times 100 \text{ mg})$
- Stage 3: To assess the effect of a high-fat meal on niraparib PK following a single 300 mg dose of the tablet formulation.

The secondary objectives of this study are as follows:

- Stage 1, Stage 2, and Stage 3: To evaluate the safety of single dose niraparib when administered as a tablet or capsule formulation in patients with advanced solid tumors
- Extension Phase: To evaluate the safety of continuously dosed niraparib in patients with advanced solid tumors.

The exploratory objectives of this study are as follows:



1.1.3. Scope and Revision History

A separate PK analysis plan will be written to address the PK objectives and data for this study.

This statistical analysis plan (SAP) is designed to outline the methods to be used in the analyses of non-pharmacokinetic study data. Patient populations to be used for analyses, data handling rules, statistical methods, and formats for data presentation are identified and provided. The statistical analyses and summary tabulations described in this SAP will provide the basis for the results sections of the clinical study report (CSR) for this trial.

The SAP will outline any differences in the currently planned analytical objectives relative to those planned in the study protocol.

The SAP is a living document that will be created during the trial conduct. It will be maintained throughout the lifecycle of the trial. Important changes following approval of SAP v1.0 will be tracked in this section.

The following changes have been implemented in the Appendix containing shells of the Planned			
Statistical Tables, Listings and Figures.			

Table/Listing		
Number	Correction	<b>Reason for Correction</b>
Table 14.1.1d	Footnotes [2] and [3] added to the table and in the	Clarification why two patients have
	footer.	been double counted in Screening.
Table 14.1.3.1c	Footnote added to the shell.	Clarification added to the output for
		Extension Phase reporting effort.
Table 14.1.4d	Added "Missing" category to Cancer stage and	Data collected has missing
	Number of prior lines of therapy.	information on the eCRF.
Table 14.3.1.1.2d	Removed "Any COVID-19 related TEAE".	Removing a duplicate entry row.
Table 14.3.1.14d	Removed "System Organ Class" from the table.	Line not required for the table in
		question as summary by Preferred
		Term is of interest.
Table 14.3.1.16.1c	Table shell added.	Table added for final study disclosure
		purposes of Extension Phase data.
Table 14.3.1.16d	Added footnote:	Added to reflect data collection and
	"NOTE: Deaths due to progressive disease were	management process and align with
	not collected as adverse events."	Stage 1 and Stage 2 programming
		practice.
Table 14.3.1.2.1.1d	Footnote added:	Added as per reviewer request.
	Note: COVID-19 Case Diagnosis is based on	
	WHO Definition as of DDMMMYYYY.	
Table 14.3.1.20d	Footnote [1] updated to:	Clarification of footnote explaining
Table 14.3.1.21d	"Note: Extension Phase for all Stages of TABLET	calendar placement of the Stages 1-3
Table 14.3.1.22d	study overlapped with COVID-19 pandemic, with	during COVID-19 pandemic.
	all Stage 3 patients commencing treatment for the	
	Extension Phase on or after 02JUN2021 placing	
	the AE onset during the pandemic, while last	
	patient commenced treatment for Stages 1 and 2	
	on 14MAY2018 and 05DEC2019, respectively,	
	placing their first Extension Phase treatment dose	
	administration prior to the start of the pandemic,	
	as defined by WHO as of 20MAR2020, with	

Table/Listing		
Number	Correction	<b>Reason for Correction</b>
	patients across all Stages ongoing until DDMMMYYYY."	
	Table titles updated to:Table 14.3.1.20d Summary of Incidenceof COVID-19 Related Adverse EventsOver Time (Safety Population in theStage 3 PK Phase)Table 14.3.1.21d Summary of Incidenceof COVID-19 Related Adverse EventsOver Time by Gender (Safety Populationin the Stage 3 PK Phase)Table 14.3.1.22d Summary of Incidenceof COVID-19 Related Adverse EventsOver Time by Gender (Safety Populationin the Stage 3 PK Phase)Table 14.3.1.22d Summary of Incidenceof COVID-19 Related Adverse EventsOver Time by Age Group (SafetyPopulation in the Stage 3 PK Phase)	Clarification of titles to reflect the reporting effort of COVID-19 related AE incidence rates.
Table 14.4.1c	Summary table of Important Protocol Deviations for Open-Label Extension Phase added.	Added upon request from study team for CSR reporting purposes.
Table 14.4.1d	Summary table of Important Protocol Deviations for the PK Phase Occurring Through End of Treatment (Safety Population in the Stage 3 PK Phase). Footnotes and corresponding references added to the table	Added upon request from study team for CSR reporting purposes. Added upon request for clarification.
Listing 16.2.2.2c	Footnote [1] updated to: "Note: Extension Phase for all Stages of TABLET study overlapped with COVID-19 pandemic, with all Stage 3 patients commencing treatment for the Extension Phase on or after 02JUN2021 placing the AE onset during the pandemic, while last patient commenced treatment for Stages 1 and 2 on 14MAY2018 and 05DEC2019, respectively, placing their first Extension Phase treatment dose administration prior to the start of the pandemic, as defined by WHO as of 20MAR2020, with patients across all Stages ongoing until DDMMMYYYY.	Clarification of footnote explaining calendar placement of the Stages 1-3 during COVID-19 pandemic.
Listing 16.2.5.1d	Added "PK Dose 1" and "PK Dose 2" date columns to the listing.	Added columns to the shells to align Stage 3 reported outputs with those reported in Stages 1 and 2.
Listing 16.2.5.3d	Moved "Patient Number" into header row. Added "Rel Day [1]" column and [1] footnote: "[1] Relative to first dose during the PK Phase."	For readability purposes.Added to the shells to align Stage 3reported outputs with those reportedin Stages 1 and 2.
Listing 16.2.5.5d	Columns "Full Dose Taken?", "If N, how much consumed?", "Reason for Change", "Nausea within specified time of dose?" removed from the listing.	Columns removed from Stage 3 listing as not applicable, as per study design.
Listing 16.2.8.1.1d and associated repeat listings	Programming note added regarding location of "Patient Number" in the outputs.	Depending on spacing/information displayed, "Patient Number" may be displayed in the header row after

Table/Listing		
Number	Correction	Reason for Correction
		"Treatment Sequence" in order to aid
		readability of the listing
Listing 16.2.8.2d	Removed "Heart Rate" column.	Data collected under "Pulse" in
2.00.00		Stage 3, added "Heart Rate" to the
		shells in error.
Listing 16.2.8.5d	Added text to footnote: "in the PK Phase"	Previously missing in error.
Listing 16.2.9.2c	Footnote [1] updated to: "Note: Extension Phase for all Stages of TABLET study overlapped with COVID-19 pandemic, with all Stage 3 patients commencing treatment for the Extension Phase on or after 02JUN2021 placing the AE onset during the pandemic, while last patient commenced treatment for Stages 1 and 2 on 14MAY2018 and 05DEC2019, respectively,	Clarification of footnote explaining calendar placement of the Stages 1-3 during COVID-19 pandemic.
	placing their first Extension Phase treatment dose administration prior to the start of the pandemic, as defined by WHO as of 20MAR2020, with patients across all Stages ongoing until DDMMMYYYY.	
Listing 16.2.2c	Listing updated to include only "Important"	Updated upon request from study
	protocol deviations; title updated to reflect change. "Protocol Deviation Severity" column dropped.	team for CSR reporting purposes. Obsolete field.
Listing 16.2.2.1d	Listing updated to include only "Important"	Updated upon request from study
	protocol deviations; title updated to reflect change.	team for CSR reporting purposes.
Section 1.2	Definition of data cut has been amended.	Definition changed to reflect study reporting requirements upon request from study team.
Table 14.1.1c	Table has been updated to include Starting Dose	Updated upon request from study
	(100 mg, 200 mg and 300 mg) and categorization by Stage (TABLET Stages 1, 2 and 3).	team for CSR reporting purposes.
Table 14.1.10c	Table added for Extension Phase.	Added upon request from study team for CSR reporting purposes.
Extension Phase tables	Treatment arm labels updated to be TABLET, CAPSULE and OVERALL, for consistency, throughout the shells	Updated for consistency.
Table 14.3.1.1.1c	Table shell spelled out for Extension Phase reporting effort, including COVID-19 summary categories.	Updated upon request from study team for CSR reporting purposes.
Table 14.3.1.1.1.1c	New repeat table added for Extension Phase.	Added upon request from study team for CSR reporting purposes.
Table 14.3.1.11.1a	New table added for PK Stage 1.	Required for plain text summary reporting effort.
Table 14.3.1.11.1b	New table added for PK Stage 2.	Required for plain text summary reporting effort.
Table 14.3.1.11.1c	New table added for Extension Phase.	Required for plain text summary reporting effort.
Table 14.3.1.11.1d	New table added for PK Stage 3.	Required for plain text summary reporting effort.
Table 14.3.1.23.1a	New table added for PK Stage 1.	Required for disclosure reporting effort.

Table/Listing		
Number	Correction	Reason for Correction
ivumbei		
Table 14.3.1.23.1b	New table added for PK Stage 2.	Required for disclosure reporting
T 11 1421221		effort.
Table 14.3.1.23.1c	New table added for Extension Phase.	Required for disclosure reporting
Table 14 2 1 22 1d	New table added for DV Stage 2	Provinced for disclosure reporting
14010 14.3.1.23.10	New table added for FK Stage 5.	effort
Table 14.3.1.23.2a	New table added for PK Stage 1.	Required for plain text summary
		reporting effort.
Table 14.3.1.23.2b	New table added for PK Stage 2.	Required for plain text summary
		reporting effort.
Table 14.3.1.23.2c	New table added for Extension.	Required for plain text summary
		reporting effort.
Table 14.3.1.23.2d	New table added for PK Stage 3.	Required for plain text summary
T 11 142114		reporting effort.
1 able 14.3.1.14c	Pootnotes omitted as not applicable for Extension	Updated for clarification.
Table 14 3 1 20c	Footnote undated to reflect reporting period for	Undated for clarification
14010 17.3.1.200	overall study population in Extension Phase	
Table 14.3.1.21c	Table added for Extension Phase reporting.	Updated upon request from study
_		team for CSR reporting purposes.
Table 14.3.1.22c	Table added for Extension Phase reporting.	Updated upon request from study
		team for CSR reporting purposes.
Table 14.3.4.1c	'Number of Cycles' changed to 'Maximum	Updated to reflect changes requested
	number of cycles'. Labels for dose	by study team.
	interruptions/reductions/re-escalations modified	
	for clarity.	
	duration (months)' and 'Dose intensity' added to	
	output	
Table 14.3.4.5.1c	Table added for Extension Phase reporting.	Updated upon request from study
		team for CSR reporting purposes.
Listing 16.2.2.2c	Listing added for Extension Phase reporting.	Updated upon request from study
		team for CSR reporting purposes.
Listing 16.2.5.1.1c	Listing added for Extension Phase reporting.	Updated upon request from study
		team for CSR reporting purposes.
Listing 16.2.5.5c	"I ablets remaining" and "Was Full Dose Taken?"	Data not collected consistently for
Listing 16261a	"Visit" column dropped	Visit data not collected only data of
Listing 10.2.0.10	visit column dropped.	assessment
	"Tumor Type" column added.	Added upon request from study team
		for CSR reporting purposes.
Listing 16.2.7.1c	Listing shell spelled out for Extension Phase	Updated upon request from study
_	reporting effort.	team for CSR reporting purposes.
	'Dose at onset of AE' variable dropped from	Data not collected consistently for
	listing.	production of reliable results.
Listing 16.2.7.2c	Listing added for Extension Phase reporting.	Added upon request from study team
		tor CSR reporting purposes
Listing 16.2.9.2c	Listing shell spelled out for Extension Phase	Updated upon request from study
Figure 1/2/2/2	Figure shell added for Extension Dhase reporting	Lindated upon request from study
1 Iguit 17.3.7.3.10	effort.	team for CSR reporting purposes.

## Table 1 Revision History

SAP	Protocol	eCRF	
version	version	version	Changes from previous version
1.0	2.0	5.0 (26FEB2018)	First Draft
2.0	4.0	8.0 (12FEB2019)	Major changes to this draft of the SAP include the following:
			Incorporate changes based on amended protocol.
			Modify Stage 2 analysis of AEs to accommodate the increase in washout time between Period 1 and Period 2 for Stage 2.
			For the Extension Phase, specify that analysis will be performed by formulation and overall to accommodate allowance of both tablet and capsule formulation in the Extension Phase.
			Define the BA/BE evaluable population and add demographic and baseline characteristic summaries for this population.
			Clarify definition of concomitant medications and add additional table for Stage 2 to analyze only medications taken during the PK collection period.
			Clarifications to mock table and listing shells (e.g., numbering, footnotes).
3.0	5.0	10.0 (31JUL2019)	Major changes to this draft of the SAP include the following:
			• Incorporate changes based on amended protocol, including:
			<ul> <li>Updated numbers of patients enrolled to account for non-evaluability.</li> </ul>
			<ul> <li>Specification of reasons for non-evaluability for the analysis of bioequivalence.</li> </ul>
			• Focus Extension Phase laboratory summaries on select laboratory assessments hemoglobin, neutrophils, platelets, bilirubin, creatinine, AST, and ALT).
4.0	6.0	11.0 (16APR2020)	Major changes to this draft of the SAP include the following:
			• Incorporate changes based on amended protocol, to address the objectives for Stage 3 of the study.
			• Addition of sections relating to COVID-19 reporting.
5.0	6.0	13.0 (17MAR2021)	Primary changes to this draft associated with addition of Important Protocol Deviation table and updates to the associated listing to reporting effort.
			Minor updates to align Stage 1, 2 and 3 TLFs with shells, and associated update to Protocol Deviation reporting, as per the SAP.

SAP version	Protocol version	eCRF version	Changes from previous version
6.0	6.0	13.0 (17MAR2021)	Primary change to this draft of the SAP is change of the data cut for reporting of final Stage 3 analysis.
			Minor update to footnotes of Important Protocol Deviation summary table.
			Minor update to Section 5 formatting.
7.0	6.0	14.0 (17NOV2021)	Minor updates to template output/column header and title formatting to align with produced output header and title formatting.
			CRF versions updated to align with CRF booklet version upgrades starting from SAP version 4.0 onwards.
			COVID-19 related output shell added for Extension phase.
			Definitions of exposure and compliance derivations expanded to include dose intensity.
			Additional tables and listings have been added/modified for Extension Phase; disclosure and plain language summary reporting tables have been added across all study stages.
			Section 3.2 'Dose at onset of AE' has been removed from AE listings; output shells added for adverse event reporting in the Extension Phase/to cover time between end of PK Phase and start of Extension Phase.
			Section 2 updated to include definition for dose intensity in exposure table for Extension Phase.
			Section 4.4.2 updated AE classification for PK Period 1 for Stage 3.

## 1.2. Study Design

#### 1.2.1. Synopsis of Study Design

This is a multicenter, open-label study in patients with advanced solid tumors. This is a 3-stage, randomized-sequence, single-crossover study to assess the relative BA and BE of niraparib tablet formulation relative to the capsule formulation. In addition, Stage 3 of the protocol is a single cohort, randomized-sequence, 2 period, single dose, crossover study to assess effect of food on the PK of the niraparib tablet formulation.

Pharmacokinetics (PK) Phase: In Stages 1 and 2, patients will be randomized 1:1 to receive tablet formulation followed by capsule formulation or capsule formulation followed by tablet formulation. In Stage 3, patients will be randomized 1:1 to receive tablet formulation in a fasted state followed by tablet taken with a high-fat meal, or by tablet taken with a high-fat meal followed by tablet formulation taken in a fasted state.

Statistical Analysis Plan

Stage 1: Following an 8-hour fast on Day 1, patients will receive a single dose of the formulation (tablet  $[1 \times 300 \text{ mg}]$  or capsule  $[3 \times 100 \text{ mg}]$ ) followed by a 7-day (+1 day) Washout/PK period, followed by a dose of the alternate formulation also in a fasted state, followed by a 7-day (+1 day) Washout/PK period for Stage 1 of the study followed by a dose of the alternate formulation also in a fasted state, followed by a 7-day (+1 day) Washout/PK period a 7-day Washout/PK period. Patients receiving the tablet in the first treatment period will receive the capsules in the second treatment period and vice versa (Figure 1). Extensive PK sampling will be carried out after niraparib dosing.

Stage 2: Following an 8-hour fast on Day 1, patients will receive a single dose of the formulation (tablet  $[1 \times 300 \text{ mg}]$  or capsule  $[3 \times 100 \text{ mg}]$ ) followed by a 14-day (+/- 4 days) Washout/PK period followed by a dose of the alternate formulation also in a fasted state, followed by a 7-day Washout/PK period. Patients receiving the tablet in the first treatment period will receive the capsules in the second treatment period and vice versa (Figure 1). Extensive PK sampling will be carried out after niraparib dosing.

Stage 3: In Period 1, patients will receive a single 300 mg niraparib tablet either following a 10-hour fast or directly following consumption of a high-fat meal, followed by a 14-day (+4 days) PK sampling and Washout period. In Period 2, patients will be crossed over to receive a single 300 mg niraparib tablet in a fasted state or with a high-fat meal, followed by a 7-day PK sampling period. All patients will fast for a minimum of 4 hours post-dose in both periods. Patients receiving the tablet in the fasted state in the first treatment period will receive the tablet with a high-fat meal in the second treatment period and vice versa.

In the rare instance where a delay of the entire PK Period 2 is needed for any reason beyond the 4 day window specified above the site must contact the Sponsor's medical monitor to discuss the patient circumstances, the Sponsor will decide if the patient can continue with PK Period 2 with a delay. Similarly, should the laboratory results on Day 15 (D15) (the day of niraparib administration in PK Period 2) show changes in organ function such that the original inclusion criteria for laboratory values are no longer met, or in the event of a significant change of patient's clinical status as judged by the Investigator, the site must consult with the Sponsor to discuss the patient's continued participation in PK Period 2. Note that sites need not wait for the pre-dose laboratory results to begin PK Period 2, but rather consult the Sponsor once the results are available as needed. In Stage 2, patients who experience emesis within 9 hours of dosing or who miss a critical PK sample (such as the last PK sample on Day 8 in each period) will be discontinued from the PK Phase and will be allowed to be screened for the Extension Phase. In Stage 3, patients who experience emesis within 10 hours of dosing will be discontinued from the PK Phase and will be allowed to be screened for the Extension Phase. Patients who miss sufficient samples to render calculation of AUC unreliable will be discontinued from the PK Phase; those that meet other criteria for continued niraparib therapy will be eligible to be screened for the Extension Phase.

For Stage 1, the PK parameters that will be estimated include area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUC<sub>0-t</sub>), area under the plasma concentration-time curve from time 0 extrapolated to infinity (AUC<sub>0- $\infty$ </sub>), apparent total body clearance (CL/F), maximum observed plasma concentration (C<sub>max</sub>), time to reach C<sub>max</sub> (t<sub>max</sub>), termination elimination half-life (t<sub>1/2</sub>), apparent terminal volume of distribution (Vz/F) and BA of tablet formulation relative to the capsule formulation based on AUC<sub>0-t</sub>, AUC<sub>0- $\infty$ </sub>, and C<sub>max</sub>. Relative bioavailability will be assessed based on the ratio of geometric least-squares (LS) means of the test (tablet) to reference

(capsule). Additionally, the pharmacokinetics of CC (Stage 1 only).

will be determined

For Stage 2, the same PK parameters as above will be estimated. To conclude bioequivalence, the 90% confidence interval (CI) of the ratio of geometric LS means of the test (tablet) to reference (capsule) product should be within 0.800 - 1.250 (80% - 125%) for AUC<sub>0-∞</sub>, AUC<sub>0-t</sub>, and C<sub>max</sub>.

For Stage 3, the same PK parameters as above will be estimated. In addition,  $t_{lag}$ , the time from administration of the dose to the first quantifiable concentration, will be determined, and  $t_{max}$  will be compared between the fed and fasted states. The relative bioavailability of the 300 mg niraparib tablet administered with a high-fat meal relative to fasted dosing will be based on the ratio of geometric LS means of AUC<sub>0-t</sub>, AUC<sub>0-∞</sub>, and C<sub>max</sub>.

Additional PK parameters may be estimated (e.g., residual area), if deemed appropriate.

Extension Phase: When patients complete the PK Phase of the study (at least 7-days from the beginning of PK Period 2), they may be eligible to participate in the Extension Phase following review of the Extension Phase inclusion criteria and completion of the required Extension Phase screening assessments. The starting dose of niraparib in the Extension Phase will be based on the patient's baseline actual body weight or platelet count. Patients with a baseline actual body weight of >77 kg and screening platelet count of  $\geq$ 150,000/µL (obtained after completion of the PK Phase, as part of Extension Phase screening) will take one 300 mg strength tablet or  $3 \times 100$  mg tablet/capsules at each dose administration (once a day [QD]). Patients with a baseline actual body weight of <77 kg or screening platelet count of  $<150,000/\mu$ L will take one 200 mg strength tablet or  $2 \times 100$  mg tablet/capsules at each dose administration (QD). For patients whose initial starting dose is 200 mg QD, escalation to 300 mg QD is permitted after 2 cycles of therapy if no treatment interruption or discontinuation was required during the first 2 cycles of Extension Phase therapy and after approval from the Sponsor. Additional dose modifications will not be based upon changes in the patient's actual body weight during study participation. If laboratory values at the beginning of Extension Phase are outside of the range specified in the inclusion criteria, the patient may continue to participate in the study only upon Sponsor approval with consideration for an appropriately reduced dose. Should a patient start the Extension Phase at 100 mg, consideration may be given to escalate to 200 mg after 2 cycles of therapy if no treatment interruption or discontinuation was required during the first 2 cycles of Extension Phase therapy and after approval from the Sponsor.

Patients have up to 28 days (21 days for Stage 3 only; up to 28 days may be acceptable following discussion between the Sponsor and Investigator) after completion of the PK Phase to complete the screening assessments and the Extension Phase Screening Visit.

A tumor assessment is to be performed prior to the first dose of the Extension Phase (pre-Extension Phase). The pre-Extension Phase tumor assessment need not be completed if the baseline tumor assessment was performed  $\leq$  56 days before the first dose of the Extension Phase.

The Cycle 1/Day 1 Visit can occur on the same day as the Extension Phase Screening Visit, dependent upon availability of radiographic results obtained  $\leq$  56 days of the first planned dose in the Extension Phase. If the Extension Phase Screening Visit and the Cycle 1/Day 1 Visit occur on the same day, the clinical laboratory results will be reviewed by the study personnel prior to study drug administration to

ensure eligibility. At the Cycle 1/Day 1 Visit, patients will undergo safety assessments and will receive study drug supply for the duration of 1 cycle (300 mg or 200 mg tablets of niraparib for QD dosing or  $3 \times 100$  mg or  $2 \times 100$  mg tablet/capsules of niraparib for QD dosing, depending on availability). It is preferred that patients remain on the same formulation (tablet versus capsule) throughout the Extension Phase. Patients will return on the first day of every treatment cycle ( $28 \pm 7$  days) to receive study drug and for safety assessments. Visits will continue approximately every 4 weeks until treatment discontinuation. In line with the niraparib United States Package Insert (US PI), dose interruption (no longer than 28 days) will be allowed based on adverse events (AEs). In addition, dose reductions to 200 mg QD and subsequently to 100 mg QD will be allowed based on AEs (please refer to US PI). Any dose reductions differing from this must be discussed with the medical monitor. Patients can continue in the Extension Phase until the patient meets 1 of the withdrawal criteria.

End-of-treatment (EOT) and Safety Follow-up Visits: The EOT visit will occur within 7 days of the decision to discontinue study drug, for any reason, or completion of the PK Phase for patients who participate in the Extension Phase (Stage 3 only), whichever occurs first. Should the first dose of a new anti-cancer therapy occur within 14 days of the decision to discontinue study drug, all assessments required for the Safety Follow-up visit should occur at the EOT visit and this visit will be considered the Safety Follow-up visit. If the first dose of the new anti-cancer therapy occurs >14 days of the decision to discontinue study, the Safety Follow-up visit will occur 30 +7 days after the last dose of the study drug, or at the start of any new anti-cancer therapy, whichever occur first.

For Stage 3 of the PK Phase only, the data cut will occur when all patients have completed the PK Phase. Data collected up to and including PK EOT visit prior to the data cut will be presented in the FE Stage 3 PK CSR for all randomized and treated patients. Additionally, the Sponsor will include safety data related to the PK Phase, as identified up to Cycle 1/Day 1 of the Extension Phase.



collection

14-day washout

period, including

7-day PK sample collection

Niraparib

Dose 1:

Capsule

Figure 1 Study Design: Single-Crossover Study

Randomization

Niraparib

Dose 2:

Tablet

7-day PK sample

collection

Option to qualify

for treatment in

Extension Phase

Stage 1 (completed):



Abbreviations: PK = pharmacokinetics.

## 1.2.2. Randomization Methodology

Randomization will occur centrally using an interactive voice response system/integrated web response system. In Stage 1 and Stage 2, patients will be assigned randomly in a 1:1 ratio to a dosing sequence: capsule formulation followed by tablet formulation, or vice versa. In Stage 3, patients will be assigned randomly in a 1:1 ratio to a dosing sequence: dosing after receiving a high-fat meal (fed) followed by dosing after fasting, or vice versa. The period between randomization and Cycle 1/Day 1 should be no longer than 5 calendar days.

#### 1.2.3. Unblinding

Unblinding is not applicable as this is an open-label study.

#### 1.2.4. Study Procedures

Refer to the latest protocol for the schedule of assessments.

1.2.5. Efficacy, Safety, and Pharmacokinetic parameters

#### 1.2.5.1. Efficacy parameters

Investigator assessment of response will occur every 3-cycles while on study or per the Institution's standard practice.

#### 1.2.5.2. Safety parameters

Safety parameters to be assessed include:

- Treatment emergent adverse events (TEAE)
- Discontinuations due to AEs
- Physical examination (PE) findings
- Vital signs
- Clinical laboratory results (hematology, chemistry, urinalysis)
- Electrocardiograms (ECG)
- Use of concomitant medications.

#### 1.2.5.3. PK parameters

PK parameters and analysis methodology will be addressed in the PK analysis plan.

## 2. Patient Population

## 2.1. Population Definitions

The following patient populations will be evaluated for analyses specified in this SAP. Additional populations, relevant to the PK analysis will be defined in the PK analysis plan.

- Safety Population in the Stage 1 PK Phase: All patients who receive any amount of niraparib during the Stage 1 PK Phase of the study.
- Safety Population in the Stage 2 PK Phase: All patients who receive any amount of niraparib during the Stage 2 PK Phase of the study.
- Safety Population in the Stage 3 PK Phase: All patients who receive any amount of niraparib during the Stage 3 PK Phase of the study.
- Safety Population in the Extension Phase: All patients who receive any amount of niraparib in the Open-Label Extension Phase of the study.

• BA/BE Evaluable Population: All patients who complete both PK periods and have sufficient PK sample collection to accurately estimate PK parameters, without significant niraparib carryover (baseline concentration > 5% of  $C_{max}$ ), in both PK Periods. Patients who have significant niraparib carryover from Period 1 in Period 2 will be completely excluded from the BA/BE Evaluable Population. The terminology BA Evaluable Population will be used for Stage 1 and BE Evaluable Population will be used for Stage 2.

• Food effect (FE) Evaluable Population: All patients who complete both PK periods and have sufficient PK sample collection to accurately estimate PK parameters in both periods. Patients meeting non-evaluability criteria or having significant niraparib carryover (baseline concentration >5% of  $C_{max}$ ) will be completely excluded from the FE Population.

#### 2.2. Protocol Deviations

Protocol deviations will be assessed and classified as important and/or significant per Sponsor's SOP. The Medical Data Review Plan (MDRP) prospectively identifies classification criteria for important deviations. All protocol deviations will be identified, classified and finalized prior to database lock.

A listing of protocol deviations will be provided for the Stage 1 PK Phase, Stage 2 PK Phase; for Stage 3 PK Phase and the Open-Label Extension Phase a listing of only "Important" protocol deviations will be provided.

For Stage 3 PK Phase and Open-Label Extension Phase, tables summarizing "Important" protocol deviations will be provided.

## 3. General Statistical Methods

#### 3.1. Sample Size Justification Stage 1

No formal sample size calculation was performed for Stage 1. Approximately 24 patients will be enrolled in Stage 1. This sample size is considered adequate for preliminary assessment of the relative bioavailability of the tablet compared to the capsules and for estimating the intra-subject coefficient of variation, after accounting for patient drop-outs and potential carryover.

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#### Stage 2

Based on estimates from Stage 1, 100 BA/BE evaluable patients are required in Stage 2. With 100 evaluable patients, assuming the intra-subject coefficient of variation (CV) is 25% and the true ratio of means is 0.89 (89%), there is at least 90% power to demonstrate the bioequivalence (bioequivalence range: 0.80 to 1.250 [80% – 125%], alpha=0.05). Power calculations were also performed under alternative assumptions for the CV and mean ratio. Assuming the CV is 30% and the true ratio of means is 0.89 (89%), with 100 evaluable patients, there is at least 82% power to demonstrate bioequivalence. Assuming the true ratio is 0.90 (90%), the power is 96% and 88% assuming CVs of 25% and 30%, respectively.

The final analysis of bioequivalence will be based on Stage 2 BA/BE evaluable patients only, with a target sample size of 100 evaluable patients. Patients may be identified as non-evaluable due to issues arising during the study conduct, such as:

- Emesis within 9 hours of dosing,
- Dosing errors,
- Patient did not fast prior to dosing,
- Missing critical PK sample on Day 8,
- Failure to complete both PK periods, and
- Significant changes to the patient medical status that would potentially affect the PK profile as determined by the Sponsor in consultation with the Investigator prior to PK data analysis.

In this patient population, approximately 170 total patients are targeted for enrollment, assuming a 35% non-evaluability rate during the study conduct, and an additional 10% non-evaluability rate during PK analysis. The non-evaluability rate arising during the study conduct will be continuously monitored by the Sponsor and the total number of enrolled patients may be adjusted accordingly with the aim to target the resulting sample size of 100 BA/BE evaluable patients.

#### Stage 3

Assuming the true ratio of means is 1 and the intra-subject CV is 20% for AUC<sub>0-t</sub> and AUC<sub>0- $\infty$ </sub>, with 16 evaluable patients, there is approximately 83% probability that the 90% CI of the ratio of geometric means will be within 0.800 and 1.250 (80% - 125%). Based on the results of a FE study conducted using the capsule formulation, an effect of a high-fat meal on C<sub>max</sub> is possible. The sample size of 16 patients is deemed adequate to characterize this effect. AUC<sub>0-t</sub> and AUC<sub>0- $\infty$ </sub> will be the primary parameters for analysis.

The primary analysis will be based on the FE Evaluable Population as it is the most conservative approach, which maximizes the benefits of the crossover design, where each patient serves as their own control. Results for the PK Evaluable Population will also be summarized and reported for this study.

To account for non-evaluable patients, approximately 20 total patients are targeted for enrollment. The final analysis will be based on Stage 3 FE evaluable patients only. Patients may be identified as non-evaluable due to issues arising during the study conduct, such as:

• Emesis within 10 hours of dosing,

- Dosing errors,
- Patient did not follow dietary requirements prior to dose and post-dose,
- Failure to complete both PK periods, and
- Significant changes to the patient medical status that would potentially affect the PK profile as determined by the Sponsor in consultation with the Investigator prior to PK data analysis.

Patients who miss critical PK samples or miss sufficient samples to render calculation of AUC unreliable will be discontinued from the PK Phase; those that meet other criteria for continued niraparib therapy will be eligible to be screened for the Extension Phase. The non-evaluability rate arising during the study conduct will be continuously monitored by the Sponsor and the total number of enrolled patients may be adjusted accordingly with the aim to target the resulting sample size of 16 evaluable patients.

#### 3.2. General Methods

All statistical analyses will be performed using SAS statistical software v9.4 or later, unless otherwise noted. All output will be incorporated into Microsoft Word or Excel files, or Adobe Acrobat PDF files, sorted and labeled according to the International Council for Harmonisation (ICH) recommendations, and formatted to the appropriate page size(s).

For categorical variables, summary tabulations of the number and percentage of patients within each category of the parameter will be presented. Percentages will be based on the patients with a non-missing parameter unless missing category is presented. Percentages will be reported to one decimal place. Percentages will not be presented for zero counts.

For continuous variables, the number of patients, mean, standard deviation (SD), median, first quartile  $(Q_1)$ , third quartile  $(Q_3)$ , minimum, and maximum values will be presented. Mean, median,  $Q_1$ , and  $Q_3$  will be reported to 1 more decimal place than the raw data, while the SD will be reported to 2 more decimal places than the raw data.

All data listings that contain an evaluation date will also contain a relative study day. A unique relative study day will be calculated for the PK Phase and Extension Phase based on the first date of dosing within the respective study phase. Pre-treatment and on-treatment study days are numbered relative to the day of the first dose of study drug which is designated as Day 1. The preceding day is Day -1, the day before that is Day -2, etc. Post-treatment study days are numbered relative to the first dose and are designated as Day +1, Day +2, etc.

In addition:

- Medical history and AEs will be coded using the most up-to-date version of Medical Dictionary for Regulatory Activities (MedDRA).
- Laboratory parameter changes during the Extension Phase for selected laboratory tests will be described using shift tables, relative to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v4.03.
- Concomitant medications will be coded using the latest version of the World Health Organization's (WHO) Anatomical Therapeutic Chemical (ATC) classification.
- CIs will be presented to one more decimal place than the raw data.

Summaries in the Extension Phase will be performed by formulation and overall, regardless of starting dose, unless otherwise specified. The niraparib formulation will be included in the listing for the Extension Phase.

All tables, figures, and listings will include footers at the bottom of the page reflecting the programs used to generate the tables, figures, and listings, and date and time of the generation of the output.

Some minor modifications may be necessary to the planned design of tables, figures, and listings to accommodate data collected during the actual study conduct.

#### 3.3. Baseline Definitions

For all analyses unless otherwise noted, baseline is defined as the most recent measurement prior to the first administration of study drug, for each phase of the study. Baseline can be the same date as first dose, given the measurement is expected prior to first dose when only date information is available.

3.4. Methods of Pooling Data Data will be pooled across study sites.

3.5. Adjustments for Covariates

No formal statistical analyses that adjust for possible covariate effects are planned for the safety endpoints.

3.6. Multiplicity Adjustment Multiplicity is not adjusted in this study.

3.7. Subpopulations Not applicable.

#### 3.8. Withdrawals, Drop-outs, Loss to Follow-up

Patients will not be replaced during Stage 1. During Stage 2 and Stage 3, patients who do not complete Period 1 or Period 2, or who are missing PK samples which render the determination of the primary PK parameters not possible, will be replaced. After evaluation, patients receiving concomitant medications which may affect the final analysis may be replaced.

#### 3.9. Missing Data

In general, there will be no imputations made to accommodate missing data points. All data recorded on the eCRF will be included in data listings for the CSR.

When tabulating AE data, partial dates will be handled as follows:

• If the day of the month is missing, the onset day will be set to the first day of the month unless it is the same month and year as first study treatment. In this case, in order to conservatively report the event as treatment-emergent, the onset date will be assumed to be the date of first study treatment.

• If the onset day and month are both missing, the day and month will be assumed to be January 1, unless the event occurred in the same year as the first study treatment. In this case, the event onset will be coded to the day of first study treatment in order to conservatively report the event as treatment-emergent.

• A missing onset date will be coded as the first day of study treatment. If the resulting onset date is after a reported date of resolution, the onset date will be set equal to the date of resolution, after considering any required imputation.

Imputation of partial dates is used only to determine whether an event is treatment-emergent; data listings will present the partial date as recorded in the eCRF.

Partial start dates for prior/concomitant medication, growth factor and transfusion data will be handled in the same way as described above for adverse events. Stop dates will be imputed as follows:

- If only day of the month is missing, the end day will be set to the last day of the month.
- If end day and end month are missing, and the year is not missing, then the day and month will be set to December 31 (or date of study discontinuation/completion if earlier than December 31).
- If the stop date is completely missing, it will be set to the date of study discontinuation/completion.
- If the imputed stop date is greater than the date of study discontinuation/completion then the date will be set to the date of study discontinuation/completion.

#### 3.10. Visit Windows

By-visit summaries and analyses will be performed by nominal visit. All data will be tabulated per the evaluation visit as recorded on the eCRF even if the assessment is outside of the visit window for analysis.

#### 3.11. Interim Analysis

There will be no interim analysis for this study.

#### 3.12. COVID-19

COVID-19 pandemic may impact the conduct of clinical studies. Challenges may arise from quarantines, site closures, travel limitations interruptions to the supply chain for the investigational product or other considerations if site personnel or patients become infected with COVID-19. These challenges may lead to difficulties in meeting protocol specified procedures, including administering or using the investigational product or adhering to protocol-mandated visits and laboratory/diagnostic testing.

This study was initiated by TESARO, which was subsequently acquired by GSK. Prior to the acquisition, protocol deviations were classified using TESARO definitions. The TESARO protocol deviation system was decommissioned in May 2020, and thereafter, protocol deviations were classified using GSK definitions.

All protocol deviations collected during the study will be reviewed by the TESARO (for Stage 1 and Stage 2) or GSK (for Stage 3 only) study team, as appropriate, in order to identify TESARO "Significant"/"Important" protocol deviations and GSK "Important" protocol deviations, respectively. Consistent with ICH E3 guidance, only protocol deviations identified as "Important" (GSK) are evaluated in the CSR for impact on the Stage 3 primary endpoint.

## 4. Study Analyses

#### 4.1. Patient Disposition

A by-patient data listing of patient disposition information will be presented for each phase.

For the PK Phase (Stage 1, Stage 2, and Stage 3 separately), patient disposition will be tabulated and will include the number of patients in each of the following categories:

- Patients screened
- Patients randomized
- Patients treated with each formulation (Stage 1 and 2)
- Patients treated in fed and fasted state (Stage 3)
- Patients in the Safety Population
- Patients completing the PK Phase
- Primary reason for discontinuation from the PK Phase
- Primary reason for discontinuation from the study, for patients who do not continue to the Extension Phase.

For the Open-Label Extension Phase, patient disposition will be tabulated and will include the number of patients in each of the following categories:

- Patients treated with at least one dose
- Patients who discontinue treatment and the reason(s) for withdrawal
- Patients who discontinue the study and the reason(s) for withdrawal.

#### 4.2. Demographics, Baseline Characteristics and Medical History

Demographics, baseline characteristics, primary cancer history, and medical history information will be summarized for the PK Safety Population by sequence and overall (Stage 1, Stage 2 and Stage 3 separately) and for the Open-Label Extension Phase, using descriptive statistics for the Safety Population. No formal statistical comparisons will be performed. Demographics and baseline characteristics will also be summarized for the BA for Stage 1, BE Evaluable Population for Stage 2 and FE Evaluable Population for Stage 3.

The demographic and baseline characteristics tables will include the following variables:

- Age at time of screening (years)
- Age categories (18 to <65, 65 to <75,  $\geq$ 75; and  $\geq$ 65)
- Sex
- Race (White, Black, Asian, American Indian/Alaska Native, Native Hawaiian or other Pacific Islander, Other and Not Reported)
- Ethnicity (Hispanic or Latino, not-Hispanic or Latino, Not Reported and Unknown)
- Baseline weight (in kilograms)
- Baseline height (in centimeters)
- Baseline body mass index (BMI) (kg/m<sup>2</sup>), calculated using the patient's height and weight at screening [BMI (kg/m<sup>2</sup>) = weight (kg) / height (m)<sup>2</sup>]
- Eastern Cooperative Oncology Group (ECOG) performance status at baseline.

Primary cancer history will be summarized for the safety population and will include the following variables:

- Tumor type
- Time from first diagnosis to informed consent (years)
- Cancer stage (most recent) (Locally advanced, Metastatic)
- Number of prior lines of therapy
- Any prior radiotherapy.

Prior anti-cancer treatments will be coded using the most current version of the WHO Drug Dictionary. The number and percentage of patients reporting the use of at least one preferred term will be reported for the Safety Population in the PK Phase (Stage 1, Stage 2 and Stage 3 separately) and the Safety Population in the Extension Phase.

Medical history will be coded using the most current version of MedDRA, and the number and percentage of patients experiencing at least one such diagnosis by MedDRA System Organ Class (SOC) and preferred term (PT) will be reported for the Safety Population in the PK Phase (Stage 1, Stage 2 and Stage 3 separately) and the Safety Population in the Extension Phase.

Demographics, baseline characteristics, primary cancer history, and medical history information for each patient will be provided in data listings.

#### 4.3. Investigator Assessment of Response

Investigator assessment of response will be provided in data listings for the Extension Phase. Additional descriptive summaries of response may be performed by tumor type.

# 4.4. Safety Evaluation4.4.1. Treatment Exposure and Compliance<u>PK Phase</u>

The number and percentage of patients receiving capsules and tablets during the PK Phase (Stage 1 and Stage 2, separately) will be summarized. For Stage 3, the number of tablets received will be summarized by fed/fasted state.

A by-patient listing of the niraparib treatment data will be produced for the PK Safety Population.

#### Extension Phase

Study treatment exposure and compliance will be summarized by formulation (Capsule; Tablet) and overall, including:

- Number and percentage of patients who initiated 1, 2, 3, 4, 5,  $\geq 6$  treated cycles (Maximum Number of Cycles).
- Median number of cycles started.
- Duration of treatment (months), defined as:

[last dose date - first dose date in the Extension Phase + 1] / 30.4375.

• Duration on study (months), defined as:

[last contact date - first dose date in the Extension Phase + 1] / 30.4375, where last contact date is the last visit date or date of death.

• Dose intensity (mg/day), defined as:

Sum of daily doses consumed / [last dose date - first dose date in Extension Phase + 1]

- Number of patients with at least one dose interruption.
- Number of patients with at least one dose reduction.
- Number of patients with at least one dose re-escalation.

In addition, the starting niraparib dose for each cycle will be summarized.

A by-patient listing of the niraparib treatment data will be produced for the Open-Label Extension Phase safety population.

#### 4.4.2. Adverse Events

All AEs will be classified by SOC and PT using the most up-to-date version of MedDRA.

Per protocol, all SAEs will be collected from the signing of the ICF for this study through 90 days after the last dose of study drug (or until the start of alternate anticancer therapy, whichever occurs first, and recorded in the eCRF.

All AEs, regardless of the source of identification (e.g., physical examination, laboratory assessment, ECG, or reported by patient), will be collected and recorded in the eCRF for each patient from the time of randomization and/or treatment assignment until 30 days after the last dose of study drug.

All AEs experienced by a patient, regardless of the suspected causality, will be monitored until the AE or SAE has resolved, until AE(s) or SAE(s) have returned to baseline or normal levels, until stabilized with a satisfactory explanation for the changes observed, until the patient is lost to follow-up, or until the patient has died, starts alternate anti-cancer therapy, or until the patient withdraws consent.

For analysis, TEAEs will be defined as any AEs collected with a start date on or after the first dose of study drug. Any AEs recorded in the database that occur from the time of ICF to first dose will be listed only and not included in safety analyses. Pre-existing conditions will be recorded in the eCRF on the Medical History or appropriate page.

The severity of the toxicities will be graded according to the NCI CTCAE v4.03. Within the same MedDRA PT, only the most severe AE for each patient will be counted in tabulations by severity. Within a MedDRA SOC, patients with more than 1 MedDRA PT will be counted only once for the most severe AE reported.

The Investigator must provide a causality assessment (related or not related) regarding the relationship of the event with the study drug and/or study procedure for all AEs. In Stage 1, for analysis of the PK Phase, AEs considered related to either tablet or capsule will be considered to be related to study drug. Any AEs for which the relationship is missing (for either tablet or capsule during the Stage 1 PK Phase) will be considered related to study treatment. During Stage 2 PK Phase, Stage 3 PK Phase and Extension Phase, relationship relative to niraparib will be considered. Within the same MedDRA PT, only the AE with the highest ranked relationship to treatment for each patient will be counted in tabulations by relationship to treatment. Within a MedDRA SOC, patients with more than 1 MedDRA PT will be counted only once for

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the AE that is most related to treatment. The imputation for a missing relationship will take place prior to determining the most related AE within a SOC or PT for a given patient.

If the start date is missing for an AE and the actual start date cannot be determined from a partial date, the AE will be considered treatment-emergent.

Adverse Events of Special Interest (AESI) for niraparib are the following:

- Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML)
- Secondary cancers (new malignancies [other than MDS or AML])
- Pneumonitis (for Stage 1 and Stage 2 only)
- Embryo-fetal toxicity (for Stage 1 and Stage 2 only).

AEs will be classified into the following time periods for analysis.

- PK Phase (for Stage 1, Stage 2, and Stage 3 separately):
  - Period 1: Any AE that begins on or after Dose 1 but prior to Dose 2.
    - For Stage 1, Period 1 will be defined as 7-days post Dose 1 for patients who do not receive Dose 2.
    - For Stage 2 and Stage 3, Period 1 will be defined as 14-days post Dose 1 for patients who do not receive Dose 2.
  - Period 2: Any AEs that begins on or after Dose 2 but prior to the end of the PK Phase as defined by 7-days post Dose 2.
  - Safety Follow-Up/Extension Screening Period:
    - For patients not participating in the Extension Phase, AEs that begin after the end of the PK Phase.
    - For patients participating in the Extension Phase, AEs that begin after the end of the PK Phase until the date of first dose in the Extension Phase.
- Open-Label Extension Phase:
  - $\circ$   $\;$  Any AEs that start on or after the first dose in the Extension Phase.
- Any AEs with onset during the PK Phase/Safety Follow-Up/Extension Screening Period and ongoing/ resolved during the Extension Phase will be listed separately.

The analyses indicated below will be performed for each of the above-mentioned phases.

A high-level overview of TEAEs will be presented in a summary table. This table will include the number and percentage of patients for the following categories:

- Any TEAE
- Any related TEAEs
- Any serious TEAEs
- Any related serious TEAEs
- Any TEAEs with CTCAE toxicity grade 3 or above
- Any related TEAEs with CTCAE toxicity grade 3 or above
- Any TEAEs leading to treatment discontinuation
- Any related TEAEs leading to treatment discontinuation

- Any TEAEs leading to dose interruption
- Any TEAEs leading to dose reduction
- Any TEAEs leading to death.

The number and percentage of patients reporting a TEAE will be summarized in the following additional AE tables. AE tabulations will be ordered in terms of decreasing frequency for SOC (alphabetically for SOCs with the same number of AEs reported), and decreasing frequency for PT within SOC (alphabetically for PTs with the same number of AEs reported within a SOC) considering the overall rate.

- TEAE by SOC and PT
- Related TEAE by SOC and PT
- Treatment emergent SAEs by SOC and PT
- Related treatment emergent SAEs by SOC and PT
- TEAE with toxicity grade 3 or above by SOC and PT
- Related TEAE with toxicity grade 3 or above by SOC and PT
- TEAEs leading to treatment discontinuation by SOC and PT
- TEAEs leading to dose interruption by SOC and PT (Extension Phase Only)
- TEAEs leading to dose reduction by SOC and PT
- TEAEs leading to death by SOC and PT
- TEAE by PT (sorted by frequency)
- TEAE by SOC, PT, and maximum toxicity grade
- Treatment emergent AESI.

For Stage 1 and Stage 2 PK Phase, primary tabulations for the PK Phase data will be provided by formulation (regardless of period), those occurring during the Follow-up/Extension Screening, and overall. In addition, the high-level overview of TEAEs and summary of TEAEs by SOC and PT will be summarized by sequence and formulation. For Stage 3 PK Phase, primary tabulations for the PK Phase data will be provided by fed/fasted state (regardless of period), and overall. In addition, the high-level overview of TEAEs by SOC and PT will be summarized by sequence and fed/fasted state (regardless of period), and overall. In addition, the high-level overview of TEAEs and summary of TEAEs by SOC and PT will be summarized by sequence and fed/fasted state. For the Open-Label Extension Phase, data will be summarized by formulation and for all patients overall.

The following by-patient listings will be produced for the PK Phase (Stage 1, Stage 2, and Stage 3 separately) and the Open-Label Extension Phase:

- All TEAEs
- Treatment emergent SAEs
- All Deaths
- TEAEs leading to dose interruption (Extension Phase Only)
- TEAEs leading to dose reduction
- TEAEs leading to treatment discontinuation
- Any TEAEs with onset during PK Phase (including Safety Follow-Up/Extension Screening Period) and ongoing/resolved during Extension Phase.

#### 4.4.3. Laboratory Data

Laboratory assessments for safety oversight are performed locally at each center's laboratory by means of their established methods. All laboratory values will be converted to SI units and classified as normal, low, or high based on normal ranges supplied by the local laboratories and upon employing standardization.

A by-patient listing of all laboratory data will be provided, with laboratory reference ranges and abnormal values highlighted, and including center, patient identifier, and visit for the PK Phase and the Extension Phase of the study.

For the Extension Phase, select hematology (hemoglobin, neutrophils and platelets) and chemistry (bilirubin, creatinine, aspartate aminotransferase [AST] and alanine aminotransferase [ALT]) will be analyzed using change from baseline by visit.

For the Extension Phase, select hematology (hemoglobin, neutrophils and platelets) and chemistry tests (bilirubin, creatinine, ALT, and AST), baseline and post-baseline results will be categorized by NCI CTCAE v4.03 grade (Table 2). Shift tables will be produced by maximum post-baseline grade. Results that are considered 'normal' will be assigned a Grade 0.

#### Table 2 NCI Common Terminology Criteria for Adverse Events v4.03 (CTCAE)

CCI - This section contained Clinical Outcome Assessment data collection questionnaires or indices, which are protected by third party copyright laws and therefore have been excluded.



4.4.4. Vital Signs and Physical Examination Vital sign measurements will be presented for each patient in a data listing. Baseline physical examination findings will be presented in a data listing. Any new or changed condition will be captured as an adverse event and will be summarized in the AE tables and listings.

#### 4.4.5. Electrocardiogram

Standard 12-lead ECGs will be performed locally for patients in the study. Any ECG findings that are assessed as clinically significant and are reported as an AE or SAE will be summarized in the AE tables and listings.

All ECG results (i.e., interpretations) for each patient will be provided in a data listing.

#### 4.4.6. Prior and Concomitant Mediations

Medications collected at Screening and during the study will be coded using the current version of the WHO Drug dictionary. Study treatment, prior anti-cancer treatments for primary cancer, transfusions and growth factors are collected and summarized separately. For each of the study phases (Stage 1 PK, Stage 2 PK, Stage 3 PK and Extension Phase), medications will be categorized as prior or concomitant using the following definitions:

- Prior medications during the PK Phase: any medications which started prior to the first dose date of study treatment during the PK Phase.
- Concomitant medications during the PK Phase: any medications being taken on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase.
  - For Stage 2 PK Phase, concomitant medications will be further identified as those taken during the PK collection period, defined by dates of the first PK-draw to last PK-draw.

• Prior medications during the Extension Phase: any medications which started prior to the first dose date of study treatment during the Extension Phase.

- Concomitant medications during the Extension Phase: any medications on or after the first treatment dosing date in the Extension Phase through 30 days after the last dose of treatment.
- Any concomitant medication taken during PK Phase that were ongoing during the Extension Phase will be classified as Both, i.e., concomitant and prior, for the purposes of the Extension Phase.

Note: medications can be classified as both prior and concomitant.

Both prior medications and concomitant medications will be summarized by ATC classification drug class and WHO preferred name using the number and percentage of patients for each cohort. A patient reporting the same medication more than once will be counted only once when calculating the number and percentage of patients who received that medication in a given time category (prior or concomitant). The summary of concomitant medications will be ordered alphabetically by drug class and then by descending frequency of preferred name in total within the drug class. For drugs with the same frequency, sorting will be done alphabetically. Summaries will be based on the safety population.

For PK Stage 2, an additional summary of concomitant medications used during the PK collection period will be provided for the BE Evaluable Population.

For each phase of the study, all prior and concomitant medications will be provided in a by-patient listing sorted by patient ID number and administration date in chronological order.

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#### 4.4.7. Prior and Concomitant Transfusions and Growth Factors

The number and percentage of patients receiving prior and concomitant growth factors during the PK Phase and Extension Phase will be summarized. The data will be classified as prior or concomitant using similar logic as provided in Section 4.4.6.

For each phase of the study, all prior and concomitant transfusions and growth factor use will be provided in a by-patient listing sorted by patient ID number and administration date in chronological order.

#### 4.4.8.COVID-19

The PK Phase Stage 3 of the trial takes place during COVID-19 pandemic, as a result, some of the trial procedures could be impacted in terms of missing visits and/or assessments. Missing protocol required data/visits due to COVID-19 must be noted in participant notes and recorded as COVID-19-related protocol deviations.

A summary of the following COVID-19 assessments will be produced: case diagnosis, COVID-19 test performed, and results of the COVID-19 test.

The incidence of COVID-19 related AEs and SAEs will be summarized as part of the safety reporting summaries along with COVID-19-related as reasons for treatment discontinuation.

A listing of all patients with COVID-19 assessments and symptom assessments will be produced and will include the following:

- Treatment sequence
- Patient number
- COVID-19 case diagnosis
- COVID-19 test performed
- Result of the COVID-19 test
- Assessments and symptom assessments performed
- Results of the assessments and symptom assessments.

For PK Phase Stage 3, a separate listing defining "Important" GSK protocol deviations related to COVID-19 will be presented.

For protocol deviation reporting during the Extension Phase, a listing will be produced to present TESARO Classification of protocol deviations for patients continuing from Stage 1 and Stage 2, and GSK Classification of protocol deviations for patients continuing from Stage 3.

## 5. Changes to Planned Analyses

There is no change between the protocol-defined statistical analyses and those planned in this SAP.

#### 4.5. Changes in v5.0 of the SAP

Section 2.2 updated to include a summary tables of Important protocol deviations for Stage 3 PK Phase and Open-Label Extension Phases, as well as clarification of associated deviation listings presenting only protocol deviations classified as "Important".

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#### 4.6. Changes in v6.0 of the SAP

Section 1.2 updated to reflect the change in PK data cut requirements for final Stage 3 analysis.

#### 4.7. Changes in v7.0 of the SAP

Case record form (CRF) versions updated to align with CRF booklet version upgrades starting from SAP version 4.0 onwards.

Section 2 updated to include definition for dose intensity in exposure table for Extension Phase.

Section 3.2 'Dose at onset of AE' column removed from AE listings.

Section 4.4.2 updated AE classification for PK Period 1 for Stage 3.

Table 2 header row labels updated to correct CTCAE version.

Table numbering and output header formatting updated to reflect the produced outputs.

Header row labels for Extension Phase updated to TABLET, CAPSULE and OVERALL for consistency.

Additional tables and listings have been added/modified for Extension Phase; disclosure and plain language summary reporting tables added across all study stages.

All-Cause Mortality table added for final study disclosure reporting purposes of the Extension Phase.

# 6. Appendix

# 6.1. Planned Statistical Tables, Listings, and Figures

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## TABLES

General guidelines:

Tables will be provided for the Stage 1 PK Phase, Stage 2 PK Phase, Stage 3 PK Phase and the Open-Label Extension Phase. For the PK Phase (Stage 1, Stage 2 and Stage 3):

- Treatment=Sequence and Overall, in general. For PK and AE data, please see mock tables.
- Population=Safety Population in Stage 1 PK (Stage 2 PK or Stage 3 PK) Phase, unless otherwise specified.
- PK Phase Data:
  - For patients who do not continue to Extension Phase, PK Phase is any data collected.
  - For patients who do continue to Extension Phase,
    - AEs prior to first dose in Extension Phase
    - Prior meds/procedures/etc. prior to first dose in PK Phase
    - Concomitant meds meds prior to first dose in Extension Phase.
- Assessments (Labs, ECGs, Vitals, ECOG, PE, etc.) use visit to identify data.

For the Extension Phase:

- Treatment=Niraparib Tablet or Capsule (regardless of starting dose); Summarize by Tablet; Capsule; Overall, unless otherwise specified.
- Population=Safety Population in the Open-Label Extension Phase (i.e., those who receive at least 1 dose), unless otherwise specified.
- Extension Phase Data:
  - For patients who do not continue to Extension Phase, there is no Extension Phase data.
  - For patients who do continue to Extension Phase,
    - AEs on or after first dose in Extension Phase
    - Prior meds/procedures/etc. prior to first dose in Extension Phase
    - Concomitant meds meds on or after the first dose in Extension Phase
    - Assessments (Labs, ECGs, Vitals, ECOG, PE, etc.) use visit to identify data.

Sort order: All AE tabulations, unless otherwise specified, will be ordered in terms of decreasing frequency for SOC (alphabetically for SOCs with the same number of AEs reported), and decreasing frequency for PT within SOC (alphabetically for PTs with the same number of AEs reported within a SOC) considering the overall rate.

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Protocol: XXXXX					
	Table 14.1.	1a			
Subject Disposition in the PK	Phase (All H	Patients in the Sta	age 1 PK Phase)		
Parameter	Statistic	Sequence	Sequence		
		TABLET/CAPSULE	CAPSULE/TABLET	Overall	
Number of Patients					
Screened	n			XX	
Randomized	n	Х	х	Х	
Received Tablet	n	Х	X	X	
Received Capsule	n	Х	х	Х	
Received Both Tablet and Capsule	n	Х	Х	Х	
PK Phase Safety Population	n	х	х	х	
Completed PK Phase	n	Х	Х	Х	
Discontinuation from PK Phase	n	х	х	Х	
Reason1	n	Х	Х	Х	
Reason2	n	Х	Х	Х	
Participate in Extension Phase	n	Х	Х	Х	
Discontinuation from Study Prior to Entering the Extension					
Phase					
Reason1	n	XX	XX	XX	
Reason2	n	XX	XX	XX	
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[Programming Notes] Only include DC from study for those patients who do not enter the Extension Phase.

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14.1.1b				
(All Patient	s in the Stage 2 H	PK Phase)		
Statistic	Sequence	Sequence		
	TABLET/CAPSULE	CAPSULE/TABLET	Overall	
n			XX	
n	Х	Х	Х	
n	Х	Х	Х	
n	Х	Х	Х	
n	Х	Х	Х	
n	х	х	х	
n	Х	Х	Х	
n	Х	Х	Х	
n	Х	Х	Х	
n	Х	Х	Х	
n	Х	х	Х	
n	Х	х	Х	
n	XX	XX	XX	
n	XX	XX	XX	
	fidential <pre>fidential fidential f</pre>	fidential          fidential         14.1.1b         (All Patients in the Stage 2 F         Statistic       Sequence         TABLET/CAPSULE         n          n          n       x         n       x         n       x         n       x         n       x         n       x         n       x         n       x         n       x         n       x         n       x         n       x         n       x         n       x         n       x         n       x         n       x         n       xx         n       xx         n       xx         n       xx         n       xx         n       xx         n       xx	fidential          14.1.1b         (All Patients in the Stage 2 PK Phase)         Statistic       Sequence TABLET/CAPSULE       Sequence CAPSULE/TABLET         n          n       xx         n	

[1] Includes patients in the Safety Population (i.e., treated patients) only.

[Programming Notes]

Only include DC from study for those patients who do not enter the Extension Phase.

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Table 14.1.1c								
Subject Disposition in the Extens	ion Phase (A	all Patients in th	e Extension Phase)					
Parameter	Statistic	TABLET	CAPSULE	OVERALL				
Number of Patients								
Dosed	n	XX	XX	XX				
By Stage:								
Dosed in Stage 1	n (%)	XX ( XX.X)	xx ( xx.x)	XX ( XX.X)				
Dosed in Stage 2	n (%)	XX ( XX.X)	xx ( xx.x)	XX ( XX.X)				
Dosed in Stage 3	n (%)	xx ( xx.x)	xx ( xx.x)	XX ( XX.X)				
By Starting Dose:								
100mg/d	n (%)	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)				
200mg/d	n (%)	XX ( XX.X)	xx ( xx.x)	XX ( XX.X)				
300mg/d	n (%)	xx ( xx.x)	xx ( xx.x)	xx ( xx.x)				
Discontinued Treatment After Receiving at Least 1 Dose	n	XX	XX	XX				
Reason 1	n	XX	XX	XX				
Reason 2	n	XX	XX	XX				
Discontinued Study	n	XX	XX	XX				
Reason 1	n	XX	XX	XX				
Reason 2	n	XX	XX	XX				
NOTE: The starting dose of 100 mg/day was selected based on	Investigato	r decision.						
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Protocol: XXXXX	1 4 1 1 1				
	14.1.1a				
Subject Disposition in the PK Phase	(All Patients	s in the Stage 3 PK	Phase)		
Parameter	Statistic	Sequence	Sequence		
		NIRAPARIB TABLET	NIRAPARIB TABLET		
		FASTED/FED	FED/FASTED	OVERALL	
Number of Patients					
Screened [1]	n			XX	
Randomized	n	х	х	х	
Not Treated	n	х	х	х	
Received Tablet in Fasted State	n	х	х	Х	
Received Tablet in Fed State	n	х	х	Х	
Received Tablet in Both Fasted and Fed State	n	х	х	х	
PK Phase Safety Population	n	Х	Х	Х	
Completed PK Phase	n	х	Х	х	
Discontinuation from PK Phase [2]	n	X	х	Х	
Reason 1	n	X	Х	х	
Reason 2	n	х	х	х	
Participate in Extension Phase	n	X	Х	Х	
Discontinuation from Study Prior to Entering the Extension Phase					
Reason 1	n	XX	XX	ХХ	
Reason 2	n	XX	XX	XX	

[1] Patient xxxxxx-xxxx (Screen Failure ID: XXi) and xxxxxx-xxxx (Screen Failure ID: YYi) re-screened and reconsented after screen failure are counted twice in Screening.

[2] Includes patients in the Safety Population (i.e., treated patients) only.

[Programming Note] XXi/YYi is ID that was SF. Programming, please note footnote references changed order in the shell and footer.

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Protocol: XXXXX				
	Table 14.1.2a			
Demographics (Sa	fety Population in the	Stage 1 PK Phase)		
Parameter	Statistic	Sequence	Sequence	
		TABLET/CAPSULE	CAPSULE/TABLET	OVERALL
		(N=xx)	(N=xx)	(N=XX)
Age (yrs)	n	XX	XX	XX
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	XX.X (XX.XX)
	Median	XX.X	XX.X	XX.X
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX
Age Group				
18 -< 65	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
65 -< 75	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
≥ 75	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sex				
Male	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race				
White	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
African American	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
American Indian or Alaska Native	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native Hawaiian or other Pacific Islander	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Reported	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity				
Hispanic or Latino	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic or Latino	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Reported	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:

Table 14.1.2.1a Demographics (BA Evaluable Population in the Stage 1 PK Phase)

Table 14.1.2.1b Demographics (Safety Population in the Stage 2 PK Phase)

Table 14.1.2.2b Demographics (BE Evaluable Population in the Stage 2 PK Phase)

Table 14.1.2c Demographics (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.
- Add footnote: "Note: Age was collected at PK Phase entry only."

Table 14.1.2.1d Demographics (Safety Population in the Stage 3 PK Phase)

Table 14.1.2.2d Demographics (FE Evaluable Population in the Stage 3 PK Phase)

• Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL.

TESARO, Inc.	Cc	onfidential			Page 1 of x
Protocol: XXXXX					
	Tab.	le 14.1.3a			
	Baseline Characteristics (Safet	y Population i	n the Stage 1 PK Pha	ise)	
				2	
Parameter		Statistic	Sequence	CADQUIE (MADIEM	OVEDALI
			(N-vv)	(N-vv)	(N-YY)
Weight (kg)		n			
weight (kg)		Mean (SD)	xx x (xx xx)	XX X (XX XX)	
		Median		XX.X (XX.XX)	
					vv v vv v
		Min May			vv vv
		hill, hax			
Height (cm)		n	××	XX	XX
		Mean (SD)	 	XX.X (XX.XX)	××.× (××.××)
		Median		XX.X	××.×
		01, 03	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
		Min, Max	XX, XX	XX, XX	xx, xx
BMI (kg/m <sup>2</sup> )		n	XX	XX	XX
-		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	XX.X	XX.X	XX.X
		Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
		Min, Max	xx, xx	XX, XX	XX, XX
ECOG Performance Status					
0		n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1		n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2		n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3		n (%)	xx (xx.x)	XX (XX.X)	xx (xx.x)
4		n (%)	xx (xx.x)	XX (XX.X)	XX (XX.X)
Missing		n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)

ECOG = Eastern Cooperative Oncology Group:

0=Fully active, able to carry on all pre-disease performance without restriction 1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature 2=Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours 3=Capable of only limited self-care, confined to bed or chair more than 50% of waking hours 4=Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

Repeat for:

Table 14.1.3.1a Baseline Characteristics (BA Evaluable Population in the Stage 1 PK Phase)

Table 14.1.3.1b Baseline Characteristics (Safety Population in the Stage 2 PK Phase)

Table 14.1.3.2b Baseline Characteristics (BE Evaluable Population in the Stage 2 PK Phase)

Table 14.1.3c Baseline Characteristics (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.
- Add footnote for Extension Phase and relevant reference in the table:
- [1] Only weight and ECOG Performance Status were repeated at Extension Phase entry.

Table 14.1.3.1d Baseline Characteristics (Safety Population in the Stage 3 PK Phase)

• Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL Table 14.1.3.2d Baseline Characteristics (FE Evaluable Population in the Stage 3 PK Phase)

• Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

TESARO, Inc. Con:	fidential			Page 1 of x
Protocol: XXXXX				2
Table	14.1.4a			
Primary Cancer History (Safety H	Population in the S	tage 1 PK Phase)		
Parameter	Statistic	Sequence	Sequence	
		TABLET/CAPSULE	CAPSULE/TABLET	OVERALL
		(N=xx)	(N=xx)	(N=xx)
Tumor Type				
Хххххххх	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Хххххххх	n (%)	xx (xx.x)	XX (XX.X)	xx (xx.x)
Хххххххх	n (응)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Time from first diagnosis to informed consent (years)	n	XX	XX	XX
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	XX.X	XX.X	XX.X
	Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX
Cancer Stage (most recent)				
Locally advanced	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Metastatic	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of prior lines of therapy				
0	n (%)	xx (xx.x)	XX (XX.X)	xx (xx.x)
1	n (%)	xx (xx.x)	XX (XX.X)	XX (XX.X)
2	n (%)	xx (xx.x)	XX (XX.X)	XX (XX.X)
3	n (%)	xx (xx.x)	XX (XX.X)	XX (XX.X)
4	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
5	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>=6	n (%)	xx (xx.x)	XX (XX.X)	xx (xx.x)
Missing	n (%)	xx (xx.x)	XX (XX.X)	XX (XX.X)
Any prior radiotherapy	n (%)	xx (xx.x)	XX (XX.X)	XX (XX.X)

Source: Listing XXXXXXXX. Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:

Table 14.1.4b Primary Cancer History (Safety Population in the Stage 2 PK Phase)

Table 14.1.4c Primary Cancer History (Safety Population in the Extension Phase)

• Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.

Table 14.1.4d Primary Cancer History (Safety Population in the Stage 3 PK Phase)

• Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

TESARO, Inc.	Confidential			Page 1 of x	
Table 14.1.5a					
Prior Anti-Cancer Tr	reatment (Safety Population in the	Stage 1 PK Phase)			
Preferred Term	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)	
Agent 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Agent 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Agent 3	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)	
Source: Listing XXXXXXXX. Program: XXXXXXXXXXXX Data Extract Date: DDMMMYYYY, Data Cutoff Date:	XXXXXX. Output: xxxxxxxxxxxx.rtf. DDMMMYYYY	Generated on DDMMM	YYYY:HH:MM:SS	1	

[Programming Notes]

Sort by decreasing frequency in the OVERALL column.

Repeat for:

Table 14.1.5b Prior Anti-Cancer Treatment (Safety Population in the Stage 2 PK Phase)

Table 14.1.5c Prior Anti-Cancer Treatment (Safety Population in the Extension Phase)

• Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.

Table 14.1.5d Prior Anti-Cancer Treatment (Safety Population in the Stage 3 PK Phase)

• Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED AND OVERALL.

TESARO, Inc. Confi	Confidential							
Table 14.1.6a								
Medical History (Safety Popula	tion in the Stage	e 1 PK Phase)						
System Organ Class Preferred Term	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)				
Any condition	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
SOC1	n (응)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
PT1	n (응)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
SOC2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
· · ·								
				L				

Source: Listing XXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes] Sort alphabetically by SOC/PT.

Repeat for: Table 14.1.6b Medical History (Safety Population in the Stage 2 PK Phase)

Table 14.1.6c Medical History and Prior Blood Disorders (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.
- Add footnote: "Note: The table summarizes combined data from Medical History and Prior Blood Disorders eCRFs. Duplicate events reported across both eCRFs are counted only once per patient in this table."

Table 14.1.6d Medical History (Safety Population in the Stage 3 PK Phase)

• Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

TESARO, Inc.	Confidential			Page 1 of >
Protocol: XXXXX				
	Table 14.1.7a			
Prior Medications k	by ATC and PT (Safety Population in th	ne Stage 1 PK Phase	)	
ATC (Level 3)	Statistic	Sequence	Sequence	
Preferred Term		TABLET/CAPSULE	CAPSULE/TABLET	OVERALL
		(N=XX)	(N=XX)	(N=xx)
Any prior medication	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2.7701	(0)	,		
ATCI	n (%)	XX (XX.X)	XX (XX.X)	xx (xx.x)
	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
P,T,Z	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
· · ·				
ATC2	n (2)	xx (xv v)	XX (XX V)	xx (vv v)
PT1	n (%)			xx (xx x)
<u></u> рт2	n (%)	XX (XX X)		XX (XX X)
	11 ( 0 )		AA (AA•A)	AA (AA•A)
Data Extract Date: DDMMMYYYY, Data Cutoff Data Programming Notes] Sort alphabetically by ATC3 and Preferred Term. 1	e: DDMMMYYYY If there are uncoded terms due to no A	ATC level 3 term no	t being available,	, add footnc
for uncoded term: [1] ATC level 3 term is not ava	ailable through WHO Drug Dictionary.			
Repeat for: Table 14.1.7b Prior Medications by ATC and PT (Sa	afety Population in the Stage 2 PK Pha	ase)		
Cable 14.1.7c Prior Medications by ATC and PT (Sa	afety Population in the Extension Phas	se)		
• Summarize Extension Phase Data with columns fo	or TABLET; CAPSULE; OVERALL.			
Programming Notes]				
Footnote - Extension Phase: Prior medications a rith a start date earlier than the first dose dat rersion YYYYMM.	are any medications, other than study t e of study treatment during the Extens	reatments and pre-r sion Phase and are	nedications for st coded using WHO D:	udy treatmer rug Dictiona
Prior anti-cancer treatments for primary cance	er are not included.			
able 14.1.7d Prior Medications by ATC and PT (Sa	afety Population in the Stage 3 PK Pha	ase)		

• Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL.

TESARO, Inc.	Confidential								
Protocol: XXXXX									
	Table 14.1.8a								
Concomitant Medicat:	ions by ATC and PT (Safety Population i	in the Stage 1 PK	Phase)						
ATC (Level 3)	Statistic	Sequence	Sequence						
Preferred Term		TABLET/CAPSULE	CAPSULE/TABLET	OVERALL					
		(N=xx)	(N=xx)	(N=XX)					
Any concomitant medication	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)					
ATC1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)					
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)					
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)					
ATC2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)					
PT1	n (%)	xx (xx.x)	XX (XX.X)	XX (XX.X)					
PT2	n (%)	xx (xx.x)	XX (XX.X)	xx (xx.x)					

Note: Concomitant medications are any medications being taken on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase. They are coded using WHO Drug Dictionary version YYYYMM.

[Programming Notes]

Sort alphabetically by ATC3 and Preferred Term. If there are uncoded terms due to no ATC level 3 term not being available, add footnote for uncoded term: [1] ATC level 3 term is not available through WHO Drug Dictionary.

Repeat for:

Table 14.1.8.1b Concomitant Medications by ATC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.1.8.2b Concomitant Medications During the PK Collection Period by ATC and PT (BE Evaluable Population in the Stage 2 PK Phase)

• Footnote: Concomitant medications during the PK collection period are any concomitant medications taken between the first PK-draw until the last PK-draw. They are coded using WHO Drug Dictionary version YYYYMM.

Table 14.1.8c Concomitant Medications by ATC and PT (Safety Population in the Extension Phase)

• Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.

[Programming Notes]

• Footnote - Extension Phase: Concomitant medications are any medications being taken on or after the initial study treatment dosing date during the Extension Phase through 30 days after the last dose. They are coded using WHO Drug Dictionary version YYYYMM. Table 14.1.8d Concomitant Medications by ATC and PT (Safety Population in the Stage 3 PK Phase)

• Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

• Footnote - Stage 3: Concomitant medications are any medications being taken on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase. They are coded using WHO Drug Dictionary version YYYYMM.

ESARO, Inc. Confidential					
11000001. AAAAA	Table $1/1$ 9a				
Concernitant Transfusions on	d Crowth Easters (Cafety Depulation	in the Stage 1 DV	Dhace)		
	a Growin Factors (Salety Population	In the stage I PK	rilase)		
Darameter	Statistic	Seguence	Sequence		
Talameter	Statistic	TABLET/CAPSULE	CAPSULE/TABLET	OVERALL.	
		(N=XX)	(N=XX)	(N=XX)	
Any Concomitant Transfusions	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Red Blood Cells	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)	
Platelet	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)	
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any Concomitant Growth Factors	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
G-CSF	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)	
GM-CSF	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Recombinant Erythropoietin	n (%)	xx (xx.x)	XX (XX.X)	xx (xx.x)	
Other	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)	

Note: Concomitant transfusions or growth factors are any transfusion or growth factor given on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose for those not continuing into the Extension Phase.

Repeat for:

Table 14.1.9b Concomitant Transfusions and Growth Factors (Safety Population in the Stage 2 PK Phase)

Table 14.1.9c Concomitant Transfusions and Growth Factors (Safety Population in the Extension Phase)

• Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.

[Programming Notes]

• Footnote - Extension Phase: Concomitant transfusions or growth factors are any transfusion or growth factor given on or after the initial study treatment dosing date during the Extension Phase through 30 days after the last dose.

Table 14.1.9d Concomitant Transfusions and Growth Factors (Safety Population in the Stage 3 PK Phase)

• Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

• Footnote - Stage 3: Concomitant transfusions or growth factors are any transfusion or growth factor given on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose for those not continuing into the Extension Phase.

TESARO, Inc.	Confidential					Page 1 of x		
Protocol: XXXXX								
Table 14.1.10c								
Summary of Inv	vestigator-Assessed E	Best Response by T	Cumor Type (Safety	Population in t	he Extension Phase	e)		
Treatment: <tablet, capsule=""></tablet,>	(N=xx)							
			Investigato	r Assessment				
	Complete	Partial	Stable Disease	Progressive	Not Evaluable			
Tumor type [1]	Response (CR)	Response (PR)	(SD)	Disease (PD)	(NE)	Total [2]		
Prostate Cancer	xx (xx.x)	XX (XX.X)	XX (XX.X)	xx (xx.x)	XX (XX.X)	XX (XX.X)		
Mesothelioma Malignant	xx (xx.x)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		
Duodenal Adenocarcinoma	xx (xx.x)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		
Colon Cancer	xx (xx.x)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		
Malignant Melanoma	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	XX (XX.X)		
•••								
						1		
						1		
						1		
Other: xxx								
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
					·			
N=Number of patients in Safet	ty Population.							
Note: 'Total' represents the	number of patients w	with non-missing :	investigator asses	ssment.				
[1] The percentages are based	d on row totals.							
[2] The percentages are based	d on overall response	e totals.						

Source: Listing 16.2.6.1c. Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]

Present by decreasing order of total frequency of tumor types observed, in the event of tie, sort in alphabetical order. If better fit requires taking Treatment out into the header row, split table across pages with each treatment on a new page.

TESARO, Inc.	Confidential					
Protocol: XXXXX						
	Table 14.3.1.1.1a	a				
Overall Summary of Treatment Emergent	Adverse Events (Sa	fety Population in t	the Stage 1 PK Phase	)		
	TABLET [1]	CAPSULE [2]	FU/Ext Screening	Total [4]		
	(N=xx)	(N=xx)	[3] (N=xx)	(N=xx)		
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Any Related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Any Serious TEAE	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)		
Any Related Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Any TEAE with CTCAE Toxicity Grade $\geq$ 3	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)		
Any Related TEAE with CTCAE Toxicity Grade $\geq$ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Any TEAE leading to Dose Interruption	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Any TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Any Related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Any TEAE Leading to Death	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)		
			*			
[1] Includes TEAEs with onset date in Period 1 or Perio	d 2 where patient re	eceived niraparib ta	ablet.			
[2] Includes TEAEs with onset date in Period 1 or Perio	d 2 where patient re	eceived niraparib ca	apsules.			
[3] For patients not participating in the Extension Pha	se, includes TEAEs t	that began after the	end of the PK Phase	e through the End of		
Study. For patients participating in the Extension Phas	se, includes TEAEs t	that began after the	e end of the PK Phas	e until the date of		
first dose in the Extension Phase.						
[4] Includes TEAEs occurring at any time during the PK	Phase.					
Source: Program: XXXXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS						
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMM	МҮҮҮҮ					

Repeat for:

Table 14.3.1.1.1b Overall Summary of Treatment Emergent Adverse Events (Safety Population in the Stage 2 PK Phase)

TESARO, Inc.	Confidential						
Protocol: XXXXX							
Table 14.3.1.1.1c							
Overall Summary of Treatment Emergent	Adverse Events (Safety E	opulation in the Extensi	lon Phase)				
	TABLET	CAPSULE	OVERALL				
	(N=xx)	(N=xx)	(N=xx)				
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
Any Related TEAE	xx (xx.x)	XX (XX.X)	xx (xx.x)				
Any Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)				
Any Related Serious TEAE	xx (xx.x)	XX (XX.X)	xx (xx.x)				
Any TEAE with CTCAE Toxicity Grade $\geq$ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)				
Any Related TEAE with CTCAE Toxicity Grade $\geq$ 3	xx (xx.x)	XX (XX.X)	xx (xx.x)				
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)				
Any TEAE leading to Dose Interruption	xx (xx.x)	XX (XX.X)	xx (xx.x)				
Any TEAE leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)				
Any Related TEAE Leading to Treatment Discontinuation	xx (xx.x)	XX (XX.X)	xx (xx.x)				
Any TEAE leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)				
Any COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)				
Any Serious COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)				
Any COVID-19 related TEAE Leading to Treatment Discontinu	ation xx (xx.x)	XX (XX.X)	XX (XX.X)				
Note: This table reports Treatment Emergent Adverse Event	s (TEAEs) with onset du	ing Extension Phase only	/.				

Source: Listing XXXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]

• Sort order: All AE tabulations, unless otherwise specified, will be ordered in terms of decreasing frequency for SOC (alphabetically for SOCs with the same number of AEs reported), and decreasing frequency for PT within SOC (alphabetically for PTs with the same number of AEs reported within a SOC) considering the overall rate.

Repeat for: Table 14.3.1.1.1.1 Overall Summary of Treatment Emergent Adverse Events Ongoing from PK Phase (Safety Population in the Extension Phase)

[Programming Notes for Table 14.3.1.1.1.1c] Footnote: "Note: This table reports Treatment Emergent Adverse Events (TEAEs) with onset during PK Phase of the study.

This table summarizes data from Listing 16.2.7.2c, please use this listing as source reference in the footnote.

TESARO, Inc. Protocol: XXXXX	Page 1 of x						
Table 14.3.1.1.1d							
Overall Summary of Treatment Emergent	t Adverse Events (Sa:	fety Population in t	the Stage 3 PK Phase)				
	NIRAPARIB	NIRAPARIB	FU/Ext				
	TABLET FASTED [1]	TABLET FED [2]	Screening [3]	Total [4]			
	(N=xx)	(N=xx)	(N=xx)	(N=xx)			
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
Any Related TEAE	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)			
Any Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
Any Related Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
Any TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
Any Related TEAE with CTCAE Toxicity Grade $\geq$ 3	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)			
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
Any TEAE leading to Dose Interruption	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
Any TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)			
Any Related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)			
Any TEAE Leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
Any COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)			
Any Serious COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
Any COVID-19 related TEAE Leading to Treatment	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
Discontinuation							

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.

[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.

[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.

[4] Includes TEAEs occurring at any time during the PK Phase.

TESARO, Inc.		Confidential				Page 1 of x
Protocol: XXXXX						2
	Tabl	e 14.3.1.1.2a				
Overall Summary of Treatment Emergent Adv	erse Events by	Sequence and	Period (Safetv	Population in	the Stage 1 PK	Phase)
		· · 1 · · · · · ·			, -	,
		Sequence			Sequence	
		TABLET/CAPSULE			CAPSULE/TABLET	1
		(N=XX)			(N=XX)	
	TABLET	CAPSULE	FU/Ext	CAPSULE	TABLET	FU/Ext
	Period 1	Period 2	Screening	Period 1	Period 2	Screening
	(N=XX)	(N=xx)	(N=XX)	(N=xx)	(N=xx)	(N=XX)
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE with CTCAE Toxicity Grade $\geq$ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE with CTCAE Toxicity Grade $\geq$ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE leading to Dose Interruption	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Related TEAE Leading to Treatment	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)
Discontinuation						
Any TEAE Leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxxxxxxxxxx.rt	f. Generated	on DDMMMYYYY:HI	H:MM:SS		
Data Extract Date: DDMMMYYYY, Data Cutoff Date	: DDMMMYYYY					

Repeat for:

Table 14.3.1.1.2b Overall Summary of Treatment Emergent Adverse Events by Sequence and Period (Safety Population in the Stage 2 PK Phase)

TESARO, Inc.	Confidential					Page 1 of x	
Table 14.5.1.1.2a							
Overall Summary of Treatment Emergent Adverse Events by Sequence and Period (Safety Population in the Stage 3 PK Phase)							
		Sequence			Sequence		
	NIRAPA	RIB TABLET FAS	TED/FED	NIRAE	PARIB TABLET FED/F	ASTED	
		(N=XX)	1		(N=XX)		
	NIRAPARIB	NIRAPARIB		NIRAPARIB			
	TABLET	TABLET		TABLET	NIRAPARIB		
	FASTED	FED	FU/Ext	FED	TABLET FASTED	FU/Ext	
	Period I	Period 2	Screening	Period I	Period 2	Screening	
	(N=XX)	(N=XX)	(N=XX)	(N=XX)	(N=XX)	(N=XX)	
Any Treatment Emergent Adverse Event (TEAE)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Any Related TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Any Serious TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Any Related Serious TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Any TEAE with CTCAE Toxicity Grade $\geq$ 3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Any Related TEAE with CTCAE Toxicity Grade $\geq$							
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any TEAE leading to Dose Interruption	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any Related TEAE Leading to Treatment							
Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	XX (XX.X)	
Any TEAE Leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	XX (XX.X)	
Any COVID-19 related TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Any Serious COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any COVID-19 related TEAE Leading to	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Treatment Discontinuation							

TESARO, Inc.	Conf		Page 1 of x			
Protocol: XXXXX						
	Table 1	4.3.1.2.1a				
Summary of Treatme	nt Emergent Adverse Events by SC	)C and PT (Safety Popu	lation in the Stage 1 PK Ph	.ase)		
System Organ Class	TABLET [1]	CAPSULE [2]	FU/Ext Screening [3]	Total [4]		
Preferred Term	(N=xx)	(N=xx)	(N=xx)	(N=XX)		
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
SOC1	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)		
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
PT 2	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)		
SOC2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
		-	•			

[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib capsules.

[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.

[4] Includes TEAEs occurring at any time during the PK Phase.

[Programming Notes]

For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported.

Table 14.3.1.2.1b Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 2 PK Phase)

TESARO, Inc.	Cor	fidential	Page 1 of x					
Protocol: XXXXX								
	Table 1	14.3.1.2.1c						
Summary of Tre	atment Emergent Adverse Events by S	SOC and PT (Safety Population in t	the Extension Phase)					
System Organ Class	TABLET	CAPSULE	OVERALL					
Preferred Term	(N=xx)	(N=xx)	(N=xx)					
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)					
SOC1	xx (xx.x)	XX (XX.X)	xx (xx.x)					
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)					
PT 2	XX (XX.X)	xx (xx.x)	xx (xx.x)					
SOC2	xx (xx.x)	xx (xx.x)	xx (xx.x)					
PT 1	xx (xx.x)	XX (XX.X)	xx (xx.x)					
PT 2	XX (XX.X)	xx (xx.x)	xx (xx.x)					
Source: Listing XXXXXXXXX. Pr	ogram: XXXXXXXXXXXXXXXXXX. Outpu	t: xxxxxxxxxxxx.rtf. Generated or	n DDMMMYYYY:HH:MM:SS					
Data Extract Date: DDMMMYYYY,	Data Cutoff Date: DDMMMYYYY							

[Programming Notes]

For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported.

TESARO, Inc.	Confidential			Page 1 of x
Protocol: XXXXX				
	Table 14.3.1.2.1d			
Summary of Treatment Emergent Advers	e Events by SOC and PT (	Safety Population in	n the Stage 3 PK Pha	ase)
				,
	NTRAPARTB	NTRAPARTB	FU/Ext.	
System Organ Class	TABLET FASTED [1]	TABLET FED [2]	Screening [3]	Total [4]
Preferred Term	(N=XX)	(N=xx)	(N=XX)	(N=XX)
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	·	•		•
[1] Includes TEAEs with onset date in Period 1 or Pe	eriod 2 where patient rec	ceived niraparib tak	olet in fasted state	

[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.

[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.

[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Listing XXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]

For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported.

ESARO, Inc. Confidential									
Protocol: XXXXX	: XXXX								
	Table 14.3.1.2.1.1d	l							
Summary of COVID-19 related Adverse Ever	nts by SOC and PT (Sa	afety Population in	the Stage 3 PK Phas	e)					
	NIRAPARIB	NIRAPARIB	FU/Ext						
System Organ Class	TABLET FASTED [1]	TABLET FED [2]	Screening [3]	Total [4]					
Preferred Term	(N=XX)	(N=xx)	(N=xx)	(N=xx)					
Any COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)					
SOC1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)					
PT 1	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)					
PT 2	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)					
SOC2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)					
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)					
PT 2	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)					
Note: COVID-19 Case Diagnosis is based on WHO Definition as of DDMMMYYYY.									
[1] Includes COVID-19 related TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.									
[2] Includes COVID-19 related TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.									
[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of									
Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of									
first dose in the Extension Phase.									
[4] Includes COVID-19 related TEAEs occurring at any time during the PK Phase.									

Source: Listing XXXXXXXX. Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]

For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported.

Select only COVID-19 related TEAEs.

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Protocol: XXXXX							
Table 14.3.1.2.2a							
Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 1 PK Phase)							
		Sequence			Sequence		
		TABLET/CAPSULE			CAPSULE/TABLET		
		(N=xx)	-		(N=xx)		
	TABLET	CAPSULE	FU/Ext	CAPSULE	TABLET	FU/Ext	
System Organ Class	Period 1	Period 2	Screening	Period 1	Period 2	Screening	
Preferred Term	(N=xx)	(N=xx)	(N=xx)	(N=xx)	(N=xx)	(N=xx)	
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)	
SOC1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)	
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
SOC2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX							

[Programming Notes]

For tables of adverse events by SOC and PT by sequence and period, sort alphabetically by SOCs and PTs.

Table 14.3.1.2.2b Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 2 PK Phase)

TESARO, Inc.		Confi	dential			Page 1 of x
FIOLOCOI. AAAAA		Table 14	3 1 2 2d			
Summary of Troatmor	+ Emorgont Advor	a Eventa by SOC	· ord DT (Cofoty	Repulation in the	Stage 3 DK Dhage	1
Summary Of Treatmen	it Emergent Adver	Se Events by Soc	and Fi (Salety	roputation in the	Staye 5 FR Fliase	)
		Comonao			Comonao	
	NTDADA	Sequence	ת הא הא	NITDAD	Sequence	A CHED
	NIRAPP	(N=)		(N-WY)		
	NTRADADTD	(IN-XX)	1		(N-XX)	
	NIKAPARIB	NIKAPAKIB		NIRAPARIB	NIKAPAKIB	
Gueter Owner Glass	TABLET FASTED	TABLET FED	FU/EXt	TABLET FASTED	TABLET FED	FU/EXt
System Organ Class	Period I	Period 2	Screening	Period 1	Period 2	Screening
Preferred Term	(N=XX)	(N=XX)	(N=XX)	(N=XX)	(N=XX)	(N=XX)
Any TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
SOC1	XX (XX.X)	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	XX (XX.X)	XX (XX.X)	xx (xx.x)	XX (XX.X)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC2	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	xx (xx.x)	XX (XX.X)	XX (XX.X)
			•			•
Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XX. Output: xxxx	xxxxxxxx.rtf.	Generated on DDN	MMMYYYY:HH:MM:SS		
Data Extract Date: DDMMMYYYY, Da	ta Cutoff Date:	DDMMMYYYY				

[Programming Notes]

For tables of adverse events by SOC and PT by sequence and period, sort alphabetically by SOCs and PTs.

Using Mock Shell (Table 14.3.1.2.1a, Table 14.3.1.2.1b, Table 14.3.1.2.1c, Table 14.3.1.2.1d) Repeat for: Table 14.3.1.3a Summary of Related TEAE by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.3b Summary of Related TEAE by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.3c Summary of Related TEAE by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.3d Summary of Related TEAE by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.4a Summary of Serious TEAE by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.4b Summary of Serious TEAE by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.4c Summary of Serious TEAE by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.4d Summary of Serious TEAE by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.5a Summary of Related Serious TEAE by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.5b Summary of Related Serious TEAE by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.5c Summary of Related Serious TEAE by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.5d Summary of Related Serious TEAE by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.6a Summary of TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.6b Summary of TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.6c Summary of TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.6d Summary of TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.7a Summary of Related TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.7b Summary of Related TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.7c Summary of Related TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.7d Summary of Related TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.8a Summary of TEAE Leading to Treatment Discontinuation by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.8b Summary of TEAE Leading to Treatment Discontinuation by SOC and PT (Safety Population in the Stage 2 PK Phase)

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Table 14.3.1.8c Summary of TEAE Leading to Treatment Discontinuation by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.8d Summary of TEAE Leading to Treatment Discontinuation by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.9c Summary of TEAE Leading to Treatment Dose Interruption by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.10a Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.10b Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.10c Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.10c Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.10d Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.10d Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.11d Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.11b Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.11c Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.11c Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.11d Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.11.1a Summary of Related TEAE Leading to Death by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.11.1a Summary of Related TEAE Leading to Death by SOC and PT (Safety Population in the Stage 1 PK Phase) (Programming notes) - TABLE FOR PLAIN TEXT SUMMARY PURPOSES ONLY.

Table 14.3.1.11.1b Summary of Related TEAE Leading to Death by SOC and PT (Safety Population in the Stage 2 PK Phase) [Programming notes] - TABLE FOR PLAIN TEXT SUMMARY PURPOSES ONLY.

Table 14.3.1.11.1c Summary of Related TEAE Leading to Death by SOC and PT (Safety Population in the Extension Phase) [Programming notes] - TABLE FOR PLAIN TEXT SUMMARY PURPOSES ONLY.

Table 14.3.1.11.1d Summary of Related TEAE Leading to Death by SOC and PT (Safety Population in the Stage 3 PK Phase) [Programming notes] - TABLE FOR PLAIN TEXT SUMMARY PURPOSES ONLY.

Table 14.3.1.12a Summary of Treatment Emergent AESI by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.12b Summary of Treatment Emergent AESI by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.12c Summary of Treatment Emergent AESI by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.12d Summary of Treatment Emergent AESI by SOC and PT (Safety Population in the Stage 3 PK Phase)

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- Table 14.3.1.23.1a Summary of Non-Serious TEAE (≥5%) by SOC and PT (Safety Population in the Stage 1 PK Phase) [Programming notes] - TABLE FOR DISCLOSURE PURPOSES ONLY.
- Table 14.3.1.23.1b Summary of Non-Serious TEAE (≥5%) by SOC and PT (Safety Population in the Stage 2 PK Phase) [Programming notes] - TABLE FOR DISCLOSURE PURPOSES ONLY.
- Table 14.3.1.23.1c Summary of Non-Serious TEAE (≥5%) by SOC and PT (Safety Population in the Extension Phase) [Programming notes] - TABLE FOR DISCLOSURE PURPOSES ONLY.
- Table 14.3.1.23.1d Summary of Non-Serious TEAE (≥5%) by SOC and PT (Safety Population in the Stage 3 PK Phase) [Programming notes] - TABLE FOR DISCLOSURE PURPOSES ONLY.
- Table 14.3.1.23.2a Summary of Related Non-Serious TEAE by SOC and PT (Safety Population in the Stage 1 PK Phase) [Programming notes] - TABLE FOR PLAIN TEXT SUMMARY PURPOSES ONLY.
- Table 14.3.1.23.2b Summary of Related Non-Serious TEAE by SOC and PT (Safety Population in the Stage 2 PK Phase) [Programming notes] - TABLE FOR PLAIN TEXT SUMMARY PURPOSES ONLY.
- Table 14.3.1.23.2c Summary of Related Non-Serious TEAE by SOC and PT (Safety Population in the Extension Phase) [Programming notes] - TABLE FOR PLAIN TEXT SUMMARY PURPOSES ONLY.
- Table 14.3.1.23.2d Summary of Related Non-Serious TEAE by SOC and PT (Safety Population in the Stage 3 PK Phase) [Programming notes] - TABLE FOR PLAIN TEXT SUMMARY PURPOSES ONLY.

TECADO INC	Confidential			Dago 1 of			
Drotocol, YYYY	confidential			Page I OI X			
Protocol: XXXX	mabla 14 0 1 10a						
	Table 14.3.1.13a			. 1			
Summary of Treatment Emergent Adverse Events by SOC	Summary of Treatment Emergent Adverse Events by SOC and PT and CTCAE Toxicity Grade (Safety Population in the Stage I PK Phase)						
			FU/Ext				
System Organ Class	TABLET [1]	CAPSULE [2]	Screening [3]	Total [4]			
Preferred Term	(N=xx)	(N=xx)	(N=xx)	(N=xx)			
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)				
Grade 1							
Grade 5							
SOC1	xx (xx.x)	xx (xx.x)	xx (xx.x)				
Grade 1							
Grade 5							
PT 1	XX (XX.X)	XX (XX.X)	XX (XX.X)				
Grade 1		()	()				
Grade 5							
[1] Includes TEAEs with onset date in Period 1 or Perio	d 2 where patient re	ceived niraparib ta	hlet				
[2] Includes TEAEs with onset date in Period 1 or Perio	d 2 where patient re	ceived niraparib ca					
[3] For patients not participating in the Extension Pha	se, includes TEAEs t	hat began after the	end of the PK Phase	through the End of			
Study For patients participating in the Extension Pha	se, includes TEAEs t	hat began after the	end of the PK Phase	until the date of			
first dose in the Extension Phase		inde began dreer ene	cha of the fit flabe	and the date of			
[4] Includes TEAEs occurring at any time during the PK	Phase						
[4] Includes Thinks occurring at any time during the In	inase.						
Source: Listing XXXXXXXX, Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	X. Outout: xxxxxxx	xxxxx.rtf. Generate	d on DDMMMYYYY:HH:MM	. 55			
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDM	ΜΥΥΥΥ						
Demost for							
Repeat for:							
Table 14.5.1.15b Summary of Treatment Emergent Adverse E	venus by soc and Pr	and Maximum Toxicity	y (Salety Population	in the Stage 2 PK			
Phase)							
Table 14.3.1.13c Summary of Treatment Emergent Adverse E	events by SOC and PT	and Maximum Toxicity	y (Safety Population	in the Extension			
Phase)							

• Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.

[Programming Notes]

For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported. Within each PT, sort by presented maximum toxicity grade.

TESARO, Inc.	Confidential			Page 1 of x				
Protocol: XXXX								
Table 14.3.1.13d								
Summary of Treatment Emergent Adverse Events by SOC	and PT and CTCAE Tox	kicity Grade (Safety	Population in the S	tage 3 PK Phase)				
			-	- · ·				
	NIRAPARIB	NIRAPARIB	FU/Ext					
System Organ Class	TABLET FASTED [1]	TABLET FED [2]	Screening [3]	Total [4]				
Preferred Term	(N=xx)	(N=xx)	(N=xx)	(N=XX)				
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	XX (XX.X)				
Grade 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)				
	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)				
Grade 5	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)				
SOC1	xx (xx.x)	XX (XX.X)	XX (XX.X)	xx (xx.x)				
Grade 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)				
	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)				
Grade 5	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)				
PT 1	xx (xx.x)	XX (XX.X)	XX (XX.X)	xx (xx.x)				
Grade 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)				
	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)				
Grade 5	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)				

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.

[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.

[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.

[4] Includes TEAEs occurring at any time during the PK Phase.

Source: Listing XXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

TESARO, Inc.	Confidential Page 1 of						
Protocol: XXXXX	COL: XXXXX						
Ourrenaut of Theorem Theorem	Table 14.	.J.I.I4d	in the Change 1 DK Dhas	- )			
Summary of freatment emerg	gent Adverse Events by	PT (Salety Population	in the stage i PK Phas	e)			
	TABLET [1]	CAPSULE [2]	FU/Ext Screening [3]	Total [4]			
Preferred Term	(N=xx)	(N=XX)	(N=XX)	(N=XX)			
Any TEAE	XX (XX.X)	xx (xx.x)	XX (XX.X)	xx (xx.x)			
PT 1	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
PT 2	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
PT 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet. [2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib capsules. [3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase. [4] Includes TEAEs occurring at any time during the PK Phase. Source: Listing XXXXXXXX. Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYY, Data Cutoff Date: DDMMMYYY							

Repeat for:

Table 14.3.1.14b Summary of Treatment Emergent Adverse Events by PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.14c Summary of Treatment Emergent Adverse Events by PT (Safety Population in the Extension Phase)

- Summarize Extension Phase Data with columns for TABLET; CAPSULE; OVERALL.
- [1], [2], [3] and [4] are not applicable.

[Programming Notes] Sort PTs by descending overall frequency of events reported.

TESARO, Inc. Protocol: XXXXX	Confidential			Page 1 of x		
	Table 14.3.1.14d					
Summary of Treatme	nt Emergent Adverse Events by PT (Safe	ety Population in th	ne Stage 3 PK Phase)			
	NIRAPARIB	NIRAPARIB	FU/Ext			
Preferred Term	TABLET FASTED [1]	TABLET FED [2]	Screening [3]	Total [4]		
Any TEAE	XX (XX.X)	(N-XX) XX (XX.X)	(N-XX) XX (XX.X)	(N-XX) XX (XX.X)		
PT 1	xx (xx.x)	xx (xx.x)	 	XX (XX.X)		
PT 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		
PT 3						
<ul> <li>[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.</li> <li>[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.</li> <li>[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.</li> <li>[4] Includes TEAEs occurring at any time during the PK Phase.</li> </ul>						
Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY						

TESARO,	Inc.				Confid	lential					Page 1 of x
Protoco	DI: XXXXX			ŢъЪ	10 14	3 1 15a					
		Listing of Serious TEAR	ls Durin	ia PK Ph	ase (S	afetv Pop	ulation i	n the Stage 1	PK Phase	)	
										,	
Treatmer	t Sequence: <st< td=""><td>age 1 &amp; 2: TABLET/CAPSULE</td><td>or CAP</td><td>SULE/TA</td><td>BLET&gt; 0</td><td>or <stage< td=""><td>3: FASTER</td><td>D/FED or FED/E</td><td>ASTED&gt; o:</td><td>r <extension:< td=""><td>TABLET or</td></extension:<></td></stage<></td></st<>	age 1 & 2: TABLET/CAPSULE	or CAP	SULE/TA	BLET> 0	or <stage< td=""><td>3: FASTER</td><td>D/FED or FED/E</td><td>ASTED&gt; o:</td><td>r <extension:< td=""><td>TABLET or</td></extension:<></td></stage<>	3: FASTER	D/FED or FED/E	ASTED> o:	r <extension:< td=""><td>TABLET or</td></extension:<>	TABLET or
CAPSULE>	, as applicable	:									
[			Start	Stop				T			<u> </u>
			Date	Date							
			Time/	Time							
	Dosing Period/	Adverse Event	(Rel	(Rel		SAE/		Action Taken	Other		
Patient	Niraparib	[P]MedDRA Preferred Term	Day	Day		Reason		on Study	Action	Relationship	
Number	Treatment	[S]System Organ Class	[1])	[1])	TEAE?	[2]	Severity	Treatment[3]	Taken	[3]	Outcome
	Period 1/	*****	уууу-	уууу-	Y	N	Grade 1	T: NA		T: NA	Recovered/
	Capsule	[P]XXXXXXXXXXXXXXXXXXXXXX	mm-dd	mm-dd				C: Dose Not		C: Related	Resolved
		[S]XXXXXXXXXXXXXXXXXXXXXX	hh:mm	[x]				Changed			
			[x]								
	Period 2/	*****	уууу-	уууу-	Y	Ν	Grade 1	T: Dose Not		T: Related	Recovered/
	Tablet	[P]XXXXXXXXXXXXXXXXXXXXXX	mm-dd	mm-dd				Changed		C: NA	Resolved
		[S]XXXXXXXXXXXXXXXXXXXXX	hh:mm	[x]				C: NA			
			[X]								
Ļ	PK Safety FU										
[1] Rela [2] Rea 4 = Req [3] T=Ta Source: Data Ext	tive to the dat son for SAE: 1 uires or prolon blet; C=Capsule Listing XXXXXXX ract Date: DDM	e of first dose in PK Pha = Result in death; 2 gs hospitalization; 5 = C  XX. Program: XXXXXXXXXX MMYYYY, Data Cutoff Date	se. = Life ongenit XXXXXXX : DDMM	threate al abno: X. Out: MYYYY	ening; rmality put: x:	3 = Rest y/birth de	alt in pe fect; 6 = xx.rtf. (	ersistent or = Other medica Generated on I	significa lly impo DDMMMYYYY	ant disability rtant event. :HH:MM:SS	/incapacity
L											
[Program Please a	ming notes] dd time to Star	t Date column for PK Phas	e Stage	2 and 1	Extensi	ion Phase.					
Repeat f	or:										
Table 14	.3.1.15b Listin	g of Serious TEAEs During	the PK	Phase	(Safety	y Populati	on in the	e Stage 2 PK P	hase)		
Table 14	.3.1.15c Listin	g of Serious TEAEs During	the Ex	tension	Phase	(Safetv B	opulatior	n in the Exten	sion Phas	se)	

Table 14.3.1.15d Listing of Serious TEAEs During the PK Phase (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.16a Listing of Deaths During the PK Phase (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.16b Listing of Deaths During the PK Phase (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.16c Listing of Deaths During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.16d Listing of Deaths During the PK Phase (Safety Population in the Stage 3 PK Phase)

• Footnote: 'NOTE: Deaths due to progressive disease were not collected as adverse events.'

Table 14.3.1.17c Listing of TEAE Leading to Dose Interruption During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.17d Listing of TEAE Leading to Dose Interruption During the PK Phase (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.18a Listing of TEAE Leading to Dose Reduction During the PK Phase (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.18b Listing of TEAE Leading to Dose Reduction During the PK Phase (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.18c Listing of TEAE Leading to Dose Reduction During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.18d Listing of TEAE Leading to Dose Reduction During the PK Phase (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.19a Listing of TEAE Leading to Treatment Discontinuation During the PK Phase (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.19b Listing of TEAE Leading to Treatment Discontinuation During the PK Phase (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.19c Listing of TEAE Leading to Treatment Discontinuation During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.19d Listing of TEAE Leading to Treatment Discontinuation During the PK Phase (Safety Population in the Stage 3 PK Phase)

## [Programming Notes]

- Stage 3: Treatment Sequence will be NIRAPARIB TABLET FASTED/FED and NIRAPARIB TABLET FED/FASTED.
- Stage 3: Column 2: Dosing Period/Treatment Treatment should be NIRAPARIB FASTED or NIRAPARIB FED.

• Stage 3: Treatment discontinuation during PK Phase - add column to record if discontinuation was due to COVID-19 ["COVID-19 Reason" with Options "COVID-19 infection" or "Issues rel. to COVID-19 pandemic"].

- Extension Phase: Replace column for Dosing Period/Treatment with Treatment (TABLET, CAPSULE) and Starting Dose.
- Extension Phase: Do not need time with start/stop dates.
- Extension Phase: Footnote: [1] Relative to first dose during the Extension Phase.

TESARO, Inc.	Conf	Page 1 of x	
Protocol: XXXXX	Table 14 All-Cause Mortality (Safety Pop		
	TABLET (N=xx)	CAPSULE (N=xx)	OVERALL (N=xx)
Death due to any cause	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
NOTE: Deaths occurring outside Source: Listing 16.2.1c. Prog Data Extract Date: DDMMMYYYY,	30-day window following end of Exter ram: XXXXXXXXXXXXXXXXXXXXXXX Output: xx Data Cutoff Date: DDMMMYYYY	sion Phase treatment are included	l in the counts. MMYYYY:HH:MM:SS

[Programming Notes] This table is for final disclosure reporting purposes ONLY. All deaths reported/recorded in the database should be included.

TESARO, Inc.	Confiden	Confidential						
Protocol: XXXXX	mahla 14 0	1 00-1						
	Table 14.3.	1.20d						
Summary of Incidence of (	COVID-19 Related Adverse Events Ov	ver Time (Safety Population in the	Stage 3 PK Phase)					
		NIRAPARIB	NIRAPARIB					
		TABLET FASTED	TABLET FED					
	Period during COVID-19	(N=XX)	(N=xx)					
	Pandemic [1]	n/Patients at Risk (%)	n/Patients at Risk (%)					
Any COVID-19 Related AE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)					
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)					
Any COVID-19 Related SAE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)					
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)					
Any COVID-19 Related Grade ≥3 AE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)					
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)					
[1] TABLET PK Phase Stage 3 opened t	:o recruitment on DDMMMYYYY, with	first patient consented on DDMMMY	YYYY, placing the start of the					
recruitment during the COVID-19 pande	emic.							
1								
Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	. Output: xxxxxxxxxx.rtf. Gene	erated on DDMMMYYYY:HH:MM:SS						
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY								

TESARO, Inc.	Confi	Page 1 of x						
	Table 14.3.1.20c							
Summary of Incidence of COVID-19 Related Adverse Events Over Time								
(Safety Population in the Extension Phase)								
	TABLET	CAPSULE	OVERALL					
	n/Patients at Risk (%)	n/Patients at Risk (%)	n/Patients at Risk (%)					
Any COVID-19 Related AE	xx/xxx (xx.x%)	xx/xxx (xx.x%)	xx/xxx (xx.x%)					
Any COVID-19 Related SAE	xx/xxx (xx.x%)	xx/xxx (xx.x%)	xx/xxx (xx.x%)					
Any COVID-19 Related Grade ≥3 AE	xx/xxx (xx.x%)	xx/xxx (xx.x%)	xx/xxx (xx.x%)					
Note: Extension Phase for all Stage for the Extension Phase on or afte Stages 1 and 2 on 14MAY2018 and 05 the start of the pandemic, as defir	es of TABLET study overlapped with r 02JUN2021 placing the AE onse DEC2019, respectively, placing t ned by WHO as of 20MAR2020, with	h COVID-19 pandemic, with all Stat t during the pandemic, while las their first Extension Phase treat patients across all Stages ongoi	ge 3 patients commencing treatment t patient commenced treatment for ment dose administration prior to ng until DDMMMYYYY.					

[Programming Notes]

N accounts for all patients in Safety Population of the Extension Phase.

n - number of patients with an event related to COVID-19.

Patients at Risk (%) - number of patients who were ongoing on Extension Phase treatment on or after 20MAR2020.

TESARO, Inc.	Co	Page 1 of x					
inste 14.5.1.210							
Summary of incidence of COV	VID-19 Related Adverse Events C	ver time by Gender (Salety Populatio	in in the stage 3 PK Phase)				
Report on separate page for each:	<gender: female="" male,=""></gender:>						
		NIRAPARIB	NIRAPARIB				
		TABLET FASTED	TABLET FED				
	Period during COVID-19	(N=xx)	(N=xx)				
	Pandemic [1]	n/Patients at Risk (%)	n/Patients at Risk (%)				
Any COVID-19 Related AE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)				
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)				
Any COVID-19 Related SAF	Period 1	vv/vvv (vv v%)	<u>vv/vvv (vv v</u> &)				
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)				
Any COVID-19 Related Grade ≥3 AE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)				
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)				
[1] TABLET PK Phase Stage 3 opene	d to recruitment on DDMMMYYYY,	with first patient consented on DDN	MMMYYYY, placing the start of the				
recruitment during the COVID-19 pa	andemic.						

## Repeat for:

Table 14.3.1.22d Summary of Incidence of Adverse Events Over Time by Age Group (Safety Population in the Stage 3 PK Phase)

• Use the FDAAA age groups <=18, 18-64, >=65.

TESARO, Inc. Protocol: XXXXX	Confi	Page 1 of x					
	Table 14	.3.1.21c					
Summary of Incidence of COVID-19 Related Adverse Events Over Time by Gender							
	(Safety Population in	the Extension Phase)					
		,					
Report on separate page for each:	<gender: female="" male,=""></gender:>						
	TABLET	CAPSULE	OVERALL				
	(N=xx)	(N=xx)	(N=xx)				
	n/Patients at Risk (%)	n/Patients at Risk (%)	n/Patients at Risk (%)				
Any COVID-19 Related AE	xx/xxx (xx.x%)	xx/xxx (xx.x%)	xx/xxx (xx.x%)				
Any COVID-19 Related SAE	xx/xxx (xx.x%)	xx/xxx (xx.x%)	xx/xxx (xx.x%)				
Any COVID-19 Related Grade ≥3 AE	xx/xxx (xx.x%)	xx/xxx (xx.x%)	xx/xxx (xx.x%)				
Note: Extension Phase for all Stag for the Extension Phase on or aft Stages 1 and 2 on 14MAY2018 and 0 the start of the pandemic, as defi	es of TABLET study overlapped wit er 02JUN2021 placing the AE onse 5DEC2019, respectively, placing t ned by WHO as of 20MAR2020, with	h COVID-19 pandemic, with all Stag t during the pandemic, while last their first Extension Phase treat patients across all Stages ongoir	ge 3 patients commencing treatment c patient commenced treatment for ment dose administration prior to ag until DDMMMYYYY.				

Repeat for:

Table 14.3.1.22c Summary of Incidence of Adverse Events Over Time by Age Group (Safety Population in the Extension Phase)

• Use the FDAAA age groups <=18, 18-64, >=65.

TESARO, Inc. Protocol: XXXXX	Confidential						
	Table 14.3.4.1a						
Summary of Study Treatment Exposure During the PK Phase (Safety Population in the Stage 1 PK Phase)							
	StatisticSequenceSequenceTABLET/CAPSULECAPSULE/TABLETOVERALL(N=xx)(N=xx)(N=xx)						
# of 100 mg Caps	sules Received						
3		n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
2		n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
1		n (%)	xx (xx.x)	XX (XX.X)	xx (xx.x)		
# of 300 mg Tabl	lets Received						
1		n (%)	xx (xx.x)	XX (XX.X)	xx (xx.x)		
Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX							

Repeat for:

Table 14.3.4.1b Summary of Study Treatment Exposure During the PK Phase (Safety Population in the Stage 2 PK Phase)

TESARO, Inc. Confidential Page 1 or					
Protocol: XXXXX					
Ta Current of Chudu Treatment Europure During the	able 14.3.4.	lC Anno (Cofety Depulat:	on in the Extension	Dhaga	
Summary of Study freatment Exposure During the	Excension P	nase (salety Populat.	Ion in the Extension	rilase)	
		TABLET	CAPSULE	OVERALL	
Parameters	Statistic	(N=XX)	(N=xx)	(N=xx)	
Maximum Number of Cycles					
1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
2	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	
≥ 6	n (%)	 xx (xx.x)	 xx (xx.x)	 xx (xx.x)	
Median number of cycles started	n	XX	ХХ	ХХ	
Duration of Treatment (months)	n	XX	XX	XX	
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	
	Median	xx.x	XX.X	XX.X	
	QI, Q3 Min Max	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
	MIN, Max	AA, AA			
Duration on Study (months)	n Mean (SD)	XX XX X (XX XX)	XX VV V (VV VV)	XX VV V (VV VV)	
	Median	XX.X	XX.X	XX.X	
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	XX.X, XX.X	
	Min, Max	XX, XX	XX, XX	XX, XX	
Exposure duration (Months)	n	XX	XX	XX	
<1 Month	n (%)	xx (xx.x)	XX (XX.X)	xx (xx.x)	
$1 - \langle 2 \text{ Months} \rangle$	n (%)	XX (XX.X)	xx (xx.x)	xx (xx.x)	
$2 - \langle 3 \text{ Months} \rangle$	n (%)	xx (xx.x)	XX (XX.X)	XX (XX.X)	
>= 3 Months	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	
>= 12 Months	n (%)	XX (XX.X) XX (XX.X)	XX (XX.X) XX (XX.X)	XX (XX.X) XX (XX.X)	
Total Number of Patients with at least 1 dose interruption	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Total Number of Patients with at least 1 dose reduction	n (%)	xx (xx.x)	XX (XX.X)	xx (xx.x)	
Total Number of Patients with at least 1 dose re-escalation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Dose intensity (mg/day) [1]	n	XX	ХХ	XX	
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	
	Median	XX.X	XX.X	XX.X	
	Q1, Q3	XX.X, XX.X	xx.x, xx.x	xx.x, xx.x	
	Min, Max	XX, XX	XX, XX	XX, XX	
[1] Dose intensity was calculated as sum of daily doses consumed divided by overall treatment exposure, in days.					
Source, Listing YYYYYYYY Drogram, YYYYYYYYYYYYYYYY Output, yyyyyyyyy rtf Cenerated on DDMMMYYYYY, UU, MM, CC					
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY	acput. AAAAA	AAAAAA. Itti. Ocheid			

TESARO, Inc. Protocol: XXXXX	RO, Inc. Confidential							
	Table 14.3.4.1d							
	Summary of Study Treatment Exposure During the PK Phase (Safety Population in the Stage 3 PK Phase)							
		Statistic	NIRAPARIB FASTED (N=XX)	NIRAPARIB FED (N=XX)	OVERALL (N=xx)			
# of 300 mg Tabl	ets Received							
1		n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
Source: Program: Data Extract Dat	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	ated on DDMMMY	YYY:HH:MM:SS					

TESARO, Inc.			Confidential		Page 1 of x
Protocol: XXXXX					
			Table 14.3.4.2c		
Summ	nary of Nirapan	ib Dose by Cy	cle (Safety Populati	on in the Extension Phas	se)
	Starting				
	Niraparib		TABLET	CAPSULE	OVERALL
Cycle	Dose (mg)	Statistic			
1		N	XXX	XXX	XXX
	300	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	200	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)
	100	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)
2		Ν	XXX	XXX	XXX
	300	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)
	200	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)
	100	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3		N	XXX	XXX	XXX
	300	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	200	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)
	100	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	•	•	·	•	·
Source: Listing XXXXXXXXX. Proc	gram: XXXXXXXX	XXXXXXXXXXX.	Output: xxxxxxxxxxx	.rtf. Generated on DDM	MMYYYY:HH:MM:SS
Data Extract Date: DDMMMYYYY,	Data Cutoff Da	ate: DDMMMYYY	Y		

TESARO, In	с.			Confid	lential			Page 1 of x	
Protocol:	XXXXX								
				Table 14.	3.4.3.1c				
	Summ	ary and Change	e from Baseline o:	f Select Hematolo	ogy Parameters by	Visit During the	Extension Phase		
			(Safe	ty Population in	the Extension Pha	ase)			
			TABLET (N=xx)		CAPSULE (N=xx)		OVERALL (N=xx)	1	
Parameter	Visit	Statistic	Actual	Change	Actual	Change	Actual	Change	
Parameter	Baseline	n (missing)	XX (XX)		XX (XX)		XX (XX)		
1		Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		
		Median	XX.X		XX.X		XX.X		
		Q1, Q3	XX.X, XX.X		XX.X, XX.X		XX.X, XX.X		
		Min, Max	XX, XX		XX, XX		XX, XX		
	Cvcle 1	n (missing)	vv (vv)	vy (vy)	vv (vv)	vv (vv)	vv (vv)	vv (vv)	
	- Dav 8	Mean (SD)	XX (XX) XX X (XX XX)						
	- 1 -	Median	XX X	XX X	XX.X	XX.X	XX.X	XX.X	
		01, 03	XX.X. XX.X	XX.X, XX.X					
		Min, Max	xx, xx						
	Cycle 1	n (missing)	XX (XX)						
	- Day 15	Mean (SD)	XX.X (XX.XX)						
	_	Median	XX.X	XX.X	XX.X	XX.X	XX.X	xx.x	
		Q1, Q3	xx.x, xx.x						
		Min, Max	XX, XX						
	Cvcle 1	n (missing)	XX (XX)						
	- Dav 22	Mean (SD)	xx x (xx xx)						
	- 1	Median	XX.X	XX X	XX.X	XX.X	XX.X	XX.X	
		01, 03	XX.X, XX.X						
		Min, Max	XX, XX						
	Cycle 2	n (missing)	XX (XX)						
	- Dav 1	Mean (SD)	xx.x (xx.xx)						
		Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	
		01, 03	xx.x, xx.x						
		Min, Max	xx, xx						
		n (missing)	XX (XX)						
		Mean (SD)	xx.x (xx.xx)						
		Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	
		Q1, Q3	xx.x, xx.x						
		Min, Max	XX, XX						
	EOT	n (missing)	XX (XX)						
		Mean (SD)	xx.x (xx.xx)						
		Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	
		Q1, Q3	XX.X, XX.X						
		Min, Max	XX, XX						
Source: Li	sting XXXX	XXXXX. Progra	m: XXXXXXXXXXXXXXX	XXXXXX. Output:	xxxxxxxxxxx.rtf.	Generated on Di	DMMMYYYY:HH:MM:SS		
Data Extra	ct Date:	DDMMMYYYY, Da	ta Cutoff Date:	DDMMMYYYY					



Programming Notes:

• Report hemoglobin, neutrophils and platelets only.

TESARO, Inc.				Confid	ential				Page 1 of x	
Protocol: XXXXX	Table 14.3.4.3.2c									
Shift S	Shift Summary of Select Hematology Parameters During the Extension Phase (Safety Population in the Extension Phase)									
Treatment Group					Post-Base	line Maximum	CTCAE Grade			
ͲλΒΙϜͲ	Laboratory	Baseline	Statistic	Grade 0	Grade 1	Grade 2	Grade 3	Grade (	Missing	
IADLEI	Test	CTCAE Grade	Statistic	Grade 0	Grade 1	Glade 2	Grade 5	Glade 4	MISSING	
	1050	CICIL OLAGE								
	XXXXX	Grade O	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
		Grade 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
		Grade 2	n (%)	XX (XX,X)	XX (XX,X)	XX (XX,X)	XX (XX,X)	XX (XX,X)	XX (XX,X)	
		01000 1		(	(	(,	(,	(	(	
		Grade 3	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	XX (XX.X)	
		Grade 4	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
		Missing	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	
			( - <i>)</i>		, , , , , , , , , , , , , , , , , , ,					
	XXXXX									

Source: Listing XXXXXXXX. Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Include TABLET, CAPSULE and OVERALL.

Repeat for:

Table 14.3.4.4.1c Summary and Change from Baseline of Select Chemistry Parameters by Visit During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.4.4.2c Shift Summary of Select Chemistry Parameters in Maximum Toxicity Grade During the Extension Phase (Safety Population in the Extension Phase)

TESARO, Inc.	. Confidential	Page 1 of x
Protocol: XX	XXXX	5
	Table 14.3.4.4.1d	
	Summary of COVID-19 Assessments for Patients with Suspected, Probable or Confirmed COV	ID-19 Case Diagnosis
	(Safety Population in the Stage 3 PK Phase)	-
	NTRAPARTE TARI	ET NTRAPARTE TABLET
	FASTED	FED
Assessment	(N=XX)	(N=XX)
COVID-19 Cas	se Diagnosis [1] xx (xx.x%)	xx (xx.x%)
Confirmed	$xx (xx.x^{\$})$	XX (XX.X%)
Probable	xx (xx.x <sup>®</sup> )	xx (xx.x%)
Suspected	$xx (xx.x_{\theta})$	xx (xx.x%)
COVID-19 Tes	st Performed [2]	
n	XX	XX
No	xx/xx (xx.x%)	xx/xx (xx.x%)
Yes	xx/xx (xx.x%)	xx/xx (xx.x%)
Result from	the COVID-19 Test	
n	XX	XX
Negative	xx/xx (xx.x%)	xx/xx (xx.x%)
Positive	xx/xx (xx.x%)	xx/xx (xx.x%)
Indetermin	nate xx/xx (xx.x%)	xx/xx (xx.x%)
[1] COVID-19	9 Case Diagnosis is based on WHO Definition as of DDMMMYYYY.	
[2] COVID-19	9 Test Performed is only captured for patients with a COVID-19 Case Diagnosis.	
Doto Eutrope	LING XXXXXXXXX. Frogram: XXXXXXXXXXXXXXXXX. Output: XXXXXXXXXX.TtI. Generated on I	JUMMMIIII:HH:MM:SS
Data Extract	Date: Dommilie, Data cutori Date: DDMMMIlie	

[Programming Notes]

For COVID-19 Test Performed, the small n is based on the number of subjects with a COVID-19 Case Diagnosis. For Result of the COVID-19 Test, the small n is based on the COVID-19 Test Performed=Yes.

IDSL standard shell PAN1.

TESARO, Inc.	Со	nfidential		Page 1 of x						
Protocol: XXXXX	Protocol: XXXXX									
Table 14.3.4.5.1c										
Summa	ry of COVID-19 Assessments for Patients with a	Suspected, Probable or Con	firmed COVID-19 Case	Diagnosis						
	(Safety Population	in the Extension Phase)								
		TABLET	CAPSULE	OVERALL						
Assessment		(N=XX)	(N=XX)	(N=XX)						
COVID-19 Case Diag	nosis [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)						
Confirmed		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)						
Probable		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)						
Suspected		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)						
COVID-19 Test Perf	ormed [2]									
n		XX	XX	XX						
No		xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)						
Yes		xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)						
Result from the CC	VID-19 Test									
n		XX	XX	XX						
Negative		xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)						
Positive		xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)						
Indeterminate		xx/xx (xx.x%)	xx/xx (xx.x%)	xx/xx (xx.x%)						

[1] COVID-19 Case Diagnosis is based on WHO Definition as of 20MAR2020.

[2] COVID-19 Test Performed is only captured for patients with a COVID-19 Case Diagnosis.

Note: Extension Phase for all Stages of TABLET study overlapped with COVID-19 pandemic, with all Stage 3 patients commencing treatment for the Extension Phase on or after 02JUN2021 placing the AE onset during the pandemic, while last patient commenced treatment for Stages 1 and 2 on 14MAY2018 and 05DEC2019, respectively, placing their first Extension Phase treatment dose administration prior to the start of the pandemic, as defined by WHO as of 20MAR2020, with patients across all Stages ongoing until DDMMMYYYY.

Source: Listing XXXXXXXX. Program: XXXXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

TESARO, Inc.	Confidential		Page 1 of x
Protocol: XXXXX			
	l'able 14.4.1c		
Summary of Importan	nt Protocol Deviations (Safety Population in the Ex	tension Phase)	
	TABLET	CAPSULE	TOTAL
Category/Coded Term	(N=XX)	(N=XX)	(N=XX)
Any important protocol deviations	xxx (xx%)	xxx (xx%)	xxx (xx%)
CATEGORY 1	xxx (xx%)	xxx (xx%)	xxx (xx%)
SUBCATEGORY 1	xx (xx%)	xx (xx%)	xx (xx%)
SUBCATEGORY 2	xx (xx%)	xx (xx%)	xx (xx%)
CATEGORY 2	xxx (xx%)	xxx (xx%)	xxx (xx%)
SUBCATEGORY 1	xx (xx%)	xx (xx%)	xx (xx%)
SUBCATEGORY 2	xx (xx%)	xx (xx%)	xx (xx%)
Source: Listing XXXXXXXXX. Program: XXXXXX	XXXXXXXXXXXXX. Output: xxxxxxxxxxxx.rtf. Generate	d on DDMMMYYYY:HH:MM	1:SS
Data Extract Date: DDMMMYYYY, Data Cutoff	Date: DDMMMYYYY		

[Programming Notes]:

- Include only IMPORTANT protocol deviations.
- <Category 1...> represents ADDV.DVCAT. <Subcategory 1...> represents ADDV.DVDECOD.
- Sort Categories in descending order according to overall counts, if ties are present, present alphabetically.

TESARO, Inc.	Confidential			Page 1 of x			
Protocol: XXXXX	Table 14 4 1d						
	Summary of Important Protocol Deviations for the PK Ph	ase Occurring Through	End of Treatment				
	(Safety Population in the Sta	re 3 PK Phase)					
		<u> </u>					
		NIRAPARIB TABLET	NIRAPARIB TABLET				
		FASTED [1]	FED [2]	TOTAL [3]			
Category/Coded Term		(N=XX)	(N=XX)	(N=XX)			
Any important proto	col deviations	xxx (xx%)	xxx (xx%)	xxx (xx%)			
CATEGORY 1		xxx (xx%)	xxx (xx%)	xxx (xx%)			
SUBCATEGORY 1		xx (xx%)	xx (xx%)	xx (xx%)			
SUBCATEGORY 2		xx (xx%)	xx (xx%)	xx (xx%)			
CATEGORY 2		xxx (xx%)	xxx (xx%)	xxx (xx%)			
SUBCATEGORY 1		xx (xx%)	xx (xx%)	xx (xx%)			
SUBCATEGORY 2		xx (xx%)	xx (xx%)	xx (xx%)			
[1] Includes protocol deviations with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.							
[3] Includes protoc	ol deviations occurring at any time during the PK Phase	•					

[Programming Notes]:

- Include only IMPORTANT protocol deviations.
- <Category 1...> represents ADDV.DVCAT. <Subcategory 1...> represents ADDV.DVDECOD.
- Sort Categories in descending order according to overall counts, if ties are present, present alphabetically.

## LISTINGS

General guidelines:

Listings are separated for the PK Phase (Stage 1, Stage 2 and Stage 3 separately) and the Open-Label Extension Phase.

For the PK Phase:

- Treatment=Sequence (for Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET; for Stage 3: NIRAPARIB TABLET FASTED/FED or NIRAPARIB TABLET FED/FASTED).
- Population=Safety Population in the PK Phase (i.e., those who receive at least 1 dose), unless otherwise specified.
- Include all data assessments relative to the PK Phase.
  - For patients who do not continue to the Extension Phase, include all EOT/Safety FU data. Also include Extension Phase Screening for those patients who DO not proceed to the Extension Phase.
- Relative day: With respect to first date of dosing in PK period.

For the Extension Phase:

- Treatment=TABLET; CAPSULE.
- Population=Safety Population in the Open-Label Extension Phase (i.e., those who receive at least 1 dose), unless otherwise specified.
- Include all assessments relative to the Extension Phase.
  - Any assessment specific to Extension Phase, including Screening Data.
- Relative day: With respect to first date of dosing in Extension Phase.
  - "-" event taking place prior to first dose in Extension Phase.
  - "\*" event taking place after EOT in Extension Phase.

TESARO, Inc. Protocol: XXXXX Confidential

Page 1 of x

Listing 16.2.1a

Disposition for PK Phase (All Patients Enrolled in the Stage 1 PK Phase)

Treatment: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient	Date of Last	Date of	Reason for	Date of	Reason for	Date of	Date of	Protocol
Number	Niraparib Dose	Discontinuation	Discontinuation	Discontinuation	Discontinuation	Death	Progression	Version
	During PK Phase	From PK Phase	from PK Phase	from Study (Rel	from Study	(Rel	(Rel Day)	
	(Rel Day)	(Rel Day)		Day)		Day)		
			Other: specify					
			Completion					

Relative Day calculated relative to first dose in PK Phase.

Only study discontinuations, disease progressions and deaths that occur during PK Phase (i.e., before 1st dose of extension or prior to discontinuing the study for patients not entering the Extension Phase) are listed.

[Programming Notes - PK Phase]

• Include only data that falls before first-dose Open-Label Extension Phase, i.e., for those patients who DC study and do not continue in the Open-Label Extension Phase.

Repeat for: Listing 16.2.1b Disposition for PK Phase (Safety Population in the Stage 2 PK Phase)

Listing 16.2.1c Disposition for Open-Label Extension Phase (All Patients Enrolled for the Extension Phase)

Listing 16.2.1d Disposition for PK Phase (Safety Population in the Stage 3 PK Phase)

[Programming Notes - Extension Phase]

- Change 'PK Phase' to 'Extension' Phase in respective columns.
- Treatment: Niraparib Tablet or Niraparib Capsule.

• Footnote: Relative Day calculated relative to first dose in Extension Phase. '-' Rel day before first Dose during Extension Phase,

 $`\star'$  Rel day post 30-day safety window from EOT .

TESARO, Inc.		Confidential	Page 1 of x
Protocol: XXXXX			
		Listing 16.2.1.2a	
	Reasons for Screen Fa	ailure (Patients who Failed Screening in the Stage 1 PK Phase)	
Treatment Sequence: <sc< td=""><td>REEN FAILURE&gt;</td><td></td><td></td></sc<>	REEN FAILURE>		
Patient			
Number	Protocol Version	Inclusion/Exclusion Criteria Not Met	
*****	Version 1.0 (original)	INPXX: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	
*****	Version 1.0 (original)	EXPXX: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	
Source: Program: XXXXX	XXXXXXXXXXXXXXX Output:	xxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS	
Data Extract Date: DDM	MMYYYY, Data Cutoff Dat	e: DDMMMYYYY	

Repeat for:

Listing 16.2.1.2b Reasons for Screen Failure (Patients who Failed Screening in the Stage 2 PK Phase)

Listing 16.2.1.2d Reasons for Screen Failure (Patients who Failed Screening in the Stage 3 PK Phase)

TESARO, Inc.		Confi	dential	Page 1 of x						
Protocol: XXXXX Listing 16.2.2a Protocol Deviations for the PK Phase (Safety Population in the Stage 1 PK Phase)										
Treatment: <	Treatment: < Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET>									
Patient Number	Visit	Protocol Deviation Category	Protocol Deviation Severity	Description of Protocol Deviation						
Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS										

[Programming Notes]

• Include only data that falls before first-dose Open-Label Extension Phase (i.e., for those patients who DC study and do not continue in the Open-Label Extension Phase)

Repeat for:

Listing 16.2.2b Protocol Deviation for the PK Phase (Safety Population in the Stage 2 PK Phase)

Confidential TESARO, Inc. Page 1 of x Protocol: XXXXX Listing 16.2.2c Important Protocol Deviations for the Open-Label Extension Phase (Safety Population in the Extension Phase) Treatment: <TABLET, CAPSULE> Patient Number Protocol Deviation Description of Protocol GSK Visit TESARO Classification [1] Category Deviation Classification [2] <<SIGNIFICANT/ IMPORTANT>> <<IMPORTANT/NON-IMPORTANT>> [1] For Stages 1 & 2, protocol deviation classification is done based on TESARO Protocol Deviation Management System only. GSK Classification will remain blank. [2] For Stage 3, protocol deviation classification is done based on GSK Protocol Deviation Management System only. TESARO Classification will remain blank. Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming notes]

For Stage 3 Extension Phase, patients will receive NIRAPARIB TABLET formulation only.

For Stages 1 and 2 reporting, only TESARO Classifications will be populated, for Stage 3 - only GSK Classification will be populated.

Only include protocol deviation classified as Important.

TESARO, Inc.	ESARO, Inc. Confidential								
Protocol: XXXXX									
Listing 16.2.2.1d Important Protocol Deviations for the PK Phase Occurring Through End of Treatment (Safety Population for Stage 3 PK Phase)									
Treatment: <	Treatment: <niraparib fasted="" fed="" niraparib="" or=""></niraparib>								
Patient Number	Visit	Protocol Deviation Category	Protocol Deviation Severity	Description of Protocol Deviation					
Source: Prog Data Extract	Source: Program: XXXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY								

[Programming notes]:

• Only include protocol deviation classed as Important.

TESARO, Inc. Confidential								
Protocol: XXXXX								
	Listing 16.2.2.2d GSK Protocol Deviations related to COVID-19 (Safety Population for Stage 3 PK Phase)							
Treatment:	<niraparib f<="" fasted="" niraparib="" or="" td=""><td>ED&gt;</td><td></td><td></td></niraparib>	ED>						
Patient Number     Deviation Category     Description of Deviation     GSK Classification       Important/NOT-IMPORTANT>         Important     Important/NOT-IMPORTANT>								
Note: * Pa Note: This Source: Pr Data Extra	tients with probable, suspected o listing only includes COVID-19 r rogram: XXXXXXXXXXXXXXXXXXXXXXX Outp lct Date: DDMMMYYYY, Data Cutoff	r confirmed COVID-19. elated protocol deviations. ut: xxxxxxxxxxx.rtf. Generated on DDMM Date: DDMMMYYYY	MYYYY:HH:MM:SS					

TESARO, In	с.	Confidential	Page 1 of x					
Protocol: XXXXX								
	Listing 16.2.2.2c GSK Protocol Deviations related to COVID-19 (Safety Population in the Extension Phase)							
Treatment:	<tablet, capsule=""></tablet,>							
Patient Number	Deviation Category	Description of Deviation	GSK Classification	Date				
			<pre><important not="important/&lt;/pre"></important></pre>					
Note: * Pa Note: This Note: Exte treatment treatment administra DDMMMYYYY. Source: Pr Data Extra	Note: * Patients with probable, suspected or confirmed COVID-19. Note: This listing only includes COVID-19 related protocol deviations. Note: Extension Phase for all Stages of TABLET study overlapped with COVID-19 pandemic, with all Stage 3 patients commencing treatment for the Extension Phase on or after 02JUN2021 placing the AE onset during the pandemic, while last patient commenced treatment for Stages 1 and 2 on 14MAY2018 and 05DEC2019, respectively, placing their first Extension Phase treatment dose administration prior to the start of the pandemic, as defined by WHO as of 20MAR2020, with patients across all Stages ongoing until DDMMMYYY. Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX							

TESARO, Inc.		Confidential		Page 1 of x
Protocol: XXX	XX			
		Listing 16.2.3a		
l	Study Population	3 for the PK Phase (All Patients Enrolled in	the stage i PK Phase)	
Treatment: <t< td=""><td>ABLET/CAPSULE or CAPSULE/TABI</td><td>JET or SCREEN FAILURE&gt;</td><td></td><td></td></t<>	ABLET/CAPSULE or CAPSULE/TABI	JET or SCREEN FAILURE>		
Patient Number	PK Phase Safety (SAF) Population	Informed Consent Date	Randomization Date	
	Y			
Source: Progr Data Extract	am: XXXXXXXXXXXXXXXXXXXXXX Out Date: DDMMMYYYY, Data Cutof	put: xxxxxxxxxxx.rtf. Generated on DDMMMY ff Date: DDMMMYYYY	YYY:HH:MM:SS	

Repeat for:

Listing 16.2.3b Study Populations for the PK Phase (All Patients Screened in the Stage 2 PK Phase)

• For Stage 2 PK, add column for BE Evaluable Population (Y/N).

TESARO, Inc.			Confidential				Page 1 o	fх
11000001. XXXXX			Listing 16.2.3c					
	Study Populations for th	e Open-Label Exten	sion Phase (All Patient	ts Enrolled in the $E_{\lambda}$	tension Phas	e)		
Treatment: <table< td=""><td>I or CAPSULE&gt;</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></table<>	I or CAPSULE>							
Patient Number	Extension Phase Safety (SAF) Population							
	Y							
Source: Program: Data Extract Date	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX : DDMMMYYYY, Data Cutc	tput: xxxxxxxxxxxxx ff Date: DDMMMYYY	.rtf. Generated on DDM Y	MMMYYYY:HH:MM:SS				

TESARO, Inc. Confidential									
Protocol: XXX	XX								
	Listing 16.2.3d								
	Study Populations	s for the PK Phase (All Patients	s Enrolled in the Stage 3 PK Ph	ase)					
Treatment: <f< td=""><td colspan="8">Treatment: <fasted failure="" fasted="" fed="" or="" screen=""></fasted></td></f<>	Treatment: <fasted failure="" fasted="" fed="" or="" screen=""></fasted>								
Patient	PK Phase	FE Population	Informed Consent Date	Randomization Date					
Number	Safety (SAF) Population								
	Y	Y							
		N							
Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY									

TESARO,	Inc.				Confidential				Page 1 of x	
Protocol	: XXXXX									
	Listing 16.2.4.1a									
			I	Demographics	(Safety Population in the Stage 3	1 PK Phase	)			
Study Tr	eatment:	<stage< td=""><td>1 &amp; 2: NOT DOSED</td><td>or TABLET/C</td><td>CAPSULE or CAPSULE/TABLET&gt; or <sta< td=""><td>ige 3: NOT</td><td>DOSED or H</td><td>FASTED/FED</td><td>or FED/FASTED&gt; or</td></sta<></td></stage<>	1 & 2: NOT DOSED	or TABLET/C	CAPSULE or CAPSULE/TABLET> or <sta< td=""><td>ige 3: NOT</td><td>DOSED or H</td><td>FASTED/FED</td><td>or FED/FASTED&gt; or</td></sta<>	ige 3: NOT	DOSED or H	FASTED/FED	or FED/FASTED> or	
<extensi< td=""><td>on: TABL</td><td>ET or CA</td><td>APSULE&gt;, as appli</td><td>cable</td><td></td><td></td><td></td><td></td><td></td></extensi<>	on: TABL	ET or CA	APSULE>, as appli	cable						
Patient	Age	Sex	Child-Bearing	Ethnicity	Race	Height	Weight	BMI	ECOG Performance	
Number	(yrs)		Potential			(cm)	(kg)	(kg/m²)	Status	
					Other: specify					
ECOG = E	astern C	ooperati	ive Oncology Grou	p:						
0=Fully	active,	able to	carry on all pre	-disease per	formance without restriction					
1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature										
2=Ambula	tory and	capabl	e of all self-ca	ire but unab	le to carry out any work activi	ties. Up a	and about	more than	50% of waking hours	
3=Capabl	e of onl	y limite	ed self-care, con	fined to bed	l or chair more than 50% of waking	f hours				
4=Comple	tely dis	abled. (	Cannot carry on a	ny self-care	e. Totally confined to bed or chai	r				
Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS										
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY										
Repeat for:										

Listing 16.2.4.1b Demographics (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.1c Demographics (Safety Population in the Extension Phase)

Add footnote for Extension Phase and relevant reference in the listing: [1] Only weight and ECOG Performance Status were repeated at Extension Phase entry.

Listing 16.2.4.1d Demographics (Safety Population in the Stage 3 PK Phase)

	PERADO Inc. Doco 1 of y									
TESTRO, THE. Confidential										
Protocol: XXXXX										
	Listing 16.2.4.2a									
	Medical Nictory (Safety Dervices in the Stars 1 DK Dhase)									
	Medical	miscory (sa	iecy iopulación in ch	e Stage I IN INASE)						
PK Phase	Treatment: <stage &="" 1="" 2:="" cap<="" tablet="" td=""><td>SULE or CAPS</td><td>ULE/TABLET&gt; or <stage< td=""><td>3: FASTED/FED or FED/FASTED&gt; or <extension:< td=""><td>TABLET or</td></extension:<></td></stage<></td></stage>	SULE or CAPS	ULE/TABLET> or <stage< td=""><td>3: FASTED/FED or FED/FASTED&gt; or <extension:< td=""><td>TABLET or</td></extension:<></td></stage<>	3: FASTED/FED or FED/FASTED> or <extension:< td=""><td>TABLET or</td></extension:<>	TABLET or					
CAPSULE>.	as applicable		2							
	an all locate									
	Que have Que e Q1									
	System Organ Class									
Patient	Preferred Term	Start	Ongoing at							
Number	Medical Condition or Event	Date	Study Start?	Stop Date						
Includes	only patients with major medical co	nditions.								
Note: Med	DRA version XX X									
NOCC. MODINI VOISION AA.A.										
Courses D		<b>.</b>								
Source: Program: XXXXXXXXXXXXXXXXXXXX Output: XXXXXXXXXXTI. Generated on DDMMMYYYY:HH:MM:SS										
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY										

Repeat for:

Listing 16.2.4.2b Medical History (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.2c Medical History (Safety Population in the Extension Phase)

Listing 16.2.4.2d Medical History (Safety Population in the Stage 3 PK Phase)

[Programming notes]

• For Stage 3, the latest available MedDRA version is to be used.
TESARO, Inc. Protocol: XXXXX Confidential

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### Listing 16.2.4.3a Prior Anti-Cancer Treatment (Safety Population in the Stage 1 PK Phase)

Treatment: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Dationt	Pogimon	-Verbatim Term								
Factenc	Regimen	-verbacim leim								
Number	Number	Preferred Term	Reason for Administration	Best Response						
			Other: specify							
Source: P Data Extr	Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX									

Repeat for:

Listing 16.2.4.3b Prior Anti-Cancer Treatment (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.3c Prior Anti-Cancer Treatment (Safety Population in the Extension Phase)

Listing 16.2.4.3d Prior Anti-Cancer Treatment (Safety Population in the Stage 3 PK Phase)

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TESARO, Inc. Protocol: XXXXX Primary (

Listing 16.2.4.4a Primary Cancer History (Safety Population in the Stage 1 PK Phase)

Treatment: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient		Date of First		Number of Prior Lines					
Number	Tumor Type	Diagnosis	Cancer Stage (Most Recent)	of Therapy					
	<other: specify=""></other:>								
Source: Program: XXXXXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY									

Repeat for:

Listing 16.2.4.4b Primary Cancer History (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.4c Primary Cancer History (Safety Population in the Extension Phase)

Listing 16.2.4.4d Primary Cancer History (Safety Population in the Stage 3 PK Phase)

TESARO, Inc.		C	onfidential		Page 1 of x				
Protocol: XXXXX									
		Ticti	ng 16 2 4 55						
			.11g 10.2.4.Ja						
	Prior/Concom	itant Radiotherapy (S	afety Population in th	e Stage 1 PK Phase)					
Treatment Sequence: <stage &="" 1="" 2:="" capsule="" or="" tablet=""> or <stage 3:="" fasted="" fed="" or=""> or <extension: or<="" tablet="" td=""></extension:></stage></stage>									
CAPSULE>, as applicab	ple		2						
Patient					Prior/				
Number	Site or Region	Date Started	Date Stopped	Total Grays	Concomitant Flag				
Note: Includes patients with prior or concomitant radiotherapy with respect to the PK Phase. P=Prior (radiotherapy with start date earlier than the first dose date of study treatment). C=Concomitant (radiotherapy occurring on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase). Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX									

Repeat for:

Listing 16.2.4.5b Prior/Concomitant Radiotherapy (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.5c Prior/Concomitant Radiotherapy (Safety Population in the Extension Phase)

[Programming Notes for Extension Phase]

Note: Includes patients with prior or concomitant radiotherapy with respect to the Extension Phase. P=Prior (radiotherapy with start date earlier than the first dose date of Extension Phase treatment).

C=Concomitant (radiotherapy occurring on or after the initial Extension Phase treatment dosing date through EOT in Extension Phase).

Listing 16.2.4.5d Prior/Concomitant Radiotherapy (Safety Population in the Stage 3 PK Phase)

TESARO, Inc. Confidential Pag								Page 1 of x		
Protocol: XX	.XXX				Listing 1	16.2.5.1a				
	Prior and Concomitant Medications (Safety Population in the Stage 1 PK Phase)									
Treatment Se CAPSULE>, as	Treatment Sequence: <stage &="" 1="" 2:="" capsule="" or="" tablet=""> or <stage 3:="" fasted="" fed="" or=""> or <extension: capsule="" or="" tablet="">, as applicable</extension:></stage></stage>									
Patient Numb	er = xxxxx-xxxx									
ATC/ Preferred Term/ Verbatim Term	Dose per Administration	Dose Unit	Frequenc Y	Indica tion	Route of Administr ation	Start/ Stop Date	Ongoing	Prior/ Concomitant Flag	PK Dose 1 YYYY-MM-DD	PK Dose 2 YYYY-MM-DD
Note: Includ P=Prior medi Source: Prog Data Extract	Note: Includes patients with prior or concomitant medications taken during the PK Phase. P=Prior medication only; C=Concomitant medication only; B=Both prior and concomitant medications. Source: Program: XXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY									

[Programming Notes]

- For the Prior/Concomitant Flag, list all that apply.
- If ATC3 not available, use a footnote [1] ATC level 3 term is not available through WHO Drug Dictionary.

Repeat for: Listing 16.2.5.1b Prior and Concomitant Medications (Safety Population in the Stage 2 PK Phase)

Listing 16.2.5.1c Prior and Concomitant Medications (Safety Population in the Extension Phase)

[Programming Notes for Extension Phase]

Note: Includes patients with prior or concomitant medications during the Extension Phase. P=Prior (any medication taken earlier than the first dose date of Extension Phase treatment). C=Concomitant (any medication on or after the initial Extension Phase treatment dosing date through EOT in Extension Phase). Prior and concomitant medications taken during PK Phase only are classified as Prior medications during Extension Phase. Concomitant medications taken during PK Phase and ongoing during Extension Phase are classified as Both prior and concomitant medications during Extension Phase.

• Drop 'PK Dose 1' column and replace 'PK Dose 2' with 'Extension Phase'.

Listing 16.2.5.1d Prior and Concomitant Medications (Safety Population in the Stage 3 PK Phase)

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#### Listing 16.2.5.1.1c Treatment Exposure and Duration (Safety Population in the Extension Phase)

Study Stage/Formulation: <Stage 1: TABLET/CAPSULE/EXT, CAPSULE/TABLET/EXT> <Stage 2: TABLET/CAPSULE/EXT, CAPSULE/TABLET/EXT > <Stage 3: TABLET>, as applicable

						Extension	Time between PK
Patient	Randomization			PK Dose 1/ Rel	PK Dose 2/ Rel	Phase	and Extension
Number	Date	Stage	Treatment Sequence	Day [1]	Day [1]	Dose 1	Phase doses [2]
XXXXX-XXXX	YYYY-MM-DD	<stage 1="" 2=""></stage>	<tablet capsule="" ext,<="" td=""><td>YYYY-MM-DD/ -xx</td><td>YYYY-MM-DD/ -xx</td><td>YYYY-MM-DD</td><td>XX</td></tablet>	YYYY-MM-DD/ -xx	YYYY-MM-DD/ -xx	YYYY-MM-DD	XX
			CAPSULE/TABLET/EXT>				
XXXXX-XXXX	YYYY-MM-DD	Stage 3	<tablet ext=""></tablet>	YYYY-MM-DD/ -xx	YYYY-MM-DD/ -xx	YYYY-MM-DD	XX

Note: Randomized patients who did not start PK Phase treatment and proceeded to Extension Phase treatment directly will have time between PK and Extension Phase dosing set to missing.

[1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase.

 $\circle{2}$  ] The time between last non-missing PK dose and first Extension Phase dose (in days).

[Programming Notes]

For treatment sequence use actual sequence labels, as displayed in ADaMs.

Randomized patients who did not start PK Phase treatment and proceeded to Extension Phase treatment directly will have time between PK and Extension Phase dosing set to `.'.

Treatment sequence displays actual treatment formulation received during Stages 1 and 2 (T/C, C/T), and for Stage 3 displays TABLET formulation irrespective of fasting (FED/FASTED) status.

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#### Listing 16.2.5.2a

Prior/Concomitant Procedures During PK Phase (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient	Procedure	Rel Day					Prior/Concomitant
Number	Date	[1]	Procedure	Results/Findings	AE/SAE?	Indication	Flag
XXXXXX-XXXX							

[1] Relative to first dose during the PK Phase.

Note: Includes patients with prior or concomitant procedures during the PK Phase.

P=Prior (any procedure earlier than the first dose date of study treatment).

C=Concomitant (any procedure on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase).

Repeat for

Listing 16.2.5.2b Prior/Concomitant Procedures During the PK Phase (Safety Population in the Stage 2 PK Phase)

Listing 16.2.5.2c Prior/Concomitant Procedures During the Extension Phase (Safety Population in the Extension Phase)

[Programming Notes for Extension Phase]

• Footnote: [1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase, '\*' Rel day post 30-day safety window from EOT.

Note: Includes patients with prior or concomitant procedures during the Extension Phase.

P=Prior (any procedure undertaken earlier than the first dose date of Extension Phase treatment).

C=Concomitant (any procedure undertaken on or after the initial Extension Phase treatment dosing date through EOT in Extension Phase).

Prior and concomitant procedure undertaken during PK Phase only are classified as Prior procedure during Extension Phase. Concomitant procedures performed during PK Phase and ongoing during Extension Phase are classified as Both prior and concomitant procedure during Extension Phase.

Listing 16.2.5.2d Prior/Concomitant Procedures During the PK Phase (Safety Population in the Stage 3 PK Phase)

TESARO, Inc. Confidential Page 1 of x Protocol: XXXXX Listing 16.2.5.3a Prior and Concomitant Transfusions (Safety Population in the Stage 1 PK Phase) Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable Received Transfusion Patient within 14 days of first Type of Prior/ Transfusion Date Number dose or during study? Administration Units Rel Day [1] Concomitant Flag Other: specify [1] Relative to first dose during the PK Phase. Note: Includes patients with prior or concomitant transfusions during the PK Phase. P=Prior (any transfusion earlier than the first dose date of study treatment). C=Concomitant (any transfusion on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase). Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]

• For the Prior/Concomitant Flag, list all that apply.

Repeat for: Listing 16.2.5.3b Prior and Concomitant Transfusions (Safety Population in the Stage 2 PK Phase)

Listing 16.2.5.3c Prior and Concomitant Transfusions (Safety Population in the Extension Phase)

[Programming Notes for Extension Phase]

Footnote: [1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase, '\*' Rel day post 30-day safety window from EOT.

Note: Includes patients with prior or concomitant transfusions during the Extension Phase.

P=Prior (any transfusion started earlier than the first dose date of Extension Phase treatment).

C=Concomitant (any transfusion started on or after the initial Extension Phase treatment dosing date through EOT in Extension Phase).

Prior and concomitant transfusion completed during PK Phase only are classified as Prior transfusion during Extension Phase. Concomitant transfusion started during PK Phase and ongoing during Extension Phase are classified as Both prior and concomitant transfusion during Extension Phase.

Listing 16.2.5.3d Prior and Concomitant Transfusions (Safety Population in the Stage 3 PK Phase)

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TESARO, Inc. Protocol: XXXXX Confidential

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### Listing 16.2.5.4a

Prior and Concomitant Growth Factors (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient	Received growth factor within 14	Type of			Administration	Prior/
Number	days of first dose or during study?	Administration	Dose	Unit	Date	Concomitant Flag
		Other: specify		Other: specify		

Note: Includes patients with prior or concomitant growth factors during the PK Phase.

P=Prior (any growth factor earlier than the first dose date of study treatment).

C=Concomitant (any growth factor given on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase).

[Programming Notes]

• For the Prior/Concomitant Flag, list all that apply.

Repeat for: Listing 16.2.5.4b Prior and Concomitant Growth Factors (Safety Population in the Stage 2 PK Phase)

Listing 16.2.5.4c Prior and Concomitant Growth Factors (Safety Population in the Extension Phase)

[Programming Notes]

Note: Includes patients with prior or concomitant growth factors during the Extension Phase.

P=Prior (any growth factors administered earlier than the first dose date of Extension Phase treatment).

C=Concomitant (any growth factors administered on or after the initial Extension Phase treatment dosing date through EOT in Extension Phase).

Prior and concomitant growth factors administered during PK Phase only are classified as Prior growth factors during Extension Phase. Concomitant growth factors administered during PK Phase and ongoing during Extension Phase are classified as Both prior and concomitant growth factors during Extension Phase.

Listing 16.2.5.4d Prior and Concomitant Growth Factors (Safety Population in the Stage 3 PK Phase)

TESARO, Inc. Confidential									Page 1 of x	
Listing 16.2.5.5a Study Treatment (Safety Population in the Stage 1 PK Phase)										
Treatment S	Sequence: <s< td=""><td>tage 1 &amp; 2: TABL</td><td>ET/CAPSULE or CAPS</td><td>SULE/TABLE?</td><td>r&gt;</td><td></td><td></td><td></td><td></td></s<>	tage 1 & 2: TABL	ET/CAPSULE or CAPS	SULE/TABLE?	r>					
Patient Number Visit Formulation Formulation (Rel Day [1]) Taken? Full If No, how Number Visit Formulation (Rel Day [1]) Taken? Consumed? Fast 8 hrs Fast 8 hrs Formulation (Rel Day [1]) Taken? Consumed? For Change Number Administration?							Vomit within 8 hours of dose?			
[1] Relativ Source: Pro Data Extrac	[1] Relative to first dose during the PK Phase. Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY									

Repeat for:

Listing 16.2.5.5b Study Treatment (Safety Population in the Stage 2 PK Phase)

[For Stage 2 PK Phase]

- Modify label for Vomiting Question, 'Vomit within specified time of dose'.
- Add column for Nausea Question, 'Nausea within specified time of dose'.

TESARO, In Protocol:	c. XXXXX			Confidential			Page 1 of x			
			Lis Study Treatment (Safety	ting 16.2.5.5c Population in the E	Extension Phase)					
TREATMENT:	TREATMENT: < TABLET or CAPSULE>									
Patient Number	Visit	Dose Prescribed (mg)	Start Date (Rel Day [1])/ Stop Date (Rel Day [1])	Action Taken	Reason for Modification	Bottle number Dispensed	Bottle Number Returned			
					Other <specify reason&gt;</specify 					
[1] Relative to first dose during the Extension Phase.										
Data Extra	ct Date:	DDMMMYYYY, Da	ata Cutoff Date: DDMMMYYYY							

TESARO, Inc. Confidential Protocol: XXXXX										
			Listir	ng 16.2.5.5d						
		Study T:	reatment (Safety Pop	pulation in the S	Stage 3 PK Phase)					
Treatment Seque	nce: <fasted fed<="" td=""><td>or <fed fasti<="" td=""><td><d></d></td><td></td><td></td><td></td><td></td></fed></td></fasted>	or <fed fasti<="" td=""><td><d></d></td><td></td><td></td><td></td><td></td></fed>	<d></d>							
Patient Number	Visit	Fasted or Fed State	Date:Time of Administration (Rel Day [1])	Bottle Number	Fast 10 hrs prior to administration?	Vomit within protocol specified hours from dose?	Fast for minimum of 4 hours post dose?			
[1] Relative to Source: Program Data Extract Da	first dose durin : XXXXXXXXXXXXXXX te: DDMMMYYYY,		se. t: xxxxxxxxxxx.rtf Date: DDMMMYYYY	. Generated on I	DDMMMYYYY:HH:MM:SS	1				

TESARO, In		Confide	ential	Page 1 of x					
	Listing 16.2.5.6b Subsequent Anti-Cancer Therapy (Safety Population in the Stage 2 PK Phase)								
Treatment	Treatment Sequence: TABLET/CAPSULE or CAPSULE/TABLET								
Patient Number	Date of Subsequent Anti-Cancer Administration	Relative Day [1]							
[1] Relati Note: Incl Source: Pr Data Extra	[1] Relative to first dose during the PK Phase. Note: Includes only patients with subsequent anti-cancer therapy recorded for patients who do not continue to Extension Phase. Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY								

TESARO, Inc. Protocol: XXXXX Listing 16.2.5.6c Subsequent Anti-Cancer Therapy (Safety Population in the Extension Phase)						
Treatment:	< TABLET or CAPSULE>					
PatientDate of Subsequent Anti-CancerNumberAdministrationRelative Day [1]						
[1] Relati Note: Incl Source: Pr Data Extra	ve to first dose during the Exter udes only patients with subsequer cogram: XXXXXXXXXXXXXXXXX Outp cct Date: DDMMMYYYY, Data Cutoff	nsion Phase. `*' Rel day p nt anti-cancer therapy rec put: xxxxxxxxxxx.rtf. Ge Date: DDMMMYYYY	ost 30-day safety window from EOT. orded as initiated after last dose of the Exte nerated on DDMMMYYYY:HH:MM:SS	ension Phase.		

TESARO, Inc.			Confidential		Page 1 of x
Treatment Sequence	ce: <fasted fe<="" td=""><td>D or <fed fasted=""></fed></td><td></td><td></td><td></td></fasted>	D or <fed fasted=""></fed>			
Patient Number	Visit	Meal Start Date	Meal Start Time	Meal End Time	% of Meal Consumed
Source: Program: Data Extract Date	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXX. Output: xxxxxxxxxxxx Data Cutoff Date: DDMMMYYYY	.rtf. Generated on DDMM Y	MYYYY:HH:MM:SS	

TESARO, Inc. Protocol: XXXXX Listing 16.2.6.1c Investigator Assessment of Response (Safety Population in the Extension Phase)											
TREATMENT:	< TABLET or CAN	PSULE>									
Patient Number	Tumor Type	Date	Rel Day [1]	Overall Response							
				NE: <reason></reason>							
Abbreviati [1] Relati safety win Source: Pr Data Extra	ons: CP=Complete ve to first dose dow from EOT. ogram: XXXXXXXX ct Date: DDMMMY	Response, PD=Pro during the Exten XXXXXXXXXX. Outp XYY, Data Cutoff	gressive Disease, PR=Pan sion Phase. '-' Rel day ut: xxxxxxxxxxx.rtf. ( Date: DDMMMYYYY	rtial Response, SD=Stable Disease, NE=Not Evaluable. before first Dose during Extension Phase, `*' Rel day Generated on DDMMMYYYY:HH:MM:SS	post 30-day						

TESARO, Protoco	Inc. ol: XXXXX		Confid	lential						Page 1 of x
			Listing	16.2.7.	.1a					
		Adverse Ev	ents (Safety Popul	lation i	n the Sta	age 1 PK 1	Phase)			
Treatmen CAPSULE>	t Sequence: <sta , as applicable</sta 	age 1 & 2: TABLET/CAPSULE	or CAPSULE/TABLET	> or <st< th=""><th>age 3: F</th><th>ASTED/FED</th><th>) or FED/FAS</th><th>STED&gt; or &lt;</th><th>Extension:</th><th>TABLET or</th></st<>	age 3: F	ASTED/FED	) or FED/FAS	STED> or <	Extension:	TABLET or
			Start Date:Time				Action			
	Dosing Period/	Adverse Event	(Rel Day [1])		SAE/		Taken on	Other		
Patient	Niraparib	MedDRA Preferred Term	End Date (Rel		Reason		Study	Action	Relation-	
Number	Treatment	System Organ Class	Day [1])	TEAE?	[2]	Severity	Treatment	Taken	ship	Outcome
	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX									
	Period 1/	*****	yyyy-mm-dd [x]							Resolved
	Capsule	*****								
		*****	yyyy-mm-dd [x]	Y	N	Grade 1				Recovered/
	Period 2/	[P]XXXXXXXXXXXXXXXXXXXXXX	yyyy-mm-dd [x]							Resolved
	Tablet	[S]XXXXXXXXXXXXXXXXXXXXXX								
	PK Safety FU									
[1] Rela [2] Reas 4 = Requ Source: Data Ext	tive to the date on for SAE: 1 = ires or prolongs Program: XXXXX ract Date: DDMM	e of first dose in PK Phas Result in death; 2 = Life s hospitalization; 5 = Cor XXXXXXXXXXXXX. Output: XX MYYYY, Data Cutoff Date:	se. e threatening; 3 = ngenital abnormali xxxxxxxxx.rtf. DDMMMYYYY	Result ty/birth Generate	in persi n defect; ed on DDM	stent or 6 = Othe MMYYYY:HH	significant r medically :MM:SS	disabili / importan	ty/incapaci t event.	ty;

Repeat for:

Listing 16.2.7.1b Adverse Events (Safety Population in the Stage 2 PK Phase)

Listing 16.2.7.1d Adverse Events (Safety Population in the Stage 3 PK Phase)

[Programming Notes]

- Stage 3: Treatment Sequence will be Fasted/Fed and Fed/Fasted.
- Stage 3: Column 2: Dosing Period/Treatment Treatment should be Niraparib FASTED or Niraparib FED.

TESARO, Inc. Protocol: XXXXX	C	onfide	ntial					Page 1 of x
	Li:	sting :	16.2.7.10	2				
	Adverse Events (Safety	Popula	ation in	the Exter	nsion Phase)			
Treatment: <tablet capsule="" or="">, as Patient ID = XXXXXX-XXXX</tablet>	; applicable							
Adverse Event	Start Date (Rel Day [1])		SAE/			Other		
MedDRA Preferred Term	End Date (Rel Day [1])	TEAE?	Reason		Action Taken on	Action		
System Organ Class			[2]	Severity	Study Treatment	Taken	Relationship	Outcome
XXXXXXXXXXXXXX	yyyy-mm-dd [x]	Y	N	Grade 1				Recovered/
****	уууу-mm-dd [x]							Resolved
*****	vvvv-mm-dd [x]	Y	N	Grade 1			-	Recovered/
[P]XXXXXXXXXXXXXXXXXXXXXX [S]XXXXXXXXXXXXX	yyyy-mm-dd [x]							Resolved
<pre>[1] Relative to the date of first [2] Reason for SAE: 1 = Result in 4 = Requires or prolongs hospitali Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX</pre>	dose during the Extension Pl death; 2 = Life threatening .zation; 5 = Congenital abno: XXX. Output: xxxxxxxxxx.r ata Cutoff Date: DDMMMYYYY	hase. ; 3 = 1 rmalit; tf. G	<pre>`*' Rel ( Result in y/birth ( enerated</pre>	day post i persiste defect; 6 on DDMMM	30-day safety win ent or significa = Other medical YYYY:HH:MM:SS	ndow from nt disabi ly import	1 EOT. .lity/incapaci1 :ant event.	ty;

[Programming Notes]

Listings 16.2.7.1c and 16.2.7.2c should be mutually exclusive. Any AEs with onset during PK Phase or after, but prior to first dose of Extension Phase should be in Listing 16.2.7.2c. If the AE is ongoing from before 1st dose of Extension Phase, and the Grade is increased, it is still an ongoing AE.

There should be no records with relative days prior to first dose of Extension Phase. If an AE has onset after EOT, indicate this with `\*'.

TESARO, Inc.	C	onfide	ntial					Page 1 of x
Protocol: XXXXX								
	Lis	sting :	16.2.7.20					
Adverse E	vents Ongoing from PK Pha	ise (Sa	afety Pop	oulation :	in the Extension	Phase)		
Treatment: <tablet capsule="" or="">, as ap Patient ID = XXXXXX-XXXX</tablet>	plicable							
Adverse Event	Start Date (Rel Day		SAE/			Other		
MedDRA Preferred Term	[1])	TEAE?	Reason		Action Taken on	Action		
System Organ Class	End Date (Rel Day [1])		[2]	Severity	Study Treatment	Taken	Relationship	Outcome
XXXXXXXXXXXXXX	yyyy-mm-dd [x]	Y	N	Grade 1				Recovered/
*****	yyyy-mm-dd [x]	1						Resolved
*****								
XXXXXXXXXXXXXX	yyyy-mm-dd [x]	Y	N	Grade 1				Recovered/
[P]XXXXXXXXXXXXXXXXXXXX	yyyy-mm-dd [x]	1						Resolved
[S]XXXXXXXXXXXXXXXXX								
								1
<ul> <li>[1] Relative to the date of first dos. day post 30-day safety window from EO</li> <li>[2] Reason for SAE: 1 = Result in dea</li> <li>4 = Requires or prolongs hospitalizat</li> <li>Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX</li></ul>	e during the Extension Ph T. th; 2 = Life threatening; ion; 5 = Congenital abnor Output: xxxxxxxxxxx.rt Cutoff Date: DDMMMYYYY	ase. 3 = 1 cmalit; cf. G	'-' Rel c Result in y/birth c enerated	day before n persiste defect; 6 on DDMMM	e first Dose dur: ent or significan = Other medical. YYYY:HH:MM:SS	ing Exter nt disabi ly import	asion Phase, `` llity/incapaci cant event.	*' Rel ty;

[Programming Notes]

Only include AEs with date of onset during PK Phase/prior (including Extension Phase Screening/EOT for PK Phase/Safety follow-up) to first dose of Extension Phase and ongoing/resolved during Extension Phase.

Rel Day [1] should always be either zero or negative (with onset during PK Phase, Extension Screening etc.).

TESARO, I	nc.				Confide	ential			Page 1 of x			
Protocol:	XXXXX			т.i	sting 16.	2.8.1.1a						
		Hemato	logy Resul	ts in the PK Pha	ase (Safet	cy Population in	n the Stage 1 P	K Phase)				
Troatmont	Somuchae. <stag< td=""><td>0152.</td><td></td><td>Denne or Cadenne</td><td></td><td>or &lt;8+200 3. E7</td><td>STED/FED OF FEI</td><td></td><td>Extoncion, MARIER or</td></stag<>	0152.		Denne or Cadenne		or <8+200 3. E7	STED/FED OF FEI		Extoncion, MARIER or			
CAPSULE>,	as applicable	e 1 & Z:	TABLET/CA	PSULE OF CAPSULE	/TABLET>	or <stage 3:="" ff<="" td=""><td>STED/FED OF FEI</td><td>D/FASTED&gt; OF &lt;</td><td>Extension: TABLET or</td></stage>	STED/FED OF FEI	D/FASTED> OF <	Extension: TABLET or			
Patient Number	Parameter (unit)	Visit	Rel Day [1]	Sample date/time	Result	Change from baseline	Normal range	Out of range flag	Clinically significant flag			
	xx.x xx.x xx.x xx.x											
[1] Relat Scheduled the Exten Source: P Data Extra	[1] Relative to the date of first dose in the PK Phase. Scheduled and unscheduled visits through the extension screening phase or through study discontinuation for those not continuing in the Extension Phase, are included. Visits related to the extension screening phase are not included. Source: Program: XXXXXXXXXXXXXXXX. Output: xxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY											
[Programmin • If requi Repeat for Listing 16 Listing 16	Programming Notes]: If required for readability, move 'Patient Number' into Header row after 'Treatment Sequence'. Repeat for: Disting 16.2.8.1.1b Hematology Results (Safety Population in the Stage 2 PK Phase) Disting 16.2.8.1.1c Hematology Results (Safety Population in the Extension Phase)											
Listing 16	.2.8.1.1d Hemato	logy Resu	ilts Throu	gh the PK End of	Treatmen	t Visit (Safety	Population in	the Stage 3 P	K Phase)			
Listing 16	.2.8.1.2a Chemis	try Resul	lts (Safet	y Population in	the Stage	1 PK Phase)						
Listing 16	.2.8.1.2b Chemist	try Resul	lts (Safet	Y Population in	the Stage	2 PK Phase)						
Listing 16	.2.8.1.2c Chemist	try Resul	ts (Safet	y Population in	the Exten	sion Phase)						
Listing 16	.2.8.1.2d Chemist	try Resul	lts Through	n the PK End of	Treatment	Visit (Safety	Population in t	the Stage 3 PK	Phase)			
Listing 16	.2.8.1.3a Urinal	ysis Resu	ults (Safe	ty Population in	the Stage	e 1 PK Phase)						
Listing 16	.2.8.1.3b Urinal	ysis Resu	ults (Safe	ty Population in	the Stage	e 2 PK Phase)						
Listing 16	.2.8.1.3c Urinal	ysis Resu	ults (Safe	ty Population in	the Exte	nsion Phase)						
Listing 16	.2.8.1.3d Urinal	ysis Resu	ilts Throug	gh the PK End of	Treatmen	t Visit (Safety	Population in	the Stage 3 P	K Phase)			
[Programmin	ng Notes For Exte	ension Ph	nase]:									

Niraparib

• Footnote: [1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase, '\*' Rel day post 30-day safety window from EOT.

TESARO, Inc.				Confidential			Page 1 of x			
Protocol: XXXXX	ζ									
	Liver	Function Tests - Po	otential Hy'	Listing 16.2.8.1. 's Law Cases (Saf	4c ety Population in the	Extension Phase)				
TREATMENT: < TA	ABLET or CAPS	ULE>								
Laboratory Analyte (result/xULN)										
Patient Number	Visit	Sample Collection Date	Day [1]	ALT (U/L)	AST (U/L)	Total Bilirubin (umol/L)	ALP (U/L)			
		DDMMMYYYY		150/3.3	100/2.7	40/2.3	100/0.7			
							-			
							+			
ALP=alkaline ph	osphatase. AI	T=alanine aminotra	nsferase. As	ST=aspartate amin	otransferase. ULN=upp	er limit of normal.	.1			
[1] Relative to	first dose d	during the Extensio	n Phase.	-						
Source: Program Data Extract Da	: XXXXXXXXXXX te: DDMMMYYY	XXXXXXXXX. Output: YY, Data Cutoff Da	xxxxxxxxxxx te: DDMMMY	xx.rtf. Generate YYY	d on DDMMMYYYY:HH:MM:	SS				

[Programming Notes]

Include all visits for any Patients with ALT or AST >3×ULN with bilirubin >2×ULN and ALP <2×ULN at any time in Extension Phase.

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Page 1 of x

TESARO, Inc. Protocol: XXXXX

### Listing 16.2.8.2a Vital Signs (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable

Patient Number	Visit	Assessment Date	Rel Day [1]	Height (cm)	Weight (kg)	Temperature (°C)	Pulse (beats/min)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)

[1] Relative to the date of first dose in the PK Phase. Data is listed only when the vital sign assessment was performed.

Repeat for:

Listing 16.2.8.2b Vital Signs (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.2c Vital Signs (Safety Population in the Extension Phase)

[Programming Notes For Extension Phase]:

• Footnote: [1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase, '\*' Rel day post 30-day safety window from EOT.

• Drop Height column.

Listing 16.2.8.2d Vital Signs Through the PK End of Treatment Visit (Safety Population in the Stage 3 PK Phase)

TECADO INC				Confidential	Daga 1 of y					
Drotocol, VVVV	,			Confidential	rage i oi x					
PIOLOCOI: XXXXX	2									
				Listing 16.2.8.3a						
			ECG Results (Safety	7 Population in the Stage 1 PK Phase)						
Treatment Sequence: <stage &="" 1="" 2:="" capsule="" or="" tablet=""> or <stage 3:="" fasted="" fed="" or=""> or <extension: or<br="" tablet="">CAPSULE&gt;, as applicable</extension:></stage></stage>										
	1	T								
Patient										
Number	Visit	Date	Rel Day [1] ECG Interpretation							
<pre>[1] Relative to NCS = Not Clini Source: Program Data Extract Da</pre>	the da cally S n: XXXX ate: DD	te of first ignificant, XXXXXXXXXXXX MMMYYYY, Da	dose in the PK Phase. CS = Clinically Signific XX. Output: xxxxxxxxx ta Cutoff Date: DDMMMYY	cant. xx.rtf. Generated on DDMMMYYYY:HH:MM:SS YYY						

Repeat for: Listing 16.2.8.3b ECG Results (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.3c ECG Results (Safety Population in the Extension Phase)

Listing 16.2.8.3d ECG Results (Safety Population in the Stage 3 PK Phase)

[Programming Notes For Extension Phase]:

• Footnote: [1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase, '\*' Rel day post 30-day safety window from EOT.

Niraparib

TESARO, Inc.		Confid	dential	Page 1 of x							
Protocol: XXXXX	Listing 16.2.8.4a ECOG Performance Status (Safety Population in the Stage 1 PK Phase)										
Treatment Sequence: <stage &="" 1="" 2:="" capsule="" or="" tablet=""> or <stage 3:="" fasted="" fed="" or=""> or <extension: capsule="" or="" tablet="">, as applicable</extension:></stage></stage>											
Patient Number	Visit	Assessment Date	Rel Day [1]	Performance Status							
<pre>[1] Relative to th ECOG = Eastern Coo O=Fully active, at 1=Restricted in ph 2=Ambulatory and coo 3=Capable of only 4=Completely disate Source: Program: Data Extract Data</pre>	[1] Relative to the date of first dose in the PK Phase. Data is listed only when the ECOG Performance Status assessment was performed. ECOG = Eastern Cooperative Oncology Group: 0=Fully active, able to carry on all pre-disease performance without restriction 1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature 2=Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours 3=Capable of only limited self-care, confined to bed or chair more than 50% of waking hours 4=Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair										
Saca Enclace Bace.		Sada Gaborr Sado. Sprimitir									

Repeat for:

Listing 16.2.8.4b ECOG Performance Status (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.4c ECOG Performance Status (Safety Population in the Extension Phase)

[Programming Notes For Extension Phase]:

• Footnote: [1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase, '\*' Rel day post 30-day safety window from EOT.

Listing 16.2.8.4d ECOG Performance Status Through the PK End of Treatment Visit (Safety Population in the Stage 3 PK Phase)

TESARO, Inc. Confidential Page 1 of x Protocol: XXXXX Listing 16.2.8.5a Baseline Physical Examination Findings (Safety Population in the Stage 1 PK Phase) Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: TABLET or CAPSULE>, as applicable Patient Rel Number Visit Date Performed Day [1] Body System Status Abnormality Description [1] Relative to the date of first dose in the PK Phase. Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for:

Listing 16.2.8.5b Baseline Physical Examination Findings (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.5c Baseline Physical Examination Findings (Safety Population in the Extension Phase)

[Programming Notes For Extension Phase]: Footnote: [1] Relative to first dose during the Extension Phase.

Listing 16.2.8.5d Baseline Physical Examination Findings (Safety Population in the Stage 3 PK Phase)

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TESARO, I Protocol:	nc. xxxxx	• Confidential XXXX										
			Listing 16.2.8	3.6a								
		Pregnancy Tes	t (Safety Population	in the Stage 1 PK Pha	ise)							
Treatment CAPSULE>,	Sequence: < as applicab	Stage 1 & 2: TABLET/CAPSULE of le	CAPSULE/TABLET> or	<stage 3:="" fasted="" fed<="" td=""><td>or FED/FASTED&gt; or <ex< td=""><td>tension: TABLET or</td></ex<></td></stage>	or FED/FASTED> or <ex< td=""><td>tension: TABLET or</td></ex<>	tension: TABLET or						
Patient		Was										
Number	Visit	Pregnancy Test Performed?	Date of Test	Rel Day [1]	Туре	Result						
[1] Relat Scheduled the Exten	ive to the d and unsched sion Phase,	late of first dose in the PK P duled visits through the Exten are included. Visits related t	hase. sion Screening Phase to the Extension Scre	or through study dis ening Phase are not i	continuation for the ncluded.	se not continuing in						
Source: P Data Extr	rogram: XXX act Date: D	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxxxxxxx.rtf. Gener DDMMMYYYY	ated on DDMMMYYYY:HH:	MM:SS							

Repeat for:

Listing 16.2.8.6b Pregnancy Test (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.6c Pregnancy Test (Safety Population in the Extension Phase)

[Programming Notes For Extension Phase]:

Footnote: [1] Relative to first dose during the Extension Phase. '-' Rel day before first Dose during Extension Phase, '\*' Rel day post 30-day safety window from EOT.

Listing 16.2.8.6d Pregnancy Test (Safety Population in the Stage 3 PK Phase)

TESARO,	Inc.			Confider	tial	Pa	qe 1 of x
Protocol	: XXXXX						2
				Listing 16.2	2.9.2d		
	Listing	r of COVID-19 As	sessments and	Symptom Assessme	ents for Patients	with COVID-19 Adverse Events	
	2		(Safetv	Population in the	- Stage 3 PK Phase	)	
			(	<u>-</u>		,	
Treatmen	+ Semience · <star< td=""><td>re 3. Period 1.</td><td>FASTED OF FED</td><td>· Pariod 2. FAST</td><td>ED ON FEDS</td><td></td><td></td></star<>	re 3. Period 1.	FASTED OF FED	· Pariod 2. FAST	ED ON FEDS		
Treatmen	t bequeince. Stag	je J. lellou I.	TASIED OI FED	, ieiiou 2. indi	GD OI FED>		
					COVID-19 Test		
Patient	Treatment	Adverse	AF.	COVID-19 Case	Performed/ Test	Assessments and	
Number	Period (State)	Event	Start Date	Diagnosis [1]	Date/ Results	Symptom Assessments	Result
Wallber	Terroa (beace)	Livence	Deale Date	Diagnobib [i]	Date, Rebaited	Sympeom Hobeobmened	REDUIC
****	1 (FASTED)	Coronavirus	2020-04-16	Suspected	Yes/	Travel to Location with Community	No
mmm	i (inoidd)	infection	2020 01 10	bubpeeeeu	2020-04-17/	Transmission [2]	110
					Indeterminate		
						Visited Health Care Facility [2]	No
						Contact with COVID-19	Unknown
						Confirmed/Probable Case [2]	
						Medication Taken to Treat COVID-19	Yes
						Fever	Yes
						Cough	Yes
						Shortness of Breath	Yes
						Sore Throat	No
						Loss of Appetite	No
						Nausea	No
						Vomiting	No
						Diarrhea	No
						Abdominal Pain	No
						Fatigue	No
						Loss of Smell	No
						Loss of Taste	No
						Asymptomatic	No
						Home Quarantined/Isolated	Unknown
	2 (FED)						
	1	•		•		•	•
AE=Adver	se event.						
[1] COVI	D-19 Case Diagnos	sis is based on	WHO Definitio	n as of DDMMMYYY	Υ.		
[2] With	in 14 days prior	to symptom onse	et.				
Source:	Program: XXXXXXX	(XXXXXXXXXXXX. (	Output: xxxxxx	xxxxxx.rtf. Gen	erated on DDMMMYYY	Y:HH:MM:SS	
Data Ext	ract Date: DDMMM	MYYYY, Data Cu	toff Date: DD	MMMYYYY			

[Programming Notes]

The COVID-19 AE terms include: Asymptomatic COVID-19, Coronavirus infection, COVID-19, COVID-19 pneumonia, Suspected COVID-19. Note that the number of COVID-19 AE terms may change.

TESARO, Inc.				Confidential		Pa	age 1 of x
Protocol: XXXXX							
			Li	sting 16.2.9.2c			
	Listing of COV	/ID-19 Assessments	and Sympto	m Assessments for	Patients with COV	/ID-19 Adverse Events	
		(Saf	fety Populat	tion in the Exten	sion Phase)		
Treatment: <(	CAPSULE or TABLET>						
					COVID-19 Test		
Patient		Adverse	AE Start	COVID-19 Case	Performed/ Test	Assessments and	
Number	Formulation	Event	Date	Diagnosis [1]	Date/ Results	Symptom Assessments	Result
XXXX	TABLET	Coronavirus	2020-04-	Suspected	Yes/	Travel to Location with	No
		infection	16		2020-04-17/	Community Transmission [2]	
					Indeterminate		
						Visited Health Care	No
						Facility [2]	
						Contact with COVID-19	Unknown
						Confirmed/Probable Case [2]	
						Medication Taken to Treat	Yes
						COVID-19	
						Fever	Yes
						Cough	Yes
						Shortness of Breath	Yes
						Sore Throat	No
						Loss of Appetite	No
						Nausea	No
						Vomiting	No
						Diarrhea	No
						Abdominal Pain	No
						Fatigue	No
						Loss of Smell	No
						Loss of Taste	No
						Asymptomatic	No
						Home Quarantined/Isolated	Unknown
	CAPSULE					•••	

AE=Adverse event.

[1] COVID-19 Case Diagnosis is based on WHO Definition as of DDMMMYYYY.

[2] Within 14 days prior to symptom onset.

## Signature Page for 213362 TMF-16339705 v1.0

Reason for signing: Approved	Name: PPD Role: Author Date of signature: 12-Jul-2023 13:42:14 GMT+0000

Reason for signing: Approved	Name: PPD
	Role: Approver
	Date of signature: 12-Jul-2023 15:14:33 GMT+0000

Signature Page for TMF-16339705 v1.0

## Statistical Analysis Plan

### AN OPEN-LABEL, RANDOMIZED-SEQUENCE, MULTICENTER, SINGLE-CROSSOVER STUDY TO ASSESS THE RELATIVE BIOAVAILABILITY AND BIOEQUIVALENCE OF NIRAPARIB TABLET FORMULATION COMPARED TO NIRAPARIB CAPSULE FORMULATION IN PATIENTS WITH ADVANCED SOLID TUMORS

GSK/TESARO Protocol Number:	213362/3000-01-004
Protocol Version:	6.0 (Amendment 5)
Compound Number:	GSK 3985771, MK-4827
Study Drug Name:	Niraparib
Phase:	Phase 1
Methodology:	Open-Label, Cross-Over
Sponsor:	TESARO, a Glaxo Smith Kline Company
Analysis Plan Date:	21 December 2021
Analysis Plan Version:	Version 6.0

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### SPONSOR SIGNATURE PAGE

Protocol Title:	AN OPEN-LABEL, RANDOMIZED-SEQUENCE, MULTICENTER, SINGLE-CROSSOVER STUDY TO ASSESS THE RELATIVE BIOAVAILABILITY AND BIOEQUIVALENCE OF NIRAPARIB TABLET FORMULATION COMPARED TO NIRAPARIB CAPSULE FORMULATION IN PATIENTS WITH ADVANCED SOLID TUMORS
Protocol Number:	3000-01-004
Sponsor:	TESARO, a Glaxo Smith Kline Company
	980 Great West Road
	Brentford
	Middlesex, TW8 9GS
	UK

By signing this document, I acknowledge that I have read the document and approve of the planned statistical analyses described herein. I agree that the planned statistical analyses are appropriate for this study, are in accordance with the study objectives, and are consistent with the statistical methodology described in the protocol, clinical development plan, and all applicable regulatory guidance and guidelines.

Author:	Signature:	PPD
Alina Striha		
Senior Statistician		
Plus-Project Ltd.		
	Date:	
Approver:	Signature:	
Izabela Malinowska	_	
Medical Director		
Glaxo Smith Kline Company		
	Date:	

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## LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
AE(s)	adverse event(s)
AESI	Adverse Events of Special Interest
ALT	alanine aminotransferase
ALP	alkaline phosphatase
AML	Acute Myeloid Leukemia
AST	aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical
AUC	area under the plasma concentration-time curve
BA	bioavailability
BE	bioequivalence
BMI	body mass index
CI	confidence interval
CL/F	apparent total body clearance
C <sub>max</sub>	Maximum observed plasma concentration
CSR	clinical study report
CV	coefficient of variation
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic case report form
ЕОТ	end-of-treatment
FE	food effect
ICF	informed consent form
ICH	International Conference on Harmonisation
LLN	lower limit of normal
LS mean	least-squares mean
CCI	
MDRP	Medical Data Review Plan
MDS	Myelodysplastic Syndromes
MedDRA	Medical Dictionary for Regulatory Activities
NCI CTCAE	National Cancer Institute Common Terminology Criteria for Adverse Events
PI	Package Insert
РК	pharmacokinetics
РТ	preferred term

Abbreviation	Definition
Q1	first quartile
Q3	third quartile
QD	one time per day
SAE	serious adverse event
SAP	statistical analysis plan
SD	standard deviation
SOC	system organ class
t <sub>1/2</sub>	termination elimination half-life
TEAE	treatment-emergent adverse event
t <sub>max</sub>	Time to reach C <sub>max</sub>
US	United States
ULN	upper limit of normal
Vz/F	apparent terminal volume of distribution
WHO	World Health Organization
## 1 INFORMATION FROM THE STUDY PROTOCOL

#### 1.1 Introduction and Objectives

#### 1.1.1 Introduction

The approved niraparib drug product is an immediate release hard gelatin capsule dosage form that contains 100 mg of niraparib per capsule. The labelled starting dose for niraparib is 300 mg. Facilitating this dose requires the administration of three 100 mg capsules.

It is Sponsor's intent to introduce a tablet dosage form that provides the 100 mg, 200 mg and 300 mg dose in single dose strength tablets to reduce the pill burden on the patients.

To this end, the Sponsor has developed a tablet dosage form with the specific intent to provide comparable performance to the approved capsule dosage form. The formulation and manufacturing process of the tablet were selected to produce a tablet with comparable in-vitro performance to the capsule.

This study is an open-label Phase 1 study to evaluate the relative bioavailability (BA) and bioequivalence (BE) of niraparib administered as a tablet formulation compared to the reference capsule formulation manufactured by the same process as currently marketed in the United States. Specifically, a 300 mg niraparib tablet will be compared to three (3) niraparib capsules ( $3 \times 100$  mg). In addition, this study will evaluate the effect of a high-fat meal on the pharmacokinetics (PK) of the niraparib 300 mg tablet formulation (Stage 3). The Extension Phase of this study is to enable patients enrolled in the study to continue to receive treatment with niraparib if they are tolerating it and, in the Investigator's opinion, may receive benefit.

#### 1.1.2 Study Objectives

The primary objectives of this study are as follows:

- Stage 1: To obtain preliminary assessment of the relative bioavailability of 300 mg niraparib administered as a tablet versus capsule formulation and to estimate the intra-subject variability of niraparib PK
- Stage 2: To evaluate if the tablet formulation (1 × 300 mg) of niraparib is bioequivalent to the capsule formulation (3 × 100 mg)
- Stage 3: To assess the effect of a high-fat meal on niraparib PK following a single 300 mg dose of the tablet formulation.

The secondary objectives of this study are as follows:

- Stage 1, Stage 2, and Stage 3: To evaluate the safety of single dose niraparib when administered as a tablet or capsule formulation in patients with advanced solid tumors
- Extension Phase: To evaluate the safety of continuously dosed niraparib in patients with advanced solid tumors.

The exploratory objectives of this study are as follows:

#### 1.1.3 Scope and Revision History

A separate PK analysis plan will be written to address the PK objectives and data for this study.

This statistical analysis plan (SAP) is designed to outline the methods to be used in the analyses of non-pharmacokinetic study data. Patient populations to be used for analyses, data handling rules, statistical methods, and formats for data presentation are identified and provided. The statistical analyses and summary tabulations described in this SAP will provide the basis for the results sections of the clinical study report (CSR) for this trial.

The SAP will outline any differences in the currently planned analytical objectives relative to those planned in the study protocol.

The SAP is a living document that will be created during the trial conduct. It will be maintained throughout the lifecycle of the trial. Important changes following approval of SAP v1.0 will be tracked in this section.

Table/Listing Number	Correction	Reason for Correction
Table 14.1.1D	Footnotes [2] and [3] added to the table and in the footer.	Clarification why two patients have been double counted in Screening.
Table 14.1.4D	Added "Missing" category to Cancer stage and Number of prior lines of therapy.	Data collected has missing information on the eCRF.
Table 14.3.1.1.2D	Removed "Any COVID-19 related TEAE".	Removing a duplicate entry row.
Table 14.3.1.14D	Removed "System Organ Class" from the table.	Line not required for the table in question as summary by Preferred Term is of interest.
Table 14.3.1.16D	Added footnote: "NOTE: Deaths due to progressive disease were not collected as adverse events."	Added to reflect data collection and management process and align with Stage 1 and Stage 2 programming practice.
Table 14.3.1.2.1.1D	Footnote added: Note: COVID-19 Case Diagnosis is based on WHO Definition as of DDMMMYYYY.	Added as per reviewer request.
Table 14.3.1.20D	Footnote [1] updated to: "[1] TABLET PK Phase Stage 3 opened to	Clarification of footnote explaining calendar placement of the Stage 3
Table 14.3.1.21D	recruitment on DDMMMYYYY, with first	during COVID-19 pandemic.
Table 14.3.1.22D	the start of the recruitment during the COVID- 19 pandemic."	

The following changes have been implemented in the Appendix containing shells of the Planned Statistical Tables, Listings and Figures.

	<ul> <li>Table titles updated to</li> <li>Table 14.3.1.20D Summary of Incidence of COVID-19 Related Adverse Events Over Time (Safety Population in the Stage 3 PK Phase)</li> <li>Table 14.3.1.21D Summary of Incidence of COVID-19 Related Adverse Events Over Time by Gender (Safety Population in the Stage 3 PK Phase)</li> <li>Table 14.3.1.22D Summary of Incidence of COVID-19 Related Adverse Events Over Time by Age Group (Safety Population in the Stage 3 PK Phase)</li> </ul>	Clarification of titles to reflect the reporting effort of COVID-19 related AE incidence rates.
Table 14.4.1C	Summary table of Important Protocol Deviations for Open-Label Extension Phase added.	Added upon request from study team for CSR reporting purposes.
Table 14.4.1D	Summary table of Important Protocol Deviations for the PK Phase Occurring Through End of Treatment (Safety Population in the Stage 3 PK Phase). Footnotes and corresponding references added to the table	Added upon request from study team for CSR reporting purposes. Added upon request for clarification.
Listing 16.2.5.1D	Added "PK Dose 1" and "PK Dose 2" date columns to the listing.	Added columns to the shells to align Stage 3 reported outputs with those reported in Stages 1 and 2.
	Moved "Patient Number" into header row.	For readability purposes.
Listing 16.2.5.3D	Added "Rel Day [1]" column and [1] footnote: "[1] Relative to first dose during the PK Phase."	Added to the shells to align Stage 3 reported outputs with those reported in Stages 1 and 2.
Listing 16.2.5.5D	Columns "Full Dose Taken?", "If N, how much consumed?", "Reason for Change", "Nausea within specified time of dose?" removed from the listing.	Columns removed from Stage 3 listing as not applicable, as per study design.
Listing 16.2.8.1.1D and associated repeat listings	Programming note added regarding location of "Patient Number" in the outputs.	Depending on spacing/information displayed, "Patient Number" may be displayed in the header row after "Treatment Sequence" in order to aid readability of the listing.
Listing 16.2.8.2D	Removed "Heart Rate" column.	Data collected under "Pulse" in Stage 3, added "Heart Rate" to the shells in error.
Listing 16.2.8.5D	Added text to footnote: "in the PK Phase"	Previously missing in error.
Listing 16.2.2C	Listing updated to include only "Important" protocol deviations, title updated to reflect change.	Updated upon request from study team for CSR reporting purposes.
Listing 16.2.2.1D	Listing updated to include only "Important" protocol deviations, title updated to reflect change.	Updated upon request from study team for CSR reporting purposes.
Section 1.2	Definition of data cut has been amended.	Definition changed to reflect study reporting requirements upon request from study team.

## Table 1 Revision History

SAP	Protocol	eCRF		
version	version	version		
1.0	2.0	5.0 (26FEB2018)	First Draft	
2.0	4.0	8.0	Major changes to this draft of the SAP include the following:	
		(12FEB2019)	• Incorporate changes based on amended protocol.	
			• Modify Stage 2 analysis of AEs to accommodate the increase in washout time between period 1 and period 2 for Stage 2.	
			• For the Extension Phase, specify that analysis will be performed by formulation and overall to accommodate allowance of both tablet and capsule formulation in the Extension Phase.	
			• Define the BA/BE evaluable population and add demographic and baseline characteristic summaries for this population.	
			• Clarify definition of concomitant medications and add additional table for Stage 2 to analyze only medications taken during the PK collection period.	
			• Clarifications to mock table and listing shells (e.g., numbering, footnotes).	
3.0	5.0	10.0	Major changes to this draft of the SAP include the following:	
		(31JUL2019)	Incorporate changes based on amended protocol, including:	
			<ul> <li>Updated numbers of patients enrolled to account for non-evaluability.</li> </ul>	
			• Specification of reasons for non-evaluability for the analysis of bioequivalence.	
			• Focus Extension Phase laboratory summaries on select laboratory assessments hemoglobin, neutrophils, platelets, bilirubin, creatinine, AST, and ALT).	
4.0	6.0	11.0	Major changes to this draft of the SAP include the following:	
		(23MAR2021)	• Incorporate changes based on amended protocol, to address the objectives for Stage 3 of the study.	
			Addition of sections relating to COVID-19 reporting.	
5.0	6.0	11.0 (23MAR2021)	Primary changes to this draft associated with addition of Important Protocol Deviation table and updates to the associated listing to reporting effort.	
			Minor updates to align Stage 1, 2 and 3 TLFs with shells, and associated update to Protocol Deviation reporting, as per the SAP.	

SAP version	Protocol version	eCRF version	Changes from previous version
6.0	6.0	11.0 (23MAR2021)	<ul><li>Primary change to this draft of the SAP is change of the data cut for reporting of final Stage 3 analysis.</li><li>Minor update to footnotes of Important Protocol Deviation summary table.</li><li>Minor update to Section 5 formatting.</li></ul>

## 1.2 Study Design

## 1.2.1 Synopsis of Study Design

This is a multicenter, open-label study in patients with advanced solid tumors. This is a 3-stage, randomized-sequence, single-crossover study to assess the relative BA and BE of niraparib tablet formulation relative to the capsule formulation. In addition, Stage 3 of the protocol is a single cohort, randomized-sequence, 2 period, single dose, crossover study to assess effect of food on the PK of the niraparib tablet formulation.

Pharmacokinetics (PK) Phase: In Stages 1 and 2, patients will be randomized 1:1 to receive tablet formulation followed by capsule formulation or capsule formulation followed by tablet formulation. In Stage 3, patients will be randomized 1:1 to receive tablet formulation in a fasted state followed by tablet taken with a high-fat meal, or by tablet taken with a high-fat meal followed by tablet formulation taken in a fasted state.

Stage 1: Following an 8-hour fast on Day 1, patients will receive a single dose of the formulation (tablet  $[1 \times 300 \text{ mg}]$  or capsule  $[3 \times 100 \text{ mg}]$ ) followed by a 7-day (+1 day) Washout/PK period, followed by a dose of the alternate formulation also in a fasted state, followed by a 7-day (+1 day) Washout/PK period for Stage 1 of the study followed by a dose of the alternate formulation also in a fasted state, followed by a 7-day (+1 day) Washout/PK period a 7-day Washout/PK period. Patients receiving the tablet in the first treatment period will receive the capsules in the second treatment period and vice versa (Figure 1). Extensive PK sampling will be carried out after niraparib dosing.

Stage 2: Following an 8-hour fast on Day 1, patients will receive a single dose of the formulation (tablet  $[1 \times 300 \text{ mg}]$  or capsule  $[3 \times 100 \text{ mg}]$ ) followed by a 14-day (+/- 4 days) Washout/PK period followed by a dose of the alternate formulation also in a fasted state, followed by a 7-day Washout/PK period. Patients receiving the tablet in the first treatment period will receive the capsules in the second treatment period and vice versa (Figure 1). Extensive PK sampling will be carried out after niraparib dosing.

Stage 3: In period 1, patients will receive a single 300 mg niraparib tablet either following a 10-hour fast or directly following consumption of a high-fat meal, followed by a 14-day (+4 days) PK sampling and Washout period. In period 2, patients will be crossed over to receive a single 300 mg niraparib tablet in a fasted state or with a high-fat meal, followed by a 7-day PK sampling period. All patients will fast for a minimum of 4 hours post-dose in both periods. Patients receiving the tablet in the fasted state in the first treatment period will receive the tablet with a high-fat meal in the second treatment period and vice versa.

In the rare instance where a delay of the entire PK period 2 is needed for any reason beyond the 4 day window specified above the site must contact the Sponsor's medical monitor to discuss the patient circumstances, the Sponsor will decide if the patient can continue with PK period 2 with a delay. Similarly, should the laboratory results on Day 15 (D15) (the day of niraparib administration in PK period 2) show changes in organ function such that the original inclusion criteria for laboratory values are no longer met, or in the event of a significant change of patient's clinical status as judged by the Investigator, the site must consult with the Sponsor to discuss the patient's continued participation in PK period 2. Note that sites need not wait for the pre-dose laboratory results to begin PK period 2, but rather consult the Sponsor once the results are available as needed. In Stage 2, patients who experience emesis within 9 hours of dosing or who miss a critical PK sample (such as the last PK sample on Day 8 in each period) will be discontinued from the PK Phase and will be allowed to be screened for the Extension Phase. In Stage 3, patients who experience emesis within 10 hours of dosing will be discontinued from the PK Phase and will be discontinued from the PK Phase; those that meet other criteria for continued niraparib therapy will be eligible to be screened for the Extension Phase.

For Stage 1, the PK parameters that will be estimated include area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUC<sub>0-t</sub>), area under the plasma concentration-time curve from time 0 extrapolated to infinity (AUC<sub>0- $\infty$ </sub>), apparent total body clearance (CL/F), maximum observed plasma concentration (C<sub>max</sub>), time to reach C<sub>max</sub> (t<sub>max</sub>), termination elimination half-life (t<sub>1/2</sub>), apparent terminal volume of distribution (Vz/F) and BA of tablet formulation relative to the capsule formulation based on AUC<sub>0-t</sub>, AUC<sub>0- $\infty$ </sub>, and C<sub>max</sub>. Relative bioavailability will be assessed based on the ratio of geometric least-squares (LS) means of the test (tablet) to reference (capsule). Additionally, the pharmacokinetics of **CC** will be determined (Stage 1 only).

For Stage 2, the same PK parameters as above will be estimated. To conclude bioequivalence, the 90% confidence interval (CI) of the ratio of geometric LS means of the test (tablet) to reference (capsule) product should be within 0.800 - 1.250 (80% - 125%) for AUC<sub>0-x</sub>, AUC<sub>0-t</sub>, and C<sub>max</sub>.

For Stage 3, the same PK parameters as above will be estimated. In addition,  $t_{lag}$ , the time from administration of the dose to the first quantifiable concentration, will be determined, and  $t_{max}$  will be compared between the fed and fasted states. The relative bioavailability of the 300 mg niraparib tablet administered with a high-fat meal relative to fasted dosing will be based on the ratio of geometric LS means of AUC<sub>0-t</sub>, AUC<sub>0-x</sub>, and C<sub>max</sub>.

Additional PK parameters may be estimated (e.g., residual area), if deemed appropriate.

Extension Phase: When patients complete the PK Phase of the study (at least 7-days from the beginning of PK period 2), they may be eligible to participate in the Extension Phase following review of the Extension Phase inclusion criteria and completion of the required Extension Phase screening assessments. The starting dose of niraparib in the Extension Phase will be based on the patient's baseline actual body weight or platelet count. Patients with a baseline actual body weight of  $\geq$ 77 kg and screening platelet count of  $\geq$ 150,000/µL (obtained after completion of the PK phase, as part of Extension Phase screening) will take one 300 mg strength tablet or 3 × 100 mg tablet/capsules at each dose administration (once a day [QD]). Patients with a baseline actual body weight of <77 kg or screening platelet count of <150,000/µL

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will take one 200 mg strength tablet or  $2 \times 100$  mg tablet/capsules at each dose administration (QD). For patients whose initial starting dose is 200 mg QD, escalation to 300 mg QD is permitted after 2 cycles of therapy if no treatment interruption or discontinuation was required during the first 2 cycles of Extension Phase therapy and after approval from the Sponsor. Additional dose modifications will not be based upon changes in the patient's actual body weight during study participation. If laboratory values at the beginning of Extension Phase are outside of the range specified in the inclusion criteria, the patient may continue to participate in the study only upon Sponsor approval with consideration for an appropriately reduced dose. Should a patient start the Extension Phase at 100 mg, consideration may be given to escalate to 200 mg after 2 cycles, therapy if no treatment interruption or discontinuation was required during the first 2 cycles of Extension Phase therapy and after approval from the Sponsor.

Patients have up to 28 days (21 days for Stage 3 only; up to 28 days may be acceptable following discussion between the Sponsor and Investigator) after completion of the PK Phase to complete the screening assessments and the Extension Phase Screening Visit.

A tumor assessment is to be performed prior to the first dose of the Extension Phase (pre-Extension Phase). The pre-Extension Phase tumor assessment need not be completed if the baseline tumor assessment was performed  $\leq$  56 days before the first dose of the Extension Phase.

The Cycle 1/Day 1 Visit can occur on the same day as the Extension Phase Screening Visit, dependent upon availability of radiographic results obtained  $\leq 56$  days of the first planned dose in the Extension Phase. If the Extension Phase Screening Visit and the Cycle 1/Day 1 Visit occur on the same day, the clinical laboratory results will be reviewed by the study personnel prior to study drug administration to ensure eligibility. At the Cycle 1/Day 1 Visit, patients will undergo safety assessments and will receive study drug supply for the duration of 1 cycle (300 mg or 200 mg tablets of niraparib for QD dosing or  $3 \times 100$  mg or  $2 \times 100$  mg tablet/capsules of niraparib for QD dosing, depending on availability). It is preferred that patients remain on the same formulation (tablet versus capsule) throughout the Extension Phase. Patients will return on the first day of every treatment cycle ( $28 \pm 7$  days) to receive study drug and for safety assessments. Visits will continue approximately every 4 weeks until treatment discontinuation. In line with the niraparib United States Package Insert (US PI), dose interruption (no longer than 28 days) will be allowed based on adverse events (AEs). In addition, dose reductions to 200 mg QD and subsequently to 100 mg QD will be allowed based on AEs (please refer to US PI). Any dose reductions differing from this must be discussed with the medical monitor. Patients can continue in the Extension Phase until the patient meets 1 of the withdrawal criteria.

End-of-treatment (EOT) and Safety Follow-up Visits: The EOT visit will occur within 7 days of the decision to discontinue study drug, for any reason, or completion of the PK Phase for patients who participate in the Extension Phase (Stage 3 only), whichever occurs first. Should the first dose of a new anti-cancer therapy occur within 14 days of the decision to discontinue study drug, all assessments required for the Safety Follow-up visit should occur at the EOT visit and this visit will be considered the Safety Follow-up visit. If the first dose of the new anti-cancer therapy occurs >14 days of the decision to discontinue study, the Safety Follow-up visit will occur 30 + 7 days after the last dose of the study drug, or at the start of any new anti-cancer therapy, whichever occur first.

For Stage 3 of the PK Phase only, the data cut will occur when all patients have completed the PK Phase. Data collected up to and including PK EOT visit prior to the data cut will be presented in the FE Stage 3

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PK CSR for all randomized and treated patients. Additionally, the Sponsor will include safety data related to the PK Phase, as identified up to Cycle 1/Day 1 of the Extension Phase.

Figure 1 Study Design: Single-Crossover Study



Stage 2 (completed):



Stage 1 (completed):



Abbreviations: PK = pharmacokinetics.

#### 1.2.2 Randomization Methodology

Randomization will occur centrally using an interactive voice response system/integrated web response system. In Stage 1 and Stage 2, patients will be assigned randomly in a 1:1 ratio to a dosing sequence: capsule formulation followed by tablet formulation, or vice versa. In Stage 3, patients will be assigned randomly in a 1:1 ratio to a dosing sequence: dosing after receiving a high-fat meal (fed) followed by dosing after fasting, or vice versa. The period between randomization and Cycle 1/Day 1 should be no longer than 5 calendar days.

#### 1.2.3 Unblinding

Unblinding is not applicable as this is an open-label study.

#### 1.2.4 Study Procedures

Refer to the latest protocol for the schedule of assessments.

#### 1.2.5 Efficacy, Safety, and Pharmacokinetic parameters

#### 1.2.5.1 Efficacy parameters

Investigator assessment of response will occur every 3-cycles while on study or per the Institution's standard practice.

#### 1.2.5.2 Safety parameters

Safety parameters to be assessed include:

- Treatment emergent adverse events (TEAE)
- Discontinuations due to AEs
- Physical examination (PE) findings
- Vital signs
- Clinical laboratory results (hematology, chemistry, urinalysis)
- Electrocardiograms (ECG)
- Use of concomitant medications.

#### 1.2.5.3 PK parameters

PK parameters and analysis methodology will be addressed in the PK analysis plan.

## 2 Patient Population

#### 2.1 Population Definitions

The following patient populations will be evaluated for analyses specified in this SAP. Additional populations, relevant to the PK analysis will be defined in the PK analysis plan.

- Safety Population in the Stage 1 PK Phase: All patients who receive any amount of niraparib during the Stage 1 PK Phase of the study.
- Safety Population in the Stage 2 PK Phase: All patients who receive any amount of niraparib during the Stage 2 PK Phase of the study.
- Safety Population in the Stage 3 PK Phase: All patients who receive any amount of niraparib during the Stage 3 PK Phase of the study.
- Safety Population in the Extension Phase: All patients who receive any amount of niraparib in the Open-Label Extension Phase of the study.
- BA/BE Evaluable Population: All patients who complete both PK periods and have sufficient PK sample collection to accurately estimate PK parameters, without significant niraparib carryover (baseline concentration > 5% of C<sub>max</sub>), in both PK Periods. Patients who have significant niraparib carryover from period 1 in period 2 will be completely excluded from the BA/BE

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Evaluable Population. The terminology BA Evaluable Population will be used for Stage 1 and BE Evaluable Population will be used for Stage 2.

• Food effect (FE) Evaluable Population: All patients who complete both PK periods and have sufficient PK sample collection to accurately estimate PK parameters in both periods. Patients meeting non-evaluability criteria or having significant niraparib carryover (baseline concentration >5% of C<sub>max</sub>) will be completely excluded from the FE Population.

## 2.2 Protocol Deviations

Protocol deviations will be assessed and classified as important and/or significant per Sponsor's SOP. The Medical Data Review Plan (MDRP) prospectively identifies classification criteria for important deviations. All protocol deviations will be identified, classified and finalized prior to database lock.

A listing of protocol deviations will be provided for the Stage 1 PK Phase, Stage 2 PK Phase; for Stage 3 PK Phase and the Open-Label Extension Phase a listing of only "Important" protocol deviations will be provided.

For Stage 3 PK Phase and Open-Label Extension Phase, tables summarizing "Important" protocol deviations will be provided.

## 3 GENERAL STATISTICAL METHODS

## 3.1 Sample Size Justification

Stage 1

No formal sample size calculation was performed for Stage 1. Approximately 24 patients will be enrolled in Stage 1. This sample size is considered adequate for preliminary assessment of the relative bioavailability of the tablet compared to the capsules and for estimating the intra-subject coefficient of variation, after accounting for patient drop-outs and potential carryover.

#### Stage 2

Based on estimates from Stage 1, 100 BA/BE evaluable patients are required in Stage 2. With 100 evaluable patients, assuming the intra-subject coefficient of variation (CV) is 25% and the true ratio of means is 0.89 (89%), there is at least 90% power to demonstrate the bioequivalence (bioequivalence range: 0.80 to 1.250 [80% – 125%], alpha=0.05). Power calculations were also performed under alternative assumptions for the CV and mean ratio. Assuming the CV is 30% and the true ratio of means is 0.89 (89%), with 100 evaluable patients, there is at least 82% power to demonstrate bioequivalence. Assuming the true ratio is 0.90 (90%), the power is 96% and 88% assuming CVs of 25% and 30%, respectively.

The final analysis of bioequivalence will be based on Stage 2 BA/BE evaluable patients only, with a target sample size of 100 evaluable patients. Patients may be identified as non-evaluable due to issues arising during the study conduct, such as:

• Emesis within 9 hours of dosing,

- Dosing errors,
- Patient did not fast prior to dosing,
- Missing critical PK sample on Day 8,
- Failure to complete both PK periods, and
- Significant changes to the patient medical status that would potentially affect the PK profile as determined by the Sponsor in consultation with the Investigator prior to PK data analysis.

In this patient population, approximately 170 total patients are targeted for enrollment, assuming a 35% non-evaluability rate during the study conduct, and an additional 10% non-evaluability rate during PK analysis. The non-evaluability rate arising during the study conduct will be continuously monitored by the Sponsor and the total number of enrolled patients may be adjusted accordingly with the aim to target the resulting sample size of 100 BA/BE evaluable patients.

#### Stage 3

Assuming the true ratio of means is 1 and the intra-subject CV is 20% for  $AUC_{0-t}$  and  $AUC_{0-\infty}$ , with 16 evaluable patients, there is approximately 83% probability that the 90% CI of the ratio of geometric means will be within 0.800 and 1.250 (80% - 125%). Based on the results of a FE study conducted using the capsule formulation, an effect of a high-fat meal on  $C_{max}$  is possible. The sample size of 16 patients is deemed adequate to characterize this effect.  $AUC_{0-t}$  and  $AUC_{0-\infty}$  will be the primary parameters for analysis.

The primary analysis will be based on the FE Evaluable Population as it is the most conservative approach, which maximizes the benefits of the crossover design, where each patient serves as their own control. Results for the PK Evaluable Population will also be summarized and reported for this study.

To account for non-evaluable patients, approximately 20 total patients are targeted for enrollment. The final analysis will be based on Stage 3 FE evaluable patients only. Patients may be identified as non-evaluable due to issues arising during the study conduct, such as:

- Emesis within 10 hours of dosing,
- Dosing errors,
- Patient did not follow dietary requirements prior to dose and post-dose,
- Failure to complete both PK periods, and
- Significant changes to the patient medical status that would potentially affect the PK profile as determined by the Sponsor in consultation with the Investigator prior to PK data analysis.

Patients who miss critical PK samples or miss sufficient samples to render calculation of AUC unreliable will be discontinued from the PK Phase; those that meet other criteria for continued niraparib therapy will be eligible to be screened for the Extension Phase. The non-evaluability rate arising during the study conduct will be continuously monitored by the Sponsor and the total number of enrolled patients may be adjusted accordingly with the aim to target the resulting sample size of 16 evaluable patients.

## 3.2 General Methods

All statistical analyses will be performed using SAS statistical software v9.4 or later, unless otherwise noted. All output will be incorporated into Microsoft Word or Excel files, or Adobe Acrobat PDF files,

sorted and labeled according to the International Conference on Harmonisation (ICH) recommendations, and formatted to the appropriate page size(s).

For categorical variables, summary tabulations of the number and percentage of patients within each category of the parameter will be presented. Percentages will be based on the patients with a non-missing parameter unless missing category is presented. Percentages will be reported to one decimal place. Percentages will not be presented for zero counts.

For continuous variables, the number of patients, mean, standard deviation (SD), median, first quartile  $(Q_1)$ , third quartile  $(Q_3)$ , minimum, and maximum values will be presented. Mean, median,  $Q_1$ , and  $Q_3$  will be reported to 1 more decimal place than the raw data, while the SD will be reported to 2 more decimal places than the raw data.

All data listings that contain an evaluation date will also contain a relative study day. A unique relative study day will be calculated for the PK Phase and Extension Phase based on the first date of dosing within the study phase. Pre-treatment and on-treatment study days are numbered relative to the day of the first dose of study drug which is designated as Day 1. The preceding day is Day -1, the day before that is Day -2, etc. Post-treatment study days are numbered relative to the first dose and are designated as Day +1, Day +2, etc.

In addition:

- Medical history and AEs will be coded using the most up-to-date version of Medical Dictionary for Regulatory Activities (MedDRA).
- Laboratory parameter changes during the Extension Phase for selected laboratory tests will be described using shift tables, relative to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v4.03.
- Concomitant medications will be coded using the latest version of the World Health Organization's (WHO) Anatomical Therapeutic Chemical (ATC) classification.
- CIs will be presented to one more decimal place than the raw data.

Summaries in the Extension Phase will be performed by formulation and overall, regardless of starting dose, unless otherwise specified. The niraparib formulation and dose at onset will be included in the listing for the Extension Phase.

All tables, figures, and listings will include footers at the bottom of the page reflecting the programs used to generate the tables, figures, and listings, and date and time of the generation of the output.

Some minor modifications may be necessary to the planned design of tables, figures, and listings to accommodate data collected during the actual study conduct.

## 3.3 Baseline Definitions

For all analyses unless otherwise noted, baseline is defined as the most recent measurement prior to the first administration of study drug, for each phase of the study. Baseline can be the same date as first dose, given the measurement is expected prior to first dose when only date information is available.

## 3.4 Methods of Pooling Data

Data will be pooled across study sites.

### 3.5 Adjustments for Covariates

No formal statistical analyses that adjust for possible covariate effects are planned for the safety endpoints.

## 3.6 Multiplicity Adjustment

Multiplicity is not adjusted in this study.

### 3.7 Subpopulations

Not applicable.

## 3.8 Withdrawals, Drop-outs, Loss to Follow-up

Patients will not be replaced during Stage 1. During Stage 2 and Stage 3, patients who do not complete period 1 or period 2, or who are missing PK samples which render the determination of the primary PK parameters not possible, will be replaced. After evaluation, patients receiving concomitant medications which may affect the final analysis may be replaced.

## 3.9 Missing Data

In general, there will be no imputations made to accommodate missing data points. All data recorded on the eCRF will be included in data listings for the CSR.

When tabulating AE data, partial dates will be handled as follows:

- If the day of the month is missing, the onset day will be set to the first day of the month unless it is the same month and year as first study treatment. In this case, in order to conservatively report the event as treatment-emergent, the onset date will be assumed to be the date of first study treatment.
- If the onset day and month are both missing, the day and month will be assumed to be January 1, unless the event occurred in the same year as the first study treatment. In this case, the event onset will be coded to the day of first study treatment in order to conservatively report the event as treatment-emergent.
- A missing onset date will be coded as the first day of study treatment. If the resulting onset date is after a reported date of resolution, the onset date will be set equal to the date of resolution, after considering any required imputation.

Imputation of partial dates is used only to determine whether an event is treatment-emergent; data listings will present the partial date as recorded in the eCRF.

Partial start dates for prior/concomitant medication, growth factor and transfusion data will be handled in the same way as described above for adverse events. Stop dates will be imputed as follows:

- If only day of the month is missing, the end day will be set to the last day of the month.
- If end day and end month are missing, and the year is not missing, then the day and month will be set to December 31 (or date of study discontinuation/completion if earlier than December 31).

- If the stop date is completely missing, it will be set to the date of study discontinuation/completion.
- If the imputed stop date is greater than the date of study discontinuation/completion then the date will be set to the date of study discontinuation/completion.

### 3.10 Visit Windows

By-visit summaries and analyses will be performed by nominal visit. All data will be tabulated per the evaluation visit as recorded on the eCRF even if the assessment is outside of the visit window for analysis.

## 3.11 Interim Analysis

There will be no interim analysis for this study.

### 3.12 COVID-19

COVID-19 pandemic may impact the conduct of clinical studies. Challenges may arise from quarantines, site closures, travel limitations interruptions to the supply chain for the investigational product or other considerations if site personnel or patients become infected with COVID-19. These challenges may lead to difficulties in meeting protocol specified procedures, including administering or using the investigational product or adhering to protocol-mandated visits and laboratory/diagnostic testing.

This study was initiated by TESARO, which was subsequently acquired by GSK. Prior to the acquisition, protocol deviations were classified using TESARO definitions. The TESARO protocol deviation system was decommissioned in May 2020, and thereafter, protocol deviations were classified using GSK definitions.

All protocol deviations collected during the study will be reviewed by the TESARO (for Stage 1 and Stage 2) or GSK (for Stage 3 only) study team, as appropriate, in order to identify TESARO "Significant"/"Important" protocol deviations and GSK "Important" protocol deviations, respectively. Consistent with ICH E3 guidance, only protocol deviations identified as "Important" (GSK) are evaluated in the CSR for impact on the Stage 3 primary endpoint.

## 4 STUDY ANALYSES

#### 4.1 Patient Disposition

A by-patient data listing of patient disposition information will be presented for each phase.

For the PK Phase (Stage 1, Stage 2 and Stage 3 separately), patient disposition will be tabulated and will include the number of patients in each of the following categories:

- Patients screened
- Patients randomized
- Patients treated with each formulation (Stage 1 and 2)
- Patients treated in fed and fasted state (Stage 3)
- Patients in the safety population

- Patients completing the PK Phase
- Primary reason for discontinuation from the PK Phase
- Primary reason for discontinuation from the study, for patients who do not continue to the Extension Phase.

For the Open-Label Extension Phase, patient disposition will be tabulated and will include the number of patients in each of the following categories:

- Patients treated with at least one dose
- Patients who discontinue treatment and the reason(s) for withdrawal
- Patients who discontinue the study and the reason(s) for withdrawal.

## 4.2 Demographics, Baseline Characteristics and Medical History

Demographics, baseline characteristics, primary cancer history, and medical history information will be summarized for the PK safety population by sequence and overall (Stage 1, Stage 2 and Stage 3 separately) and for the Open-Label Extension Phase, using descriptive statistics for the safety population. No formal statistical comparisons will be performed. Demographics and baseline characteristics will also be summarized for the BA for Stage 1, BE Evaluable Population for Stage 2 and FE Evaluable population for Stage 3.

The demographic and baseline characteristics tables will include the following variables:

- Age at time of screening (years)
- Age categories (18 to <65, 65 to <75,  $\geq$ 75; and  $\geq$ 65)
- Sex
- Race (White, Black, Asian, American Indian/Alaska Native, Native Hawaiian or other Pacific Islander, Other and Not Reported)
- Ethnicity (Hispanic or Latino, not-Hispanic or Latino, Not Reported and Unknown)
- Baseline weight (in kilograms)
- Baseline height (in centimeters)
- Baseline body mass index (BMI) (kg/m<sup>2</sup>), calculated using the patient's height and weight at screening [BMI (kg/m<sup>2</sup>) = weight (kg) / height (m)<sup>2</sup>]
- Eastern Cooperative Oncology Group (ECOG) performance status at baseline.

Primary cancer history will be summarized for the safety population and will include the following variables:

- Tumor type
- Time from first diagnosis to informed consent (years)
- Cancer stage (most recent) (Locally advanced, Metastatic)
- Number of prior lines of therapy
- Any prior radiotherapy.

Prior anti-cancer treatments will be coded using the most current version of the WHO Drug Dictionary. The number and percentage of patients reporting the use of at least one preferred term will be reported for

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the safety population in the PK Phase (Stage 1, Stage 2 and Stage 3 separately) and the safety population in the Extension Phase.

Medical history will be coded using the most current version of MedDRA, and the number and percentage of patients experiencing at least one such diagnosis by MedDRA System Organ Class (SOC) and preferred term (PT) will be reported for the safety population in the PK Phase (Stage 1, Stage 2 and Stage 3 separately) and the safety population in the Extension Phase.

Demographics, baseline characteristics, primary cancer history, and medical history information for each patient will be provided in data listings.

## 4.3 Investigator Assessment of Response

Investigator assessment of response will be provided in data listings for the Extension Phase. Additional descriptive summaries of response may be performed by tumor type.

## 4.4 Safety Evaluation

## 4.4.1 Treatment Exposure and Compliance

#### PK Phase

The number and percentage of patients receiving capsules and tablets during the PK Phase (Stage 1 and Stage 2, separately) will be summarized. For Stage 3, the number of tablets received will be summarized by fed/fasted state.

A by-patient listing of the niraparib treatment data will be produced for the PK safety population.

#### Extension Phase

Study treatment exposure and compliance will be summarized by formulation and overall, including:

- Number and percentage of patients who initiated  $1, 2, 3, 4, 5, \ge 6$  treated cycles.
- Duration of treatment (months), defined as:
  - [last dose date first dose date in the Extension Phase + 1] / 30.4375.
- Duration on study (months), defined as:
  - [last contact date first dose date in the Extension Phase + 1] / 30.4375, where last contact date is the last visit date or date of death.
- Number of patients with at least one dose interruption.
- Number of patients with at least one dose reduction.

In addition, the starting niraparib dose for each cycle will be summarized.

A by-patient listing of the niraparib treatment data will be produced for the Open-Label Extension Phase safety population.

#### 4.4.2 Adverse Events

All AEs will be classified by SOC and PT using the most up-to-date version of MedDRA.

Per protocol, all SAEs will be collected from the signing of the ICF for this study through 90 days after the last dose of study drug (or until the start of alternate anticancer therapy, whichever occurs first, and recorded in the eCRF.

All AEs, regardless of the source of identification (e.g., physical examination, laboratory assessment, ECG, or reported by patient), will be collected and recorded in the eCRF for each patient from the time of randomization and/or treatment assignment until 30 days after the last dose of study drug.

All AEs experienced by a patient, regardless of the suspected causality, will be monitored until the AE or SAE has resolved, until AE(s) or SAE(s) have returned to baseline or normal levels, until stabilized with a satisfactory explanation for the changes observed, until the patient is lost to follow-up, or until the patient has died, starts alternate anti-cancer therapy, or until the patient withdraws consent.

For analysis, TEAEs will be defined as any AEs collected with a start date on or after the first dose of study drug. Any AEs recorded in the database that occur from the time of ICF to first dose will be listed only and not included in safety analyses. Pre-existing conditions will be recorded in the eCRF on the Medical History or appropriate page.

The severity of the toxicities will be graded according to the NCI CTCAE v4.03. Within the same MedDRA PT, only the most severe AE for each patient will be counted in tabulations by severity. Within a MedDRA SOC, patients with more than 1 MedDRA PT will be counted only once for the most severe AE reported.

The Investigator must provide a causality assessment (related or not related) regarding the relationship of the event with the study drug and/or study procedure for all AEs. In Stage 1, for analysis of the PK Phase, AEs considered related to either tablet or capsule will be considered to be related to study drug. Any AEs for which the relationship is missing (for either tablet or capsule during the Stage 1 PK Phase) will be considered as related to study treatment. During the PK Phase 2, PK Phase 3 and Extension Phase, relationship relative to niraparib will be considered. Within the same MedDRA PT, only the AE with the highest ranked relationship to treatment for each patient will be counted in tabulations by relationship to treatment. Within a MedDRA SOC, patients with more than 1 MedDRA PT will be counted only once for the AE that is most related to treatment. The imputation for a missing relationship will take place prior to determining the most related AE within a SOC or PT for a given patient.

If the start date is missing for an AE and the actual start date cannot be determined from a partial date, the AE will be considered treatment-emergent.

Adverse Events of Special Interest (AESI) for niraparib are the following:

- Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML)
- Secondary cancers (new malignancies [other than MDS or AML])
- Pneumonitis (for Stage 1 and Stage 2 only)
- Embryo-fetal toxicity (for Stage 1 and Stage 2 only).

AEs will be classified into the following time periods for analysis.

• PK Phase (for Stage 1, Stage 2 and Stage 3 separately):

- Period 1: Any AE that begins on or after Dose 1 but prior to Dose 2.
  - For Stage 1, Period 1 will be defined as 7-days post Dose 1 for patients who do not receive Dose 2.
  - For Stage 2, Period 1 will be defined as 14-days post Dose 1 for patients who do not receive Dose 2.
- Period 2: Any AEs that begins on or after Dose 2 but prior to the end of the PK Phase as defined by 7-days post Dose 2.
- Safety Follow-Up/Extension Screening Period:
  - For patients not participating in the Extension Phase, AEs that begin after the end of the PK Phase.
  - For patients participating in the Extension Phase, AEs that begin after the end of the PK Phase until the date of first dose in the Extension Phase.
- Open-Label Extension Phase:
  - $\circ$   $\;$  Any AEs that start on or after the first dose in the Extension Phase.

The analyses indicated below will be performed for each of the above-mentioned phases.

A high-level overview of TEAEs will be presented in a summary table. This table will include the number and percentage of patients for the following categories:

- Any TEAE
- Any related TEAEs
- Any serious TEAEs
- Any related serious TEAEs
- Any TEAEs with CTCAE toxicity grade 3 or above
- Any related TEAEs with CTCAE toxicity grade 3 or above
- Any TEAEs leading to treatment discontinuation
- Any related TEAEs leading to treatment discontinuation
- Any TEAEs leading to dose interruption
- Any TEAEs leading to dose reduction
- Any TEAEs leading to death.

The number and percentage of patients reporting a TEAE will be summarized in the following additional AE tables. AE tabulations will be ordered in terms of decreasing frequency for SOC (alphabetically for SOCs with the same number of AEs reported), and decreasing frequency for PT within SOC (alphabetically for PTs with the same number of AEs reported within a SOC) considering the overall rate.

- TEAE by SOC and PT
- Related TEAE by SOC and PT
- Treatment emergent SAEs by SOC and PT
- Related treatment emergent SAEs by SOC and PT
- TEAE with toxicity grade 3 or above by SOC and PT
- Related TEAE with toxicity grade 3 or above by SOC and PT
- TEAEs leading to treatment discontinuation by SOC and PT
- TEAEs leading to dose interruption by SOC and PT (Extension Phase Only)

- TEAEs leading to dose reduction by SOC and PT
- TEAEs leading to death by SOC and PT
- TEAE by PT (sorted by frequency)
- TEAE by SOC, PT, and maximum toxicity grade
- Treatment emergent AESI.

For Stage 1 and Stage 2 PK Phase, primary tabulations for the PK Phase data will be provided by formulation (regardless of period), those occurring during the follow-up/extension screening and overall. In addition, the high-level overview of TEAEs and summary of TEAEs by SOC and PT will be summarized by sequence and formulation. For Stage 3 PK Phase, primary tabulations for the PK Phase data will be provided by fed/fasted state (regardless of period), and overall. In addition, the high-level overview of TEAEs by SOC and PT will be summarized by sequence and fed/fasted state (regardless of period), and overall. In addition, the high-level overview of TEAEs and summary of TEAEs by SOC and PT will be summarized by sequence and fed/fasted state. For the Open-Label Extension Phase, data will be summarized by formulation and for all patients overall.

The following by-patient listings will be produced for the PK Phase (Stage 1, Stage 2 and Stage 3 separately) and the Open-Label Extension Phase:

- All TEAEs
- Treatment emergent SAEs
- All Deaths
- TEAEs leading to dose interruption (Extension Phase Only)
- TEAEs leading to dose reduction
- TEAEs leading to treatment discontinuation.

#### 4.4.3 Laboratory Data

Laboratory assessments for safety oversight are performed locally at each center's laboratory by means of their established methods. All laboratory values will be converted to SI units and classified as normal, low, or high based on normal ranges supplied by the local laboratories and upon employing standardization.

A by-patient listing of all laboratory data will be provided, with laboratory reference ranges and abnormal values highlighted, and including center, patient identifier, and visit for the PK Phase and the Extension Phase of the study.

For the Extension Phase, select hematology (hemoglobin, neutrophils and platelets) and chemistry (bilirubin, creatinine, aspartate aminotransferase [AST] and alanine aminotransferase [ALT]) will be analyzed using change from baseline by visit.

For the Extension Phase, select hematology (hemoglobin, neutrophils and platelets) and chemistry tests (bilirubin, creatinine, ALT, and AST), baseline and post-baseline results will be categorized by NCI CTCAE v4.03 grade (Table 2). Shift tables will be produced by maximum post-baseline grade. Results that are considered 'normal' will be assigned a grade 0.

#### Table 2 NCI Common Terminology Criteria for Adverse Events v4.03 (CTCAE)

	07	( )	
CCI - This section contained Clinical	Outcome Assessment data col	lection questionnaire	s or indices, which
and the stand base to be a standard and the standard standards at			
are protected by third party copyright	laws and therefore have been	excluded.	

#### 4.4.4 Vital Signs and Physical Examination

Vital sign measurements will be presented for each patient in a data listing.

Baseline physical examination findings will be presented in a data listing. Any new or changed condition will be captured as an adverse event and will be summarized in the AE tables and listings.

#### 4.4.5 Electrocardiogram

Standard 12-lead ECGs will be performed locally for patients in the study. Any ECG findings that are assessed as clinically significant and are reported as an AE or SAE will be summarized in the AE tables and listings.

All ECG results (i.e., interpretations) for each patient will be provided in a data listing.

#### 4.4.6 Prior and Concomitant Mediations

Medications collected at Screening and during the study will be coded using the current version of the WHO Drug dictionary. Study treatment, prior anti-cancer treatments for primary cancer, transfusions and growth factors are collected and summarized separately. For each of the study phases (Stage 1 PK, Stage 2 PK, Stage 3 PK and Extension Phase), medications will be categorized as prior or concomitant using the following definitions:

• Prior medications during the PK Phase: any medications which started prior to the first dose date of study treatment during the PK Phase.

- Concomitant medications during the PK Phase: any medications being taken on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase.
  - For PK Stage 2, concomitant medications will be further identified as those taken during the PK collection period, defined by dates of the first PK-draw to last PK-draw.
- Prior medications during the Extension Phase: any medications which started prior to the first dose date of study treatment during the Extension Phase.
- Concomitant medications during the Extension Phase: any medications on or after the first treatment dosing date in the Extension Phase through 30 days after the last dose of treatment.

Note: medications can be classified as both prior and concomitant.

Both prior medications and concomitant medications will be summarized by ATC classification drug class and WHO preferred name using the number and percentage of patients for each cohort. A patient reporting the same medication more than once will be counted only once when calculating the number and percentage of patients who received that medication in a given time category (prior or concomitant). The summary of concomitant medications will be ordered alphabetically by drug class and then by descending frequency of preferred name in total within the drug class. For drugs with the same frequency, sorting will be done alphabetically. Summaries will be based on the safety population.

For PK Stage 2, an additional summary of concomitant medications used during the PK collection period will be provided for the BE Evaluable Population.

For each phase of the study, all prior and concomitant medications will be provided in a by-patient listing sorted by patient ID number and administration date in chronological order.

#### 4.4.7 Prior and Concomitant Transfusions and Growth Factors

The number and percentage of patients receiving prior and concomitant growth factors during the PK Phase and Extension Phase will be summarized. The data will be classified as prior or concomitant using similar logic as provided in Section 4.4.6.

For each phase of the study, all prior and concomitant transfusions and growth factor use will be provided in a by-patient listing sorted by patient ID number and administration date in chronological order.

#### 4.4.8 COVID-19

The Pharmacokinetics Phase Stage 3 of the trial takes place during COVID-19 pandemic, as a result of which some of the trial procedures could be impacted in terms of missing visits and/or assessments. Missing protocol required data/visits due to COVID-19 must be noted in participant notes and recorded as a COVID-19-related protocol deviations.

A summary of the following COVID-19 assessments will be produced: case diagnosis, COVID-19 test performed, and results of the COVID-19 test.

The incidence of COVID-19 related AEs and SAEs will be summarized as part of the safety reporting summaries along with COVID-19-related as reasons for treatment discontinuation.

A listing of all patients with COVID-19 assessments and symptom assessments will be produced and will include the following:

- Treatment sequence
- Patient number
- COVID-19 case diagnosis
- COVID-19 test performed
- Result of the COVID-19 test
- Assessments and symptom assessments performed
- Results of the assessments and symptom assessments.

For PK Phase Stage 3, a separate listing defining "Important" GSK protocol deviations related to COVID-19 will be presented.

For protocol deviation reporting during the Extension Phase, a listing will be produced to present TESARO Classification of protocol deviations for patients continuing from Stage 1 and Stage 2, and GSK Classification of protocol deviations for patients continuing from Stage 3.

## 5 CHANGES TO PLANNED ANALYSES

There is no change between the protocol-defined statistical analyses and those planned in this SAP.

## 5.1 Changes in v5.0 of the SAP

Section 2.2 has been updated to include a summary tables of Important protocol deviations for Stage 3 PK Phase and Open-Label Extension Phases, as well as clarification of associated deviation listings presenting only protocol deviations classified as "Important".

## 5.2 Changes in v6.0 of the SAP

Section 1.2 has been updated to reflect the change in PK data cut requirements for final Stage 3 analysis.

## 6 APPENDIX

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# TABLES

General guidelines:

Tables will be provided for the Stage 1 PK Phase, Stage 2 PK Phase, Stage 3 PK Phase and the Open-Label Extension Phase.

For the PK Phase (Stage 1, Stage 2 and Stage 3):

- Treatment=Sequence and Overall, in general. For PK and AE data, please see mock tables.
- Population=Safety Population in Stage 1 PK (Stage 2 PK or Stage 3 PK) Phase, unless otherwise specified.
- PK Phase Data:
  - For patients who do not continue to Extension Phase, PK Phase is any data collected.
  - For patients who do continue to Extension Phase,
    - AEs prior to first dose in Extension Phase
    - Prior meds/procedures/etc. prior to first dose in PK Phase
    - Concomitant meds meds prior to first dose in Extension Phase.
- Assessments (Labs, ECGs, Vitals, ECOG, PE, etc.) use visit to identify data.

For the Extension Phase:

- Treatment=Niraparib Tablet or Capsule (regardless of starting dose); Summarize by Tablet; Capsule; Overall, unless otherwise specified.
- Population=Safety Population in the Open-Label Extension Phase (i.e., those who receive at least 1 dose), unless otherwise specified.
- Extension Phase Data:
  - For patients who do not continue to Extension Phase, there is no Extension Phase data.
  - For patients who do continue to Extension Phase,
    - AEs on or after first dose in Extension Phase
    - Prior meds/procedures/etc. prior to first dose in Extension Phase
    - Concomitant meds meds on or after the first dose in Extension Phase
    - Assessments (Labs, ECGs, Vitals, ECOG, PE, etc.) use visit to identify data.

Sort order: All AE tabulations, unless otherwise specified, will be ordered in terms of decreasing frequency for SOC (alphabetically for SOCs with the same number of AEs reported), and decreasing frequency for PT within SOC (alphabetically for PTs with the same number of AEs reported within a SOC) considering the overall rate.

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	Table 14.1.	1A		
Subject Disposition in the PK	Phase (All H	Patients in the Sta	age 1 PK Phase)	
Parameter	Statistic	Sequence	Sequence	
		TABLET/CAPSULE	CAPSULE/TABLET	Overall
Number of Patients				
Screened	n			XX
Randomized	n	Х	х	х
Received Tablet	n	Х	Х	Х
Received Capsule	n	Х	Х	Х
Received Both Tablet and Capsule	n	Х	Х	Х
PK Phase Safety Population	n	Х	Х	Х
Completed PK Phase	n	Х	Х	Х
Discontinuation from PK Phase	n	Х	Х	Х
Reason1	n	Х	Х	Х
Reason2	n	Х	Х	Х
Participate in Extension Phase	n	х	X	X
Discontinuation from Study Prior to Entering the Extension				
Phase				
Reason1	n	XX	XX	XX
Reason2	n	XX	XX	ХХ
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Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYY	Y			

[Programming Notes] Only include DC from study for those patients who do not enter the Extension Phase.

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Table	14.1.1B			
Subject Disposition in the PK Phase	(All Patient	s in the Stage 2 F	PK Phase)	
Parameter	Statistic	Sequence	Sequence	
		TABLET/CAPSULE	CAPSULE/TABLET	Overall
Number of Patients				
Screened	n			XX
Randomized	n	Х	Х	х
Not Treated	n	Х	Х	Х
Received Tablet	n	Х	Х	х
Received Capsule	n	Х	Х	Х
Received Both Tablet and Capsule	n	Х	х	Х
PK Phase Safety Population	n	х	х	Х
Completed PK Phase	n	х	х	Х
Discontinuation from PK Phase [1]	n	х	х	Х
Reason 1	n	Х	х	х
Reason 2	n	х	х	Х
Participate in Extension Phase	n	Х	х	Х
Discontinuation from Study Prior to Entering the Extension Phase				
Reason 1	n	XX	XX	XX
Reason 2	n	XX	XX	XX

[1] Includes patients in the Safety Population (i.e., treated patients) only.

[Programming Notes]

Only include DC from study for those patients who do not enter the Extension Phase.

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Subject Disposition in the Extens:	ion Phase (A	II Patients in the	Extension Phase)		
Deventer		ht i see a station	NT ! ! ].		
Parameter	Statistic	Niraparib	Niraparib	Niraparib	
		Tablet	Capsule	Overall	
Number of Patients					
Dosed	n	XX	XX	XX	
Discontinued Treatment After Receiving at Least 1 Dose	n	XX	XX	XX	
Reason 1	n	XX	XX	XX	
Reason 2	n	XX	XX	XX	
Discontinued Study	n	XX	XX	XX	
Reason 1	n	XX	XX	XX	
Reason 2	n	XX	XX	XX	
		-		· ·	
Source: Listing XXXXXXXX, Program: XXXXXXXXXXXXXXXXX, Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS					
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY	Y				

TESARO Inc. Conf	Confidential			Page 1 of x	
Protocol No: XXXXX					
Table	14.1.1D				
Subject Disposition in the PK Phase	(All Patients	s in the Stage 3 PK	Phase)		
Parameter	Statistic	Sequence	Sequence		
		NIRAPARIB TABLET	NIRAPARIB TABLET		
		FASTED/FED	FED/FASTED	OVERALL	
Number of Patients					
Screened [1]	n			XX	
Randomized	n	х	х	х	
Not Treated	n	х	х	х	
Received Tablet in Fasted State	n	х	х	х	
Received Tablet in Fed State	n	х	х	х	
Received Tablet in Both Fasted and Fed State	n	х	х	Х	
PK Phase Safety Population	n	х	Х	Х	
Completed PK Phase	n	х	х	Х	
Discontinuation from PK Phase [2]	n	х	Х	Х	
Reason 1	n	х	х	х	
Reason 2	n	х	х	х	
Participate in Extension Phase	n	Х	Х	Х	
Discontinuation from Study Prior to Entering the Extension Phase					
Reason 1	n	XX	XX	XX	
Reason 2	n	XX	XX	XX	

[1] Patient xxxxxx-xxxx (Screen Failure ID: XXi) and xxxxxx-xxxx (Screen Failure ID: YYi) re-screened and reconsented after screen failure are counted twice in Screening.

[2] Includes patients in the Safety Population (i.e., treated patients) only.

[Programming Note] XXi/YYi is ID that was SF. Programming, please note footnote references changed order in the shell and footer.

TESARO Inc.	Confidential			Page 1 of x
Protocol No: XXXXX				-
	Table 14.1.2A			
Demographics (Safety H	Population in the	Stage 1 PK Phase)		
	-	<u> </u>		
Parameter	Statistic	Sequence	Sequence	
		TABLET/CAPSULE	CAPSULE/TABLET	OVERALL
		(N=XX)	(N=xx)	(N=XX)
Age (yrs)	n	XX	XX	XX
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	XX.X	XX.X	XX.X
	Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX
Age Group				
18 -< 65	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
65 -< 75	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
≥ 75	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	n (응)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sex				
Male	n (응)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race				
White	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
African American	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	n (응)	xx (xx.x)	xx (xx.x)	xx (xx.x)
American Indian or Alaska Native	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native Hawaiian or other Pacific Islander	n (응)	xx (xx.x)	xx (xx.x)	XX (XX.X)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Reported	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity				
Hispanic or Latino	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic or Latino	n (응)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	n (응)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Reported	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Repeat for:

Table 14.1.2.1A Demographics (BA Evaluable Population in the Stage 1 PK Phase)

Table 14.1.2.1B Demographics (Safety Population in the Stage 2 PK Phase)
# Niraparib

Table 14.1.2.2B Demographics (BE Evaluable Population in the Stage 2 PK Phase)

Table 14.1.2C Demographics (Safety Population in the Extension Phase)

• Summarize Extension Phase Data with columns for Tablet; Capsule; Overall Table 14.1.2.1D Demographics (Safety Population in the Stage 3 PK Phase)

Table 14.1.2.2D Demographics (FE Evaluable Population in the Stage 3 PK Phase)

• Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL.

TESARO Inc.	Confidential			Page 1 of x
Protocol No: XXXXX				
	Table 14.1.3A			
Baselin	e Characteristics (Safety Population in	the Stage 1 PK Pha	ise)	
Parameter	Statistic	Sequence	Sequence	
		TABLET/CAPSULE	CAPSULE/TABLET	OVERALL
		(N=xx)	(N=xx)	(N=xx)
Weight (kg)	n	XX	XX	XX
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	XX.X	XX.X	XX.X
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Height (cm)	n	XX	XX	XX
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	XX.X	XX.X	XX.X
	Q1, Q3	XX.X, XX.X	XX.X, XX.X	xx.x, xx.x
	Min, Max	XX, XX	XX, XX	xx, xx
BMI (kg/m²)	n	XX	XX	XX
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	XX.X	XX.X	XX.X
	Q1, Q3	XX.X, XX.X	xx.x, xx.x	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX
ECOG Performance Status				
0	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing	n (%)	XX (XX.X)	XX (XX.X)	xx (xx.x)
		1	1	•

ECOG = Eastern Cooperative Oncology Group:

0=Fully active, able to carry on all pre-disease performance without restriction 1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature 2=Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours 3=Capable of only limited self-care, confined to bed or chair more than 50% of waking hours 4=Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

Repeat for:

Table 14.1.3.1A Baseline Characteristics (BA Evaluable Population in the Stage 1 PK Phase)

Table 14.1.3.1B Baseline Characteristics (Safety Population in the Stage 2 PK Phase)

Table 14.1.3.2B Baseline Characteristics (BE Evaluable Population in the Stage 2 PK Phase)

Table 14.1.3C Baseline Characteristics (Safety Population in the Extension Phase)

• Summarize Extension Phase Data with columns for Tablet; Capsule; Overall Table 14.1.3.1D Baseline Characteristics (Safety Population in the Stage 3 PK Phase)

• Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL Table 14.1.3.2D Baseline Characteristics (FE Evaluable Population in the Stage 3 PK Phase)

• Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

TESARO Inc. Con	nfidential			Page 1 of x
Protocol No: XXXXX				
Tabl	e 14.1.4A			
Primary Cancer History (Safety	Population in the S	tage 1 PK Phase)		
Parameter	Statistic	Sequence	Sequence	
		TABLET/CAPSULE	CAPSULE/TABLET	OVERALL
		(N=xx)	(N=xx)	(N=xx)
Tumor Type				
Хххххххх	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Хххххххх	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)
Хххххххх	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Time from first diagnosis to informed consent (years)	n	XX	XX	XX
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	XX.X	XX.X	XX.X
	Q1, Q3	xx.x, xx.x	XX.X, XX.X	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX
Cancer Stage (most recent)				
Locally advanced	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)
Metastatic	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)
Missing	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)
Number of prior lines of therapy				
0	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	n (%)	xx (xx.x)	XX (XX.X)	XX (XX.X)
2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	n (%)	xx (xx.x)	XX (XX.X)	XX (XX.X)
4	n (%)	xx (xx.x)	XX (XX.X)	XX (XX.X)
5	n (%)	xx (xx.x)	XX (XX.X)	XX (XX.X)
>=6	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	n (%)	xx (xx.x)	XX (XX.X)	XX (XX.X)
Any prior radiotherapy	n (%)	xx (xx.x)	XX (XX.X)	XX (XX.X)
	•	·	•	•
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Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY				

Repeat for:

Table 14.1.4B Primary Cancer History (Safety Population in the Stage 2 PK Phase)

Table 14.1.4C Primary Cancer History (Safety Population in the Extension Phase)

• Summarize Extension Phase Data with columns for Tablet; Capsule; Overall Table 14.1.4D Primary Cancer History (Safety Population in the Stage 3 PK Phase) Niraparib

• Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

TESARO Inc. Confidential						
Table 14.1.5A						
Prior Anti-Cancer Tr	eatment (Safety Population in the	Stage 1 PK Phase)				
Preferred Term	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)		
Agent 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Agent 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Agent 3	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)		
Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXX.rtf. Generated on DDMMMY DDMMMYYYY	YYYY:HH:MM:SS	1			

[Programming Notes]

Sort by decreasing frequency in the OVERALL column.

Repeat for:

Table 14.1.5B Prior Anti-Cancer Treatment (Safety Population in the Stage 2 PK Phase)

Table 14.1.5C Prior Anti-Cancer Treatment (Safety Population in the Extension Phase)

• Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

Table 14.1.5D Prior Anti-Cancer Treatment (Safety Population in the Stage 3 PK Phase)

• Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED AND OVERALL.

TESARO Inc. Confide:	Confidential						
Protocol No: XXXXX							
Medical History (Safety Populati	on in the Stage	l PK Phase)					
System Organ Class	Statistic	Sequence	Sequence				
Preferred Term		TABLET/CAPSULE	CAPSULE/TABLET	OVERALL			
		(N=xx)	(N=XX)	(N=XX)			
Any condition	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
SOC1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
PT1	n (%)	XX (XX.X)	xx (xx.x)	XX (XX.X)			
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
SOC2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
Source: Program: XXXXXXXXXXXXXXXXXXXXXXXX Output: xxxxxxxxxx.rtf. Gen	erated on DDMMM	YYYY:HH:MM:SS					
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY							

[Programming Notes] Sort alphabetically by SOC/PT.

Repeat for: Table 14.1.6B Medical History (Safety Population in the Stage 2 PK Phase)

Table 14.1.6C Medical History (Safety Population in the Extension Phase)

• Summarize Extension Phase Data with columns for Tablet; Capsule; Overall.

Table 14.1.6D Medical History (Safety Population in the Stage 3 PK Phase)

• Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

TESARO Inc.	Confidential				
Protocol No: XXXXX					
	Table 14.1.7A				
Prior Medicatio	ons by ATC and PT (Safety Population in the	e Stage 1 PK Phase)			
ATC (Level 3)	Statistic	Sequence	Sequence		
Preferred Term		TABLET/CAPSULE	CAPSULE/TABLET	OVERALL	
		(N=XX)	(N=xx)	(N=xx)	
Any prior medication	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
ATC1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
PT2	n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)	
ATC2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
				<u> </u>	
Note: Prior medications are any medications	with a start date earlier than the first d	lose date of study	treatment and are	coded using	
WHO Drug Dictionary version YYYYMM. Study t:	reatment, prior anti-cancer treatments for	primary cancer, tr	ansfusions and gr	owth factors	
are not included.					
				l	
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Data Extract Date: DDMMMYYYY, Data Cutoff	Date: DDMMMYYYY				

[Programming Notes]

Sort alphabetically by ATC3 and Preferred Term. If there are uncoded terms due to no ATC level 3 term not being available, add footnote for uncoded term: [1] ATC level 3 term is not available through WHO Drug Dictionary.

Repeat for:

Table 14.1.7B Prior Medications by ATC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.1.7C Prior Medications by ATC and PT (Safety Population in the Extension Phase)

• Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

[Programming Notes]

- Footnote Extension Phase: Prior medications are any medications, other than study treatments and pre-medications for study treatment, with a start date earlier than the first dose date of study treatment during the Extension Phase and are coded using WHO Drug Dictionary version YYYYMM.
- Prior anti-cancer treatments for primary cancer are not included.

Table 14.1.7D Prior Medications by ATC and PT (Safety Population in the Stage 3 PK Phase)

Confidential

Niraparib

• Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL

TESARO Inc. Confidential								
Table 14 1 80								
Concertions Medications by NEC and	DT (Cafatu Danulation	in the Steve 1 DK	Dheee)					
Concomitant Medications by Art and	Pr (Salety Population	in the stage i PK	Phase)					
	Ctatiatia	Comuchas	Companya					
Alt (Level 5)	Statistic			OVEDATI				
Preferred ferm		(N=xx)	(N=xx)	(N=XX)				
Any concomitant medication	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
ATC1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
ATC2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
PT1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
PT2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
1								

Note: Concomitant medications are any medications being taken on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase. They are coded using WHO Drug Dictionary version YYYYMM.

[Programming Notes]

Sort alphabetically by ATC3 and Preferred Term. If there are uncoded terms due to no ATC level 3 term not being available, add footnote for uncoded term: [1] ATC level 3 term is not available through WHO Drug Dictionary.

Repeat for:

Table 14.1.8.1B Concomitant Medications by ATC and PT (Safety Population in the Stage 2 PK Phase)

Table 14.1.8.2B Concomitant Medications During the PK Collection Period by ATC and PT (BE Evaluable Population in the Stage 2 PK Phase)

• Footnote: Concomitant medications during the PK collection period are any concomitant medications taken between the first PK-draw until the last PK-draw. They are coded using WHO Drug Dictionary version YYYYMM.

Table 14.1.8C Concomitant Medications by ATC and PT (Safety Population in the Extension Phase)

• Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

[Programming Notes]

• Footnote - Extension Phase: Concomitant medications are any medications being taken on or after the initial study treatment dosing date during the Extension Phase through 30 days after the last dose. They are coded using WHO Drug Dictionary version YYYYMM.

Table 14.1.8D Concomitant Medications by ATC and PT (Safety Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL
- Footnote Stage 3: Concomitant medications are any medications being taken on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase. They are coded using WHO Drug Dictionary version YYYYMM.

TESARO Inc. Confi	dential			Page 1 of x				
Table 14.1.9A								
Concomitant Transfusions and Growth Factors	(Safety Population	in the Stage 1 PK	Phase)					
Parameter	Statistic	Sequence TABLET/CAPSULE (N=xx)	Sequence CAPSULE/TABLET (N=xx)	OVERALL (N=xx)				
Any Concomitant Transfusions	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
Red Blood Cells	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
Platelet	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
Any Concomitant Growth Factors	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
G-CSF	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
GM-CSF	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
Recombinant Erythropoietin	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)				

Note: Concomitant transfusions or growth factors are any transfusion or growth factor given on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose for those not continuing into the Extension Phase.

Repeat for:

Table 14.1.9B Concomitant Transfusions and Growth Factors (Safety Population in the Stage 2 PK Phase)

Table 14.1.9C Concomitant Transfusions and Growth Factors (Safety Population in the Extension Phase)

• Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

[Programming Notes]

• Footnote - Extension Phase: Concomitant transfusions or growth factors are any transfusion or growth factor given on or after the initial study treatment dosing date during the Extension Phase through 30 days after the last dose.

Table 14.1.9D Concomitant Transfusions and Growth Factors (Safety Population in the Stage 3 PK Phase)

- Summarize Stage 3 data by Sequence with columns for NIRAPARIB TABLET FASTED/FED, NIRAPARIB TABLET FED/FASTED and OVERALL
- Footnote Stage 3: Concomitant transfusions or growth factors are any transfusion or growth factor given on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose for those not continuing into the Extension Phase.

TESARO Inc.	Confidential			Page 1 of x	
Protocol No: XXXXX					
	Table 14.3.1.1.1	4			
Overall Summary of Treatment Emergent	t Adverse Events (Sa	fety Population in	the Stage 1 PK Phase)		
	TABLET [1]	CAPSULE [2]	FU/Ext Screening	Total [4]	
	(N=XX)	(N=XX)	[3] (N=xx)	(N=xx)	
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	
Any Related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any Related Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any TEAE with CTCAE Toxicity Grade $\geq$ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any Related TEAE with CTCAE Toxicity Grade $\geq$ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any TEAE leading to Dose Interruption	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any Related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any TEAE Leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
[1] Includes TEAEs with onset date in Period 1 or Perio	od 2 where patient r	eceived niraparib t	ablet.		
[2] Includes TEAEs with onset date in Period 1 or Perio	od 2 where patient r	eceived niraparib c	apsules.		
[3] For patients not participating in the Extension Pha	.se, includes TEAEs t	that began after the	e end of the PK Phase	through the End of	
Study. For patients participating in the Extension Pha-	se, includes TEAEs t	chat began after th	e end of the PK Phase	until the date of	
first dose in the Extension Phase.					
[4] Includes TEAEs occurring at any time during the PK	Phase.				
Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxxx.rtf. Generate	d on DDMMMYYYY:HH:M	M:SS		
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMM	IMYYYY				

Repeat for:

Table 14.3.1.1.1B Overall Summary of Treatment Emergent Adverse Events (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.1.1C Overall Summary of Treatment Emergent Adverse Events (Safety Population in the Extension Phase)

• Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

[Programming Notes]

• Sort order: All AE tabulations, unless otherwise specified, will be ordered in terms of decreasing frequency for SOC (alphabetically for SOCs with the same number of AEs reported), and decreasing frequency for PT within SOC (alphabetically for PTs with the same number of AEs reported within a SOC) considering the overall rate.

TESARO Inc. Confidential										
Protocol No: XXXXX										
	Table 14.3.1.1.11	)								
Overall Summary of Treatment Emergent	t Adverse Events (Sa:	fety Population in t	he Stage 3 PK Phase)							
	NIRAPARIB	NIRAPARIB	FU/Ext							
	TABLET FASTED [1]	TABLET FED [2]	Screening [3]	Total [4]						
	(N=xx)	(N=xx)	(N=xx)	(N=xx)						
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)						
Any Related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	XX (XX.X)						
Any Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)						
Any Related Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)						
Any TEAE with CTCAE Toxicity Grade ≥ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)						
Any Related TEAE with CTCAE Toxicity Grade $\geq$ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)						
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)						
Any TEAE leading to Dose Interruption	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)						
Any TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)						
Any Related TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)						
Any TEAE Leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)						
Any COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)						
Any Serious COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)						
Any COVID-19 related TEAE Leading to Treatment	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)						
Discontinuation										

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.

[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.

[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.

[4] Includes TEAEs occurring at any time during the PK Phase.

TESARO Inc.	(	Confidential				Page 1 of x	
Protocol No: XXXXX						2	
	Tabl	e 14.3.1.1.2A					
Overall Summary of Treatment Emergent Adv	erse Events by	Sequence and I	Period (Safety	Population in	the Stage 1 PK	Phase)	
		Sequence			Sequence		
		TABLET/CAPSULE			CAPSULE/TABLET		
		(N=xx)			(N=xx)		
	TABLET	CAPSULE	FU/Ext	CAPSULE	TABLET	FU/Ext	
	Period 1	Period 2	Screening	Period 1	Period 2	Screening	
	(N=xx)	(N=xx)	(N=xx)	(N=xx)	(N=xx)	(N=xx)	
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any Related TEAE	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any Serious TEAE	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any Related Serious TEAE	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any TEAE with CTCAE Toxicity Grade $\geq$ 3	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	XX (XX.X)	
Any Related TEAE with CTCAE Toxicity Grade $\geq$ 3	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any TEAE leading to Dose Reduction	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any TEAE leading to Dose Interruption	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any TEAE Leading to Treatment Discontinuation	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any Related TEAE Leading to Treatment	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Discontinuation							
Any TEAE Leading to Death	xx (xx.x)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	
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Data Extract Date: DDMMMYYYY, Data Cutoff Date	: DDMMMYYYY						

Repeat for:

Table 14.3.1.1.2B Overall Summary of Treatment Emergent Adverse Events by Sequence and Period (Safety Population in the Stage 2 PK Phase)

TESARO Inc.		Confidential				Page 1 of x	
Protocol No: XXXXX						-	
	Tab	le 14.3.1.1.2D					
Overall Summary of Treatment Emergent Adv	verse Events b	y Sequence and	Period (Safet	y Population i	n the Stage 3 PK	Phase)	
		Sequence			Sequence		
	NIRAPAI	RIB TABLET FAS	red/fed	NIRAF	ARIB TABLET FED/F	ASTED	
		(N=XX)			(N=xx)	-	
	NIRAPARIB	NIRAPARIB		NIRAPARIB			
	TABLET	TABLET		TABLET	NIRAPARIB		
	FASTED	FED	FU/Ext	FED	TABLET FASTED	FU/Ext	
	Period 1	Period 2	Screening	Period 1	Period 2	Screening	
	(N=xx)	(N=xx)	(N=xx)	(N=xx)	(N=xx)	(N=xx)	
Any Treatment Emergent Adverse Event (TEAE)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any Related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any Related Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any TEAE with CTCAE Toxicity Grade $\geq$ 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any Related TEAE with CTCAE Toxicity Grade $\geq$							
3	XX (XX.X)	XX (XX.X)	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	
Any TEAE leading to Dose Reduction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any TEAE leading to Dose Interruption	XX (XX.X)	XX (XX.X)	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	
Any TEAE Leading to Treatment Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any Related TEAE Leading to Treatment							
Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any TEAE Leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any COVID-19 related TEAE	XX (XX.X)	XX (XX.X)	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	
Any Serious COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Any COVID-19 related TEAE Leading to	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Treatment Discontinuation							

TESARO Inc.	Conf	fidential		Page 1 of x
Protocol No: XXXXX				
	Table 1	4.3.1.2.1A		
Summary of Treatme	nt Emergent Adverse Events by S(	OC and PT (Safety Pop	ulation in the Stage 1 PK P	hase)
		·		
System Organ Class		CAPSILLE [2]	FIL/Ext Screening [3]	Total [/]
Preferred Term	(N=xx)	(N=XX)	(N=xx)	(N=XX)
Any TEAE	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)
SOC1	xx (xx.x)	XX (XX.X)	XX (XX.X)	xx (xx.x)
PT 1	xx (xx.x)	XX (XX.X)	XX (XX.X)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC2		xx (xx x)		
PT 1	XX (XX.X)	XX (XX.X)		
PT 2	xx (xx.x)	XX (XX.X)	xx (xx.x)	XX (XX.X)
[1] Includes TEAEs with onset date	e in Period 1 or Period 2 where	patient received nira	parib tablet.	
[2] Includes TEAEs with onset date	e in Period 1 or Period 2 where	patient received nira	parib capsules.	

[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.

[4] Includes TEAEs occurring at any time during the PK Phase.

[Programming Notes]

For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported.

Table 14.3.1.2.1B Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 2 PK Phase)

TESARO Inc.	Confidential							
Protocol No: XXXXX	rotocol No: XXXXX							
Table 14.3.1.2.1C								
Summary of Treatment	Emergent Adverse Events by SOC and	PT (Safety Population in the Open	-Label Extension Phase)					
	271 13	<b>N7</b> 1 13						
	Niraparib	Niraparib	Niraparib					
System Organ Class	TABLET	CAPSULE	OVERALL					
Preferred Term	(N=XX)	(N=xx)	(N=XX)					
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)					
SOC1		vv (vv v)	vv (vv v)					
PT 1	XX (XX.X)	XX (XX.X)	XX (XX.X) XX (XX.X)					
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)					
SOC2	XX (XX.X)	XX (XX.X)	XX (XX.X)					
PT 1	xx (xx.x)	XX (XX.X)	XX (XX.X)					
PT 2	XX (XX.X)	xx (xx.x)	xx (xx.x)					
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Data Extract Date: DDMMMIII,	Data cutori Date: DDMMMIIII							

[Programming Notes]

For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported.

TESARO Inc.	Confidential			Page 1 of x
Protocol No: XXXXX				
	Table 14.3.1.2.1D			
Summary of Treatment Emergent Adverse B	Events by SOC and PT (	Safety Population in	n the Stage 3 PK Pha	se)
	NIRAPARIB	NIRAPARIB	FU/Ext	
System Organ Class	TABLET FASTED [1]	TABLET FED [2]	Screening [3]	Total [4]
Preferred Term	(N=xx)	(N=xx)	(N=xx)	(N=xx)
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	XX (XX.X)
SOC1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	XX (XX.X)	XX (XX.X)	xx (xx.x)	xx (xx.x)
	·	•	•	
[1] Includes TEAEs with onset date in Period 1 or Peri	od 2 where patient rec	ceived niraparib tab	let in fasted state	
[2] Includes TEAEs with onset date in Period 1 or Peri	od 2 where patient rec	ceived niraparib tab	let in fed state.	
[3] For patients not participating in the Extension Ph	ase, includes TEAEs th	at began after the	end of the PK Phase	through the End of
Study. For patients participating in the Extension Pha	ase, includes TEAEs th	at began after the	end of the PK Phase	until the date of
first dose in the Extension Phase.				

[4] Includes TEAEs occurring at any time during the PK Phase.

[Programming Notes]

For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported.

TESARO Inc.	Confidential			Page 1 of x		
Protocol No: XXXXX				_		
	Table 14.3.1.2.1.1D	)				
Summary of COVID-19 related	Adverse Events by SOC and PT (Sa	afety Population in	the Stage 3 PK Phas	e)		
	NIRAPARIB	NIRAPARIB	FU/Ext			
System Organ Class	TABLET FASTED [1]	TABLET FED [2]	Screening [3]	Total [4]		
Preferred Term	(N=XX)	(N=xx)	(N=XX)	(N=xx)		
Any COVID-19 related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	XX (XX.X)		
SOC1	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)		
PT 1	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)		
PT 2	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)		
SOC2	xx (xx.x)	xx (xx.x)	xx (xx.x)	XX (XX.X)		
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	XX (XX.X)		
PT 2	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)		
Note: COVID-19 Case Diagnosis is based on WHG	O Definition as of DDMMMYYYY.					
[1] Includes COVID-19 related TEAEs with onse	et date in Period 1 or Period 2	where patient recei	ved niraparib table	t in fasted state.		
[2] Includes COVID-19 related TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.						
[3] For patients not participating in the Ext	tension Phase, includes TEAEs th	at began after the	end of the PK Phase	through the End of		
Study. For patients participating in the Ext	ension Phase, includes TEAEs th	lat began after the	end of the PK Phase	until the date of		
IIrst dose in the Extension Phase.	a at any time during the DK Dhas					
[4] INCLUGES COVID-19 RELATED TEAES OCCURRING	y at any time during the PK Phas	se.				

[Programming Notes]

For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported.

Select only COVID-19 related TEAEs.

TESARO Inc.	Confidential						
Protocol No: XXXXX							
Cummorry of Th	ootmont Emorgont A	duorgo Eucoto bu	COC and DT (Cafaty	Dopulation in th	o Storo 1 DV Dhoor		
Summary of it	eatment Emergent A	dverse Events by .	SOC and PI (Salety	Populación in ch	e stage i rk rhase	=)	
		Sequence			Sequence		
		TABLET/CAPSULE			CAPSULE/TABLET		
		(N=xx)			(N=xx)		
	TABLET	CAPSULE	FU/Ext	CAPSULE	TABLET	FU/Ext	
System Organ Class	Period 1	Period 2	Screening	Period 1	Period 2	Screening	
Preferred Term	(N=xx)	(N=xx)	(N=XX)	(N=xx)	(N=xx)	(N=XX)	
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	XX (XX.X)	
0001	( )				( )		
SOCI	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	
PT 1	XX (XX.X)	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)	XX (XX.X)	
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
SOC2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
PT 1	xx (xx.x)	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	XX (XX.X)	
PT 2	XX (XX.X)	xx (xx.x)	XX (XX.X)	XX (XX.X)	xx (xx.x)	XX (XX.X)	
Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY							

[Programming Notes]

For tables of adverse events by SOC and PT by sequence and period, sort alphabetically by SOCs and PTs.

Table 14.3.1.2.2B Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Population in the Stage 2 PK Phase)

'ESARO Inc. Confidential							
Protocol No: XXXXX	XXXX						
		Table 14	.3.1.2.2D				
Summary of Treatmen	t Emergent Adver	se Events by SOC	and PT (Safety	Population in the	Stage 3 PK Phase	.)	
_	-	_	_	-	-		
		Sequence			Sequence		
	NIRAPA	RIB TABLET FAST	ED/FED	NIRAP	ARIB TABLET FED/F	ASTED	
		(N=xx)			(N=xx)		
	NIRAPARIB	NIRAPARIB		NIRAPARIB	NIRAPARIB		
	TABLET FASTED	TABLET FED	FU/Ext	TABLET FASTED	TABLET FED	FU/Ext	
System Organ Class	Period 1	Period 2	Screening	Period 1	Period 2	Screening	
Preferred Term	(N=xx)	(N=xx)	(N=xx)	(N=xx)	(N=xx)	(N=xx)	
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
SOC1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
SOC2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
PT 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XX. Output: xxxx	xxxxxxxx.rtf.	Generated on DDM	MMYYYY:HH:MM:SS			
Data Extract Date: DDMMMYYYY, Da	ta Cutoff Date:	DDMMMYYYY					

[Programming Notes]

For tables of adverse events by SOC and PT by sequence and period, sort alphabetically by SOCs and PTs.

Using Mock Shell (Table 14.3.1.2.1A, Table 14.3.1.2.1B, Table 14.3.1.2.1C, Table 14.3.1.2.1D) Repeat for: Table 14.3.1.3A Summary of Related TEAE by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.3B Summary of Related TEAE by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.3C Summary of Related TEAE by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.3D Summary of Related TEAE by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.4A Summary of Serious TEAE by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.4B Summary of Serious TEAE by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.4C Summary of Serious TEAE by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.4D Summary of Serious TEAE by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.5A Summary of Related Serious TEAE by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.5B Summary of Related Serious TEAE by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.5C Summary of Related Serious TEAE by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.5D Summary of Related Serious TEAE by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.6A Summary of TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.6B Summary of TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.6C Summary of TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.6D Summary of TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.7A Summary of Related TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.7B Summary of Related TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.7C Summary of Related TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.7D Summary of Related TEAE with CTCAE Toxicity Grade ≥3 by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.8A Summary of TEAE Leading to Treatment Discontinuation by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.8B Summary of TEAE Leading to Treatment Discontinuation by SOC and PT (Safety Population in the Stage 2 PK Phase)

### Confidential

### Niraparib

## Statistical Analysis Plan

Table 14.3.1.8C Summary of TEAE Leading to Treatment Discontinuation by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.8D Summary of TEAE Leading to Treatment Discontinuation by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.9C Summary of TEAE Leading to Treatment Dose Interruption by SOC and PT (Safety Population in the Extension Phase) Table 14.3.1.10A Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.10B Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.10B Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.10D Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.10D Summary of TEAE Leading to Treatment Dose Reduction by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.11B Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.11B Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.11C Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.11D Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.11D Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 1 PK Phase) Table 14.3.1.12A Summary of TEAE Leading to Death by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.12B Summary of Treatment Emergent AESI by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.12C Summary of Treatment Emergent AESI by SOC and PT (Safety Population in the Stage 2 PK Phase) Table 14.3.1.12C Summary of Treatment Emergent AESI by SOC and PT (Safety Population in the Stage 3 PK Phase) Table 14.3.1.12D Summary of Treatme

TESARO Inc.	Confidential			Page 1 of x		
Protocol No: XXXX	internet No. YYYY					
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Owner of The share the second address the second		delte geste (Osfate	Developing in the C			
Summary of Treatment Emergent Adverse Events by SOC	and PT and CTCAE TO	Ricity Grade (Salety	Population in the S	tage I PK Phase)		
			FU/Ext			
System Organ Class	TABLET [1]	CAPSULE [2]	Screening [3]	Total [4]		
Preferred Term	(N=xx)	(N=xx)	(N=xx)	(N=XX)		
Any TEAE	XX (XX.X)	XX (XX.X)	xx (xx.x)			
Grade 1						
Grade 5						
SOC1	vv (vv v)	vv (vv v)	vv (vv v)			
Grade 1	AA (AA•A)	AA (AA•A)	AA (AA•A)			
Grade 1						
Grade 5						
Dm 1						
P'I' I	XX (XX.X)	XX (XX.X)	XX (XX.X)			
Grade 1						
Grade 5						
[1] Includes TEAEs with onset date in Period 1 or Perio	od 2 where patient r	eceived niraparib ta	blet.			
[2] Includes TEAEs with onset date in Period 1 or Perio	od 2 where patient re	eceived niraparib ca	psules.			
[3] For patients not participating in the Extension Pha	se, includes TEAEs t	that began after the	end of the PK Phase	through the End of		
Study. For patients participating in the Extension Pha	se, includes TEAEs t	hat began after the	end of the PK Phase	e until the date of		
first dose in the Extension Phase.						
[4] Includes TEAEs occurring at any time during the PK	Phase.					
Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxxxx.rtf. Generated	d on DDMMMYYYY:HH:MM	:SS			
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMM	IMYYYY					
Popost for:						
Table 14 3 1 13P Cummary of Treatment Emergent Adverge E	wonte by SOC and DT	and Maximum Toxicit	v (Safaty Dopulation	in the Stage 2 DK		
Table 14.5.1.156 Summary of Treatment Emergent Adverse E	wents by soc and Pi	and Maximum Ioxicit	y (Salety Population	III the stage 2 PK		
Phase)						
Table 14.3.1.13C Summary of Treatment Emergent Adverse E	Events by SOC and PT	and Maximum Toxicit	y (Safety Population	in the Extension		
Phase)						

• Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

[Programming Notes]

For all tables of adverse events by SOC and PT, sort SOCs by descending overall frequency of events reported. Within each SOC, sort PTs by descending overall frequency of events reported. Within each PT, sort by presented maximum toxicity grade.

TESARO Inc.	Confidential			Page 1 of x
Protocol No: XXXX				
	Table 14.3.1.13D			
Summary of Treatment Emergent Adverse Events by SOC	and PT and CTCAE To>	kicity Grade (Safety	Population in the S	tage 3 PK Phase)
	NIRAPARIB	NIRAPARIB	FU/Ext	
System Organ Class	TABLET FASTED [1]	TABLET FED [2]	Screening [3]	Total [4]
Preferred Term	(N=XX)	(N=xx)	(N=xx)	(N=XX)
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Grade 5	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
SOC1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Grade 5	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
PT 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Grade 5	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)

[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.

[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.

[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.

[4] Includes TEAEs occurring at any time during the PK Phase.

TESARO Inc.	Confidential Page 1							
PIOLOCOI NO: XXXXX	); AAAAA							
Commence of Breachmark Ener	Table IT	DT (Cafato Depulation	in the Change 1 DK Dhas					
Summary of freatment Emer	rgent Adverse Events by	PT (Salety Population	in the Stage I PK Phas	se)				
	TABLET [1]	CAPSULE [2]	FU/Ext Screening [3]	Total [4]				
Preferred Term	(N=xx)	(N=XX)	(N=XX)	(N=XX)				
Any TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)				
PT 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)				
PT 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)				
PT 3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)				
[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet. [2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib capsules. [3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase. [4] Includes TEAEs occurring at any time during the PK Phase. Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX								

Repeat for:

Table 14.3.1.14B Summary of Treatment Emergent Adverse Events by PT (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.14C Summary of Treatment Emergent Adverse Events by PT (Safety Population in the Extension Phase)

• Summarize Extension Phase Data with columns for Tablet; Capsule; Overall

[Programming Notes]

Sort PTs by descending overall frequency of events reported.

TESARO Inc.	Confidential						
Protocol No: XXXXX	Table 14 3 1 14D						
	Summary of Treatment Emergent Adverse	e Events by PT (Safe	ety Population in th	e Stage 3 PK Phase)			
		± .					
		NIRAPARIB	NIRAPARIB	FU/Ext			
Preferred Term		TABLET FASTED [1]	TABLET FED [2]	Screening [3]	Total [4]		
		(N=XX)	(N=xx)	(N=xx)	(N=xx)		
Any TEAE		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
PT 1		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
PT 2		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
PT 3							
<ul> <li>[1] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fasted state.</li> <li>[2] Includes TEAEs with onset date in Period 1 or Period 2 where patient received niraparib tablet in fed state.</li> <li>[3] For patients not participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase through the End of Study. For patients participating in the Extension Phase, includes TEAEs that began after the end of the PK Phase until the date of first dose in the Extension Phase.</li> <li>[4] Includes TEAEs occurring at any time during the PK Phase.</li> </ul>							
Source: Program: Data Extract Date:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxxx.rtf. Generated MYYYY	on DDMMMYYYY:HH:MM	:SS			

TESARO	Inc.				Confid	ential					Page 1 of x
Protoco	ol No: XXXXX				7. 14	0 1 1 5					
		Tisting of Conieus TRAT	Te Duuin	Tab Tab	le 14.	3.1.15A	.1	a the Cterre 1	DV Dhees	\ \	
		Listing of Serious TEAR	s Durin	IG PK PI	lase (s	атегу гор	ulation i	n the Stage I	PK Phase	)	
Treatmer	nt Sequence: <st< td=""><td>age 1 &amp; 2: TABLET/CAPSULE</td><td>or CAP</td><td>SULE/TA</td><td>BLET&gt; (</td><td>or <stage< td=""><td>3: FASTEI</td><td>)/FED or FED/F</td><td>ASTED&gt; 0</td><td>r <extension:< td=""><td>NIRAPARIB</td></extension:<></td></stage<></td></st<>	age 1 & 2: TABLET/CAPSULE	or CAP	SULE/TA	BLET> (	or <stage< td=""><td>3: FASTEI</td><td>)/FED or FED/F</td><td>ASTED&gt; 0</td><td>r <extension:< td=""><td>NIRAPARIB</td></extension:<></td></stage<>	3: FASTEI	)/FED or FED/F	ASTED> 0	r <extension:< td=""><td>NIRAPARIB</td></extension:<>	NIRAPARIB
TABLET (	or NIRAPARIB CAF	SULE>, as applicable				5					
	[	1	~		1		1			1	<u> </u>
			Start	Stop							
			Date minu (	Date							
			Time/	Time		a /			0.1		
Detient	Dosing Period/	Adverse Event	(Rel	(Rel		SAE/		Action Taken	Other		
Number	Mirapario	[P]MedDRA Preferred Term	Day [1])	Day [1])	כתגתח	reason	Couronitu	On Study	ACLION	Relationship	Outcome
Nullber		[S]System Organ Class	[⊥])	[1])	ILAL:	[2]	Severity	Treatment[5]	Takell	[3]	
	Period 1/		уууу-	уууу-	Y	N	Grade 1	T: NA		T: NA	Recovered/
	Capsule		mm-aa	mm-aa				C: Dose Not		C: Related	Resolved
			nn:mm	[X]				Changed			
			[X]								
	Period 2/	XXXXXXXXXXXXXXXXXXX	уууу-	уууу-	Y	N	Grade 1	T: Dose Not		T: Related	Recovered/
	Tablet		mm-dd	mm-dd				Changed		C: NA	Resolved
			hh:mm	[x]				C: NA			
			[X]								
	PK Safety FU										
[1] Rela [2] Rea 4 = Rec [3] T=Ta	ative to the dat son for SAE: 1 Juires or prolon ablet; C=Capsule	e of first dose in PK Pha = Result in death; 2 gs hospitalization; 5 = C	se. = Life ongenit	threat al abno	ening; rmality	3 = Rest //birth de	ult in pe efect; 6 =	ersistent or • Other medica	signific lly impo:	ant disability rtant event.	/incapacity;
Source: Data Ext	Program: XXXXX ract Date: DDM	XXXXXXXXXXXXXXX Output: x MMYYYY, Data Cutoff Date	: DDMM	xxxx.rt MYYYY	f. Ger	nerated or	DDMMMYYY	YY:HH:MM:SS			
[Program Please a	ming notes] dd time to Star	t Date column for PK Phas	e Stage	2 and 3	Extensi	ion Phase.					
Repeat f	or: 3 1 15B Listin	a of Serious TRARS During	the PK	Phase	(Safets	7 Populati	on in the	Stage 2 DK D	hase)		
Table 14		S OF SELLOUS TEAES DUILING	CHG LV	THASE	(Saret)	ιοραται	.on in che	. Juaye 2 FA P	11230)		
Table 14	.3.1.15C Listin	g of Serious TEAEs During	the Ex	tension	Phase	(Safety E	opulation	in the Exten	sion Phas	se)	

Table 14.3.1.15D Listing of Serious TEAEs During the PK Phase (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.16A Listing of Deaths During the PK Phase (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.16B Listing of Deaths During the PK Phase (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.16C Listing of Deaths During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.16D Listing of Deaths During the PK Phase (Safety Population in the Stage 3 PK Phase)

• Footnote: `NOTE: Deaths due to progressive disease were not collected as adverse events.'

Table 14.3.1.17C Listing of TEAE Leading to Dose Interruption During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.17D Listing of TEAE Leading to Dose Interruption During the PK Phase (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.18A Listing of TEAE Leading to Dose Reduction During the PK Phase (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.18B Listing of TEAE Leading to Dose Reduction During the PK Phase (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.18C Listing of TEAE Leading to Dose Reduction During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.18D Listing of TEAE Leading to Dose Reduction During the PK Phase (Safety Population in the Stage 3 PK Phase)

Table 14.3.1.19A Listing of TEAE Leading to Treatment Discontinuation During the PK Phase (Safety Population in the Stage 1 PK Phase)

Table 14.3.1.19B Listing of TEAE Leading to Treatment Discontinuation During the PK Phase (Safety Population in the Stage 2 PK Phase)

Table 14.3.1.19C Listing of TEAE Leading to Treatment Discontinuation During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.1.19D Listing of TEAE Leading to Treatment Discontinuation During the PK Phase (Safety Population in the Stage 3 PK Phase)

[Programming Notes]

- Stage 3: Treatment Sequence will be NIRAPARIB TABLET FASTED/FED and NIRAPARIB TABLET FED/FASTED.
- Stage 3: Column 2: Dosing Period/Treatment Treatment should be NIRAPARIB FASTED or NIRAPARIB FED.
- Stage 3: Treatment discontinuation during PK phase add column to record if discontinuation was due to COVID-19 ["COVID-19 Reason" with Options "COVID-19 infection" or "Issues rel. to COVID-19 pandemic"].
- Extension Phase: Replace column for Dosing Period/Treatment with Treatment and Starting Dose.
- Extension Phase: Do not need time with start/stop dates.
- Extension Phase: Footnote: [1] Relative to first dose during the Extension Phase.
- Extension Phase: Add column for Dose at Onset of AE.

TESARO Inc.	Confidential Page 1							
btocol No: XXXXX								
Table 14.3.1.20D								
Summary of Incidence of C	OVID-19 Related Adverse Events Ov	ver Time (Safety Population in the	Stage 3 PK Phase)					
		NIRAPARIB	NIRAPARIB					
		TABLET FASTED	TABLET FED					
	Period during COVID-19	(N=xx)	(N=xx)					
	Pandemic [1]	n/Patients at Risk (%)	n/Patients at Risk (%)					
Any COVID-19 Related AE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)					
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)					
Any COVID-19 Related SAE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)					
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)					
Any COVID-19 Related Grade ≥3 AE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)					
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)					
1								
[1] TABLET PK Phase Stage 3 opened to	> recruitment on DDMMMYYYY, with	first patient consented on DDMMMY	YYY, placing the start of the					
recruitment during the COVID-19 pande	mic.							

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Table 14.3.1.21D							
Summary of Incidence of COV	/ID-19 Related Adverse Events O	ver Time by Gender (Safety Populatio	n in the Stage 3 PK Phase)				
Report on separate page for each:	<gender: female="" male,=""></gender:>						
	Period during COVID-19	NIRAPARIB TABLET FASTED (N=xx)	NIRAPARIB TABLET FED (N=xx)				
	Pandemic [1]	n/Patients at Risk (%)	n/Patients at Risk (%)				
Any COVID-19 Related AE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)				
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)				
Any COVID-19 Related SAE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)				
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)				
Any COVID-19 Related Grade ≥3 AE	Period 1	xx/xxx (xx.x%)	xx/xxx (xx.x%)				
	Period 2	xx/xxx (xx.x%)	xx/xxx (xx.x%)				
[1] TABLET PK Phase Stage 3 opene recruitment during the COVID-19 pa	d to recruitment on DDMMMYYYY, andemic.	with first patient consented on DDM	MMYYYY, placing the start of the				

#### Repeat for:

Table 14.3.1.22D Summary of Incidence of Adverse Events Over Time by Age Group (Safety Population in the Stage 3 PK Phase)

• Use the FDAAA age groups <=18, 18-64, >=65

TESARO Inc. Confide	O Inc. Confidential					
Protocol No: XXXXX						
Table 14.3.4.1A						
Summary of Study Treatment Exposure During the PK P	hase (Safety Popu	lation in the Stag	ge I PK Phase)			
			1	-		
	Statistic	Sequence	Sequence			
		TABLET/CAPSULE	CAPSULE/TABLET	OVERALL		
		(N=XX)	(N=XX)	(N=XX)		
# of 100 mg Capsules Received						
3	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
# of 300 mg Tablets Received						
1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)		
Source: Program: XXXXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS						
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY						

Repeat for:

Table 14.3.4.1B Summary of Study Treatment Exposure During the PK Phase (Safety Population in the Stage 2 PK Phase)

TESARO Inc.	Confidential				
rotocol No: XXXXX					
Table 14.3.4.1C					
Summary of Study Treatment Exposure Durin	ng the Extension Pl	hase (Safety Populati	on in the Extension 3	Phase)	
		Niraparib	Niraparib	Niraparib	
		TABLET	CAPSULE	OVERALL	
Parameters	Statistic	(N=xx)	(N=xx)	(N=xx)	
Number of Cycles					
1	n (응)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
≥ 6	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Duration of Treatment (months)	n	XX	XX	XX	
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	
	Median	XX.X	XX.X	XX.X	
	Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
	Min, Max	XX, XX	XX, XX	XX, XX	
Duration on Study (months)	n	XX	XX	XX	
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	
	Median	XX.X	XX.X	XX.X	
	Q1, Q3	xx.x, xx.x	XX.X, XX.X	XX.X, XX.X	
	Min, Max	XX, XX	XX, XX	XX, XX	
Total Number of Patients with dose interruption	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Total Number of Patients with dose reduction	n (응)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Total Number of Patients with dose re-escalation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Source: Listing XXXXXXXX, Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY					

TESARO Inc.	RO Inc. Confidential				Page 1 of x	
Protocol No: XXXXX Table 14.3.4.1D						
Summary of Study Treatment Exposure During the PK Phase (Safety Population in the Stage 3 PK Phase)						
		Statistic	NIRAPARIB FASTED (N=XX)	NIRAPARIB FED (N=XX)	OVERALL (N=xx)	
# of 300 mg Tab	lets Received					
1		n (%)	xx (xx.x)	xx (xx.x)	XX (XX.X)	
Source: Program: XXXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY						

TESARO Inc.			Confidential		Page 1 of x			
Protocol No: XXXXX								
Table 14.3.4.2C								
Summ	ary of Nirapari	b Dose by Cyc	le (Safety Population in	the Extension Phase)				
	Starting		Niraparib	Niraparib	Niraparib			
	Niraparib		TABLET	CAPSULE	OVERALL			
Cycle	Dose (mg)	Statistic						
1		Ν	XXX	XXX	XXX			
	300	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
	200	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
	100	n (%)	xx (xx.x)	XX (XX.X)	xx (xx.x)			
2		Ν	XXX	XXX	XXX			
	300	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
	200	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
	100	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
3		N	XXX	XXX	XXX			
	300	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
	200	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
	100	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)			
		•	·					
Source: Program: XXXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS								
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY								
TESARO Inc	•			Confid	dential			Page 1 of x
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Protocol N	o: XXXXX							
				Table 14.	3.4.3.1C			
	Summ	ary and Change	e from Baseline o:	f Select Hematolo	ogy Parameters by	Visit During the	Extension Phase	
			(Safe	ty Population in	the Extension Ph	ase)		
			NIRAPARIB TABLE	ſ (N=xx)	NIRAPARIB CAPSU	LE (N=xx)	NIRAPARIB OVERA	LL (N=xx)
Parameter	Visit	Statistic	Actual	Change	Actual	Change	Actual	Change
Parameter	Baseline	n (missing)	xx (xx)		XX (XX)		XX (XX)	
1		Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
		Median	XX.X		XX.X		XX.X	
		Q1, Q3	XX.X, XX.X		XX.X, XX.X		xx.x, xx.x	
		Min, Max	XX, XX		XX, XX		XX, XX	
	Cycle 1	n (missing)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
	- Day 8	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	XX.X (XX.XX)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
		Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	xx.x, xx.x
		Min, Max	xx, xx	xx, xx	XX, XX	xx, xx	XX, XX	xx, xx
	Cycle 1	n (missing)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
	- Day 15	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	XX.X (XX.XX)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
		Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	xx.x, xx.x
		Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	xx, xx
	Cycle 1	n (missing)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
	- Day 22	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	XX.X (XX.XX)	XX.X (XX.XX)	xx.x (xx.xx)
		Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
		Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	xx.x, xx.x	xx.x, xx.x
		Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
	Cycle 2	n (missing)	XX (XX)	xx (xx)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
	- Day 1	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
		Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
		Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
	······ •	n (missing)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
		Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
		Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
	EOT	n (missing)	XX (XX)	xx (xx)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	XX.X (XX.XX)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
		Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
		Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Source: Li	sting XXXX	XXXXX, Program	: XXXXXXXXXXXXXXXX	XXXXX. Output: x	xxxxxxxxxx.rtf.	Generated on DDM	MMMYYYY:HH:MM:SS	
Data Extra	ct Date:	DDMMMYYYY, Da	ta Cutoff Date:	DDMMMYYYY				

TESARO Inc.				Confid	ential				Page 1 of x
Protocol No: XXX	XX			m-1-1-14 0	4 2 29				
			Description	Table 14.3	.4.3.20	(G - C - L - D			
Shift S	ummary of Se.	lect Hematolog	y Parameters	During the Ex	tension Phase	(Safety Pop	ulation in tr	ne Extension E	'hase)
Treatment Crown	1	1	1		Doct Doco	lino Morrimum	CHICAE Crode		
ireachient Group					rust-base.	LINE Maximum	CICAE GIAGE		
Niraparib	Laboratory	Baseline	Statistic	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Missing
Tablet	Test	CTCAE Grade							
	XXXXX	Grade 0	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 1	n (%)	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 2	n (%)	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 3	n (%)	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Grade 4	n (%)	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Missing	n (%)	xx (xx.x)	XX (XX.X)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	XXXXX								

Source: Listing XXXXXXXX, Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Include Tablet, Capsule and Overall

Repeat for:

Table 14.3.4.4.1C Summary and Change from Baseline of Select Chemistry Parameters by Visit During the Extension Phase (Safety Population in the Extension Phase)

Table 14.3.4.4.2C Shift Summary of Select Chemistry Parameters in Maximum Toxicity Grade During the Extension Phase (Safety Population in the Extension Phase)

TESARO Inc.	Confidential		Page 1 of x
Protocol No:	XXXXX		_
	Table 14.3.4.4.1D		
	Summary of COVID-19 Assessments for Patients with Suspected, Prob	able or Confirmed COVID-19 (	Case Diagnosis
	(Safety Population in the Stage 3	PK Phase)	
		NIRAPARIB TABLET	NIRAPARIB TABLET
		FASTED	FED
Assessment		(N=XX)	(N=XX)
COVID-19 Cas	e Diagnosis [1]	xx (xx.x%)	xx (xx.x%)
Confirmed		xx (xx.x%)	xx (xx.x%)
Probable		xx (xx.x%)	xx (xx.x%)
Suspected		xx (xx.x%)	xx (xx.x%)
COVID-19 Tes	Performed [2]		
n		XX	XX
No		xx/xx (xx.x%)	xx/xx (xx.x%)
Yes		xx/xx (xx.x%)	xx/xx (xx.x%)
Result from	the COVID-19 Test		
n		XX	XX
Negative		xx/xx (xx.x%)	xx/xx (xx.x%)
Positive		xx/xx (xx.x%)	xx/xx (xx.x%)
Indetermin	ate	xx/xx (xx.x%)	xx/xx (xx.x%)
[1] COVID-19	Case Diagnosis is based on WHO Definition as of DDMMMYYYY.		
[2] COVID-19	Test Performed is only captured for patients with a COVID-19 Case	Diagnosis.	
Source: Prog	ram: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY:HH:MM:SS	
Data Extract	Date: DDMMMIIII, Data CutoII Date: DDMMMIIII		

TESARO Inc. Confide	ntial		Page 1 of x
Protocol No: XXXXX	4 10		
Summary of Important Protocol Deviations (Sa	fety Population in the Exte	preion Phase)	
	fiety reputation in the like	.1151011 111450)	
	NIRAPARIB	NIRAPARIB	
	TABLET	CAPSULE	TOTAL
Category/Coded Term	(N=XX)	(N=XX)	(N=XX)
Any important protocol deviations	xxx (xx%)	xxx (xx%)	xxx (xx%)
CATEGORY 1	xxx (xx%)	xxx (xx%)	xxx (xx%)
SUBCATEGORY 1	xx (xx%)	xx (xx%)	xx (xx%)
SUBCATEGORY 2	xx (xx%)	xx (xx%)	xx (xx%)
CATEGORY 2	xxx (xx%)	xxx (xx%)	xxx (xx%)
SUBCATEGORY 1	xx (xx%)	xx (xx%)	xx (xx%)
SUBCATEGORY 2	xx (xx%)	xx (xx%)	xx (xx%)
Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	nerated on DDMMMYYYY:HH:MM:S	SS	
Data Extract Date: DDMMMIIII, Data Cutori Date: DDMMMIIII			

[Programming Notes]:

- Include only IMPORTANT protocol deviations.
- <Category 1...> represents ADDV.DVCAT. <Subcategory 1...> represents ADDV.DVDECOD.
- Sort Categories in descending order according to overall counts, if ties are present, present alphabetically.

TESARO Inc.	Confid	ential		Page 1 of x
Protocol No: XXXXX				
	Table 14	.4.1D		
	Summary of Important Protocol Deviations for the	e PK Phase Occurring Through	End of Treatment	
	(Safety Population in t	he Stage 3 PK Phase)		
			שקומגם מדמגמגמו	
		NIRAPARIB TABLET	NIRAPARIB TABLET	TOTAT [3]
Category/Coded Term		(N=XX)	(N=XX)	(N=XX)
		(******	()	(
Any important proto	col deviations	xxx (xx%)	xxx (xx%)	xxx (xx%)
CATEGORY 1		xxx (xx%)	xxx (xx%)	xxx (xx%)
SUBCATEGORY 1		xx (xx%)	xx (xx%)	xx (xx%)
SUBCATEGORY 2		xx (xx%)	xx (xx%)	xx (xx%)
CATEGORY 2		xxx (xx%)	xxx (xx%)	xxx (xx%)
SUBCATEGORY 1		xx (xx%)	xx (xx%)	xx (xx%)
SUBCATEGORY 2		xx (xx%)	xx (xx%)	xx (xx%)
<ul><li>[1] Includes protoc</li><li>[2] Includes protoc</li></ul>	ol deviations with onset date in Period 1 or Peri ol deviations with onset date in Period 1 or Peri	od 2 where patient received od 2 where patient received	niraparib tablet in niraparib tablet in	fasted state. fed state.
[3] Includes protoc	ol deviations occurring at any time during the PF	C Phase.		

[Programming Notes]:

- Include only IMPORTANT protocol deviations.
- <Category 1...> represents ADDV.DVCAT. <Subcategory 1...> represents ADDV.DVDECOD.
- Sort Categories in descending order according to overall counts, if ties are present, present alphabetically.

## LISTINGS

General guidelines:

Listings are separated for the PK Phase (Stage 1, Stage 2 and Stage 3 separately) and the Open)-Label Extension Phase.

For the PK Phase:

- Treatment=Sequence (for Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET; for Stage 3: NIRAPARIB TABLET FASTED/FED or NIRAPARIB TABLET FED/FASTED).
- Population=Safety Population in the PK Phase (i.e., those who receive at least 1 dose), unless otherwise specified.
- Include all data assessments relative to the PK Phase.
  - For patients who do not continue to the Extension Phase, include all EOT/Safety FU data. Also include Extension Phase Screening for those patients who DO not proceed to the Extension Phase.
- Relative day: With respect to first date of dosing in PK period.

For the Extension Phase:

- Treatment=Niraparib Tablet; Niraparib Capsule.
- Population=Safety Population in the Open-Label Extension Phase (i.e., those who receive at least 1 dose), unless otherwise specified.
- Include all assessments relative to the Extension Phase.
  - Any assessment specific to Extension Phase, including Screening Data.
- Relative day: With respect to first date of dosing in Extension Phase.

TESARO Inc. Protocol No: XXXXX Confidential

Page 1 of x

Listing 16.2.1A

Disposition for PK Phase (All Patients Enrolled in the Stage 1 PK Phase)

Treatment: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient	Date of Last	Date of	Reason for	Date of	Reason for	Date of	Date of	Protocol
Number	Niraparib Dose	Discontinuation	Discontinuation	Discontinuation	Discontinuation	Death	Progression	Version
	During PK Phase	From PK Phase	from PK Phase	from Study (Rel	from Study	(Rel	(Rel Day)	
	(Rel Day)	(Rel Day)		Day)		Day)		
			Other: specify					
			Completion					

Relative Day calculated relative to first dose in PK Phase.

Only study discontinuations, disease progressions and deaths that occur during PK phase (i.e., before 1st dose of extension or prior to discontinuing the study for patients not entering the Extension Phase) are listed.

[Programming Notes - PK Phase]

• Include only data that falls before first-dose Open-Label Extension Phase, i.e., for those patients who DC study and do not continue in the Open-Label Extension Phase.

Repeat for:

Listing 16.2.1B Disposition for PK Phase (Safety Population in the Stage 2 PK Phase)

Listing 16.2.1C Disposition for Open-Label Extension Phase (All Patients Enrolled for the Extension Phase)

Listing 16.2.1D Disposition for PK Phase (Safety Population in the Stage 3 PK Phase)

[Programming Notes - Extension Phase]

- Change 'PK Phase' to 'Open-Label Extension' Phase in respective columns.
- Treatment: Niraparib Tablet or Niraparib Capsule.
- Footnote: Relative Day calculated relative to first dose in Extension Phase.

TESARO Inc.		Confidential	Page 1 of x
Protocol No: XXXXX			
	Reasons for Screen F	allure (Patients who falled Screening in the Stage 1 PK Phase)	
Treatment Sequence: <	SCREEN FAILURE>		
Patient			
Number	Protocol Version	Inclusion/Exclusion Criteria Not Met	
*****	Version 1.0 (original)	INPXX: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	
XXXXXX-XXXX	Version 1.0 (original)	EXPXX: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	
Source: Program: XXXX	XXXXXXXXXXXXXXX Output:	xxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS	
Data Extract Date: DI	OMMMYYYY, Data Cutoff Dat	ce: DDMMMYYYY	

Listing 16.2.1.2B Reasons for Screen Failure (Patients who Failed Screening in the Stage 2 PK Phase)

Listing 16.2.1.2D Reasons for Screen Failure (Patients who Failed Screening in the Stage 3 PK Phase)

TESARO Inc.	TESARO Inc. Confidential								
Protocol No: XXXXX									
	Listing 16.2.2A Protocol Deviations for the PK Phase (Safety Population in the Stage 1 PK Phase)								
Treatment: <	Treatment: < Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET>								
Patient Number	Visit	Protocol Deviation Category	Protocol Deviation Severity	Description of Protocol Deviation					
-									
Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS									

[Programming Notes]

• Include only data that falls before first-dose Open-Label Extension Phase (i.e., for those patients who DC study and do not continue in the Open-Label Extension Phase)

Repeat for:

Listing 16.2.2B Protocol Deviation for the PK Phase (Safety Population in the Stage 2 PK Phase)

TESARO Inc. Confidential Page 1 of x Protocol No: XXXXX Listing 16.2.2C Important Protocol Deviations for the Open-Label Extension Phase (Safety Population for Open-Label Extension Phase) Treatment: <Extension (Stages 1 & 2): NIRAPARIB TABLET or NIRAPARIB CAPSULE; Extension (Stage 3): NIRAPARIB TABLET> Patient Protocol Deviation Protocol Deviation Description of TESARO GSK Number Visit Protocol Deviation Classification [1] Classification [2] Category Severity <<SIGNIFICANT/ <<IMPORTANT/NON-IMPORTANT>> IMPORTANT>> [1] For Stages 1 & 2, protocol deviation classification is done based on TESARO Protocol Deviation Management System only. GSK Classification will remain blank. [2] For Stage 3, protocol deviation classification is done based on GSK Protocol Deviation Management System only. TESARO Classification will remain blank. Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming notes]

For Stage 3 Extension Phase, patients will receive NIRAPARIB TABLET formulation only.

For Stages 1 and 2 reporting, only TESARO Classifications will be populated, for Stage 3 - only GSK Classification will be populated.

Only include protocol deviation classed as Important.

TESARO Inc.	TESARO Inc. Confidential P							
Protocol No:	Protocol No: XXXXX							
Listing 16.2.2.1D Important Protocol Deviations for the PK Phase Occurring Through End of Treatment (Safety Population for Stage 3 PK Phase)								
Treatment: <	Freatment: <niraparib fasted="" fed="" niraparib="" or=""></niraparib>							
Patient Number	Visit	Protocol Deviation Category	Protocol Deviation Severity	Description of Protocol Deviation				
Source: Prog Data Extract	Source: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY							

[Programming notes]:

• Only include protocol deviation classed as Important.

TESARO Inc. Confidential									
Protocol N	Io: XXXXX								
Listing 16.2.2.2D GSK Protocol Deviations related to COVID-19 (Safety Population for Stage 3 PK Phase)									
Treatment:	Treatment: <niraparib fasted="" fed="" niraparib="" or=""></niraparib>								
Patient Number	Deviation Category	Description of Deviation	GSK Classification <important not-important=""></important>	Date					
Note: * Patients with probable, suspected or confirmed COVID-19. Note: This listing only includes COVID-19 related protocol deviations. Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX									

TESARO Inc.	Inc. Confidential Pa								
Protocol No:	XXXXX								
		Listing 16.2.3A							
	Study Populations for the PK Phase (All Patients Enrolled in the Stage 1 PK Phase)								
Treatment: <t< td=""><td colspan="8"><pre>Ireatment: <tablet capsule="" failure="" or="" screen="" tablet=""></tablet></pre></td></t<>	<pre>Ireatment: <tablet capsule="" failure="" or="" screen="" tablet=""></tablet></pre>								
Patient Number	PK Phase Safety (SAF) Population	Informed Consent Date	Randomization Date						
	Y								
Source: Progr Data Extract	ource: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY								

Listing 16.2.3B Study Populations for the PK Phase (All Patients Screened in the Stage 2 PK Phase)

• For Stage 2 PK, add column for BE Evaluable Population (Y/N).

TESARO Inc.			Confidential				Page 1 of	Х
S.	tudy Populations for th	e Open-Label Exten	Listing 16.2.3C sion Phase (All Patient	s Enrolled in the Ex	tension Pha	se)		
Treatment: <nirapa< td=""><td>RIB TABLET or NIRAPARIE</td><td>CAPSULE&gt;</td><td></td><td></td><td></td><td></td><td></td><td></td></nirapa<>	RIB TABLET or NIRAPARIE	CAPSULE>						
Patient Number	Extension Phase Safety (SAF) Population Y							
Source: Program: Data Extract Date:	XXXXXXXXXXXXXXXXXXXXXX Ou DDMMMYYYY, Data Cutc	tput: xxxxxxxxxxxxx ff Date: DDMMMYYY	.rtf. Generated on DDN Y	MMMYYYY:HH:MM:SS	1		II	

TESARO Inc.		Confidential		Page 1 of x					
Protocol No:	XXXXX								
		Listing 16.2.3	D						
	Study Populations for the PK Phase (All Patients Enrolled in the Stage 3 PK Phase)								
Treatment: <f< td=""><td colspan="9">Treatment: <fasted failure="" fasted="" fed="" or="" screen=""></fasted></td></f<>	Treatment: <fasted failure="" fasted="" fed="" or="" screen=""></fasted>								
Patient Number	PK Phase Safety (SAF) Population	FE Population	Informed Consent Date	Randomization Date					
	Y	Ү							
		N							
Source: Progr Data Extract	ource: Program: XXXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY								

TESARO I	nc.				Confidential				Page 1 of x	
Protocol	No: XXXX	XX								
	Listing 16.2.4.1A									
			1	Demographics	(Safety Population in the Stage 1	PK Phase)				
Study Tr	eatment:	<stage< td=""><td>1 &amp; 2: NOT DOSED</td><td>or TABLET/C</td><td>APSULE or CAPSULE/TABLET&gt; or <stag< td=""><td>ge 3: NOT</td><td>DOSED or F</td><td>ASTED/FED</td><td>or FED/FASTED&gt; or</td></stag<></td></stage<>	1 & 2: NOT DOSED	or TABLET/C	APSULE or CAPSULE/TABLET> or <stag< td=""><td>ge 3: NOT</td><td>DOSED or F</td><td>ASTED/FED</td><td>or FED/FASTED&gt; or</td></stag<>	ge 3: NOT	DOSED or F	ASTED/FED	or FED/FASTED> or	
<extensi< td=""><td>on: NIRA</td><td>PARIB TA</td><td>ABLET or NIRAPARI</td><td>B CAPSULE&gt;,</td><td>as applicable</td><td></td><td></td><td></td><td></td></extensi<>	on: NIRA	PARIB TA	ABLET or NIRAPARI	B CAPSULE>,	as applicable					
Patient	Age	Sex	Child-Bearing	Ethnicity	Race	Height	Weight	BMI	ECOG Performance	
Number	(yrs)		Potential			(cm)	(kg)	(kg/m²)	Status	
					Other: specify					
ECOG = Eastern Cooperative Oncology Group: 0=Fully active, able to carry on all pre-disease performance without restriction 1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature 2=Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours 3=Capable of only limited self-care, confined to bed or chair more than 50% of waking hours 4=Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair Source: Program: YXYXYXYXYXYXYXYXYXYXXXXXXXXXXXXXXXXXX										
Data Ext	ract Date	e: DDMN	MYYYY, Data Cut	off Date: D	DMMMYYYY					

Listing 16.2.4.1B Demographics (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.1C Demographics (Safety Population in the Extension Phase)

Listing 16.2.4.1D Demographics (Safety Population in the Stage 3 PK Phase)

TESARO In	с.		Confidential		Page 1 of x				
Protocol	NO: XXXXX Medical	History (Sa	Listing 16.2.4.2A fety Population in th	e Stage 1 PK Phase)					
PK Phase TABLET or	PK Phase Treatment: <stage &="" 1="" 2:="" capsule="" or="" tablet=""> or <stage 3:="" fasted="" fed="" or=""> or <extension: niraparib<br="">TABLET or NIRAPARIB CAPSULE&gt;, as applicable</extension:></stage></stage>								
Patient Number	System Organ Class Preferred Term Medical Condition or Event	Start Date	Ongoing at Study Start?	Stop Date					
Includes	only patients with major medical co	nditions.							
Note: Med	Note: MedDRA version XX.X.								
Source: P Data Extr	Source: Program: XXXXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY								

Listing 16.2.4.2B Medical History (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.2C Medical History (Safety Population in the Extension Phase)

Listing 16.2.4.2D Medical History (Safety Population in the Stage 3 PK Phase)

## [Programming notes]

• For Stage 3, the latest available MedDRA version is to be used.

TESARO Ir	nc.	al	Page 1 of x						
Listing 16.2.4.3A Prior Anti-Cancer Treatment (Safety Population in the Stage 1 PK Phase)									
Treatment NIRAPARIE	reatment: <stage &="" 1="" 2:="" capsule="" or="" tablet=""> or <stage 3:="" fasted="" fed="" or=""> or <extension: niraparib="" or<br="" tablet="">IRAPARIB CAPSULE&gt;, as applicable</extension:></stage></stage>								
Patient	Regimen	-Verbatim Term							
Number	Number	Preferred Term	Reason for Administration	Best Response					
			Other: specify						
Source: H Data Exti	Program: XX ract Date:	XXXXXXXXXXXXXXXX Output: xxxxxxxxxxxx.rtf. Genera DDMMMYYYY, Data Cutoff Date: DDMMMYYYY	ated on DDMMMYYYY:HH:MM:SS						

Listing 16.2.4.3B Prior Anti-Cancer Treatment (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.3C Prior Anti-Cancer Treatment (Safety Population in the Extension Phase)

Listing 16.2.4.3D Prior Anti-Cancer Treatment (Safety Population in the Stage 3 PK Phase)

TESARO Inc	•	Confidenti	al	Page 1 of x						
Protocol No	o: XXXXX									
		Listing 16.2.	1.4A							
	Primary Cancer Hi	story (Safety Populat	ion in the Stage 1 PK Phase)							
Treatment: <stage &="" 1="" 2:="" capsule="" or="" tablet=""> or <stage 3:="" fasted="" fed="" or=""> or <extension: niraparib="" or<="" tablet="" td=""></extension:></stage></stage>										
NIRAPARIB (	NIRAPARIB CAPSULE>, as applicable									
Patient		Date of First		Number of Prior Lines						
Number	Tumor Type	Diagnosis	Cancer Stage (Most Recent)	of Therapy						
	<other: specify=""></other:>									
Source: Pro Data Extrac	ource: Program: XXXXXXXXXXXXXXXXXXXX Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS ata Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY									

Listing 16.2.4.4B Primary Cancer History (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.4C Primary Cancer History (Safety Population in the Extension Phase)

Listing 16.2.4.4D Primary Cancer History (Safety Population in the Stage 3 PK Phase)

TESARO Inc.		C	onfidential		Page 1 of x			
Protocol No: XXXXX								
		Tieti	ng 16 2 4 5A					
		11301	119 10.2.4.JA					
	Prior/Concomi	tant Radiotherapy (Sa	afety Population in the	e Stage 1 PK Phase)				
Treatment Sequence: <stage &="" 1="" 2:="" capsule="" or="" tablet=""> or <stage 3:="" fasted="" fed="" or=""> or <extension: niraparib<="" td=""></extension:></stage></stage>								
TABLET OF NIRAPARIB C	APSULE>, as applicabl	e	2					
Patient					Prior/			
Number	Site or Region	Date Started	Date Stopped	Total Gravs	Concomitant Flag			
IVUINDEL	bitte of Region	Date Startea	Date Deopped	iocar orays	concomitante i rag			
Note: Includes patien	ts with prior or conc	omitant radiotherapy	with respect to the PM	Phase.				
B-Brier (radietherapy	with start data carl	ior than the first de	and date of study troat	mont				
F-FILOI (ladiotherapy	with Start date ears	ier than the lifst do	se dale of study freat					
C=Concomitant (radiot	herapy occurring on or	after the initial st	udy treatment dosing da	te through either the :	first dose of the Extension			
Phase or through 30 d	ays after the last do	se, for those not cor	tinuing into the Exter	nsion Phase).				
Source: Program: XXX	XXXXXXXXXXXXXXX 011+	nut: xxxxxxxxxxxx rtf	. Generated on DDMMMY	YYY:HH:MM:SS				
Data Entract Data. D	DMMWWWW Doto Cutof	f Data. DDMMMYYYY	· Seneracea on Donan					
Dala ExitaCl Dale: D	DEMENTITI, Data Cutor	L Date: DDMMMIII						

Listing 16.2.4.5B Prior/Concomitant Radiotherapy (Safety Population in the Stage 2 PK Phase)

Listing 16.2.4.5C Prior/Concomitant Radiotherapy (Safety Population in the Extension Phase)

Listing 16.2.4.5D Prior/Concomitant Radiotherapy (Safety Population in the Stage 3 PK Phase)

TESARO Inc.					Confi	dential				Page 1 of x
Protocol No:	Listing 16.2.5.1A									
	Prior and Concomitant Medications (Safety Population in the Stage 1 PK Phase)									
Treatment Se TABLET or NI Patient Numb	reatment Sequence: <stage &="" 1="" 2:="" capsule="" or="" tablet=""> or <stage 3:="" fasted="" fed="" or=""> or <extension: niraparib<br="">ABLET or NIRAPARIB CAPSULE&gt;, as applicable atient Number = xxxxxx-xxxx</extension:></stage></stage>									
ATC/ Preferred Term/ Verbatim Term	Dose per Administration	Dose Unit	Frequenc y	Indica tion	Route of Administr ation	Start/ Stop Date	Ongoing	Prior/ Concomitant Flag	PK Dose 1	PK Dose 2
									YYYY-MM-DD	YYYY-MM-DD
Note: Includ P=Prior medi Source: Prog Data Extract	Note: Includes patients with prior or concomitant medications taken during the PK Phase. Perior medication only; C=Concomitant medication only; B=Both prior and concomitant medications. Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX									

[Programming Notes]

- For the Prior/Concomitant Flag, list all that apply.
- If ATC3 not available, use a footnote [1] ATC level 3 term is not available through WHO Drug Dictionary.

Repeat for:

Listing 16.2.5.1B Prior and Concomitant Medications (Safety Population in the Stage 2 PK Phase)

Listing 16.2.5.1C Prior and Concomitant Medications (Safety Population in the Extension Phase)

Listing 16.2.5.1D Prior and Concomitant Medications (Safety Population in the Stage 3 PK Phase)

TESARO Inc. Confidential Page 1 of x Protocol No: XXXXX Listing 16.2.5.2A Prior/Concomitant Procedures During PK Phase (Safety Population in the Stage 1 PK Phase) Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable Procedure Prior/Concomitant Patient Rel Day Number Date [1] Procedure Results/Findings AE/SAE? Indication Flag XXXXXX-XXXX [1] Relative to first dose during the PK Phase. Note: Includes patients with prior or concomitant procedures during the PK Phase. P=Prior (any procedure earlier than the first dose date of study treatment). C=Concomitant (any procedure on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase). Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

Repeat for

Listing 16.2.5.2B Prior/Concomitant Procedures During the PK Phase (Safety Population in the Stage 2 PK Phase)

Listing 16.2.5.2C Prior/Concomitant Procedures During the Extension Phase (Safety Population in the Extension Phase)

[Programming Notes for Extension Phase]

• Footnote: [1] Relative to first dose during the Extension Phase.

Listing 16.2.5.2D Prior/Concomitant Procedures During the PK Phase (Safety Population in the Stage 3 PK Phase)

TESARO Inc. Confidential Page 1 of x Protocol No: XXXXX Listing 16.2.5.3A Prior and Concomitant Transfusions (Safety Population in the Stage 1 PK Phase) Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable Received Transfusion Patient within 14 days of first Type of Prior/ Number dose or during study? Administration Units Transfusion Date Rel Day [1] Concomitant Flag Other: specify [1] Relative to first dose during the PK Phase. Note: Includes patients with prior or concomitant transfusions during the PK Phase. P=Prior (any transfusion earlier than the first dose date of study treatment). C=Concomitant (any transfusion on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase). Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]

• For the Prior/Concomitant Flag, list all that apply.

Repeat for:

Listing 16.2.5.3B Prior and Concomitant Transfusions (Safety Population in the Stage 2 PK Phase)

Listing 16.2.5.3C Prior and Concomitant Transfusions (Safety Population in the Extension Phase)

Listing 16.2.5.3D Prior and Concomitant Transfusions (Safety Population in the Stage 3 PK Phase)

TESARO Inc. Confidential Page 1 of x Protocol No: XXXXX Listing 16.2.5.4A Prior and Concomitant Growth Factors (Safety Population in the Stage 1 PK Phase) Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable Received growth factor within 14 Prior/ Patient Type of Administration days of first dose or during study? Number Administration Dose Unit Date Concomitant Flag Other: specify Other: specify Note: Includes patients with prior or concomitant growth factors during the PK Phase. P=Prior (any growth factor earlier than the first dose date of study treatment). C=Concomitant (any growth factor given on or after the initial study treatment dosing date through either the first dose of the Extension Phase or through 30 days after the last dose, for those not continuing into the Extension Phase). Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY

[Programming Notes]

• For the Prior/Concomitant Flag, list all that apply.

Repeat for: Listing 16.2.5.4B Prior and Concomitant Growth Factors (Safety Population in the Stage 2 PK Phase)

Listing 16.2.5.4C Prior and Concomitant Growth Factors (Safety Population in the Extension Phase)

Listing 16.2.5.4D Prior and Concomitant Growth Factors (Safety Population in the Stage 3 PK Phase)

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TESARO Inc.				Conf	idential				Page 1 of x
Listing 16.2.5.5A Study Treatment (Safety Population in the Stage 1 PK Phase)									
Treatment S	Sequence: <st< td=""><td>age 1 &amp; 2: TABL</td><td>ET/CAPSULE or CAPS</td><td>SULE/TABLE</td><td>[&gt;</td><td></td><td></td><td></td><td></td></st<>	age 1 & 2: TABL	ET/CAPSULE or CAPS	SULE/TABLE	[>				
Patient Number Visit Formulation Number Patient Number Formulation Formulation Formulation Formulation Formulation Formulation Formulation Formulation Full Full Dose Taken? Full Full Full Full Full Full Full Ful								Vomit within 8 hours of dose?	
[1] Relativ Source: Pro Data Extrac	[1] Relative to first dose during the PK Phase. Source: Program: XXXXXXXXXXXXXXXXXX Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY								

Listing 16.2.5.5B Study Treatment (Safety Population in the Stage 2 PK Phase)

[For Stage 2 PK Phase]

- Modify label for Vomiting Question, 'Vomit within specified time of dose'.
- Add column for Nausea Question, 'Nausea within specified time of dose'.

TESARO Inc Protocol N				Co	onfidential				Page 1 of x	
	Listing 16.2.5.5C Study Treatment (Safety Population in the Extension Phase)									
TREATMENT:	TREATMENT: <niraparib capsule="" niraparib="" of="" tablet=""></niraparib>									
Patient Number	Visit	Dose Prescribed (mg)	Start Date (Rel Day [1])/ Stop Date (Rel Day [1])	Was Full Dose Taken?	Action Taken	Reason for Modification	Bottle number Dispensed	Bottle Number Returned	Tablets Remaining	
				No		Other <specify reason&gt;</specify 				
[1] Relati	[1] Relative to first dose during the Extension Phase.									
Source: Pr Data Extra	ogram: XX Ict Date:	XXXXXXXXXXXXX DDMMMYYYY, D	XXX. Output: xxx ata Cutoff Date:	XXXXXXXXX.rtf DDMMMYYYY	. Generated on 1	DDMMMYYYY:HH:MM:SS				

TESARO Inc. Confidential Protocol No: XXXXX							Page 1 of x		
TIOCOCOT NO. MM			Listir	ng 16.2.5.5D					
		Study Tr	reatment (Safety Pop	pulation in the S	Stage 3 PK Phase)				
Treatment Sequence: <fasted <fed="" fasted="" fed="" or=""></fasted>									
Patient Number	Visit	Fasted or Fed State	Date:Time of Administration (Rel Day [1])	Bottle Number	Fast 10 hrs prior to administration?	Vomit within protocol specified hours from dose?	Fast for minimum of 4 hours post dose?		
	<u> </u>								
[1] Relative to Source: Program Data Extract Dat	[1] Relative to first dose during the PK Phase. Source: Program: XXXXXXXXXXXXXXXXXXXXX Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY								

TESARO Inc	-	Confide	ential	Page 1 of x				
Protocol N	Listing 16.2.5.6B Subsequent Anti-Cancer Therapy (Safety Population in the Stage 2 PK Phase)							
Treatment Sequence: TABLET/CAPSULE or CAPSULE/TABLET								
Patient Number	Date of Subsequent Anti-Cancer Administration	Relative Day [1]						
[1] Relati Note: Incl Source: Pr Data Extra	ve to first dose during the PK Ph udes only patients with subsequen ogram: XXXXXXXXXXXXXXXXX Outp .ct Date: DDMMMYYYY, Data Cutoff	hase. ht anti-cancer therapy rec put: xxxxxxxxxx.rtf. Ge Date: DDMMMYYYY	orded for patients who do not continue to Extension H nerated on DDMMMYYYY:HH:MM:SS	?hase.				

TESARO Inc	2. 1. VVVV	Confide	ential	Page 1 of x
PIOLOCOL N	Subsequent Ar	Listing 16 hti-Cancer Therapy (Safety	.2.5.6C Population in the Extension Phase)	
Treatment:	<niraparib niraparib<="" or="" tablet="" td=""><td>CAPSULE&gt;</td><td></td><td></td></niraparib>	CAPSULE>		
Patient Number	Date of Subsequent Anti-Cancer Administration	Relative Day [1]		
[1] Relati Note: Incl Source: Pr Data Extra	we to first dose during the Exter udes only patients with subsequer cogram: XXXXXXXXXXXXXXXXXXXXXXX Outp act Date: DDMMMYYYY, Data Cutoff	nsion Phase. nt anti-cancer therapy rec put: xxxxxxxxxxx.rtf. Ge E Date: DDMMMYYYY	orded. nerated on DDMMMYYYY:HH:MM:SS	

TESARO Inc.	v	Confidential								
PIOLOCOI NO: XXXX										
Treatment Sequenc	e: <fasted fed<="" td=""><td>or <fed fasted=""></fed></td><td></td><td></td><td></td></fasted>	or <fed fasted=""></fed>								
Patient Number	Visit	Meal Start Date	Meal Start Time	Meal End Time	% of Meal Consumed					
Source: Program: Data Extract Date	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXX. Output: xxxxxxxxxxxx Data Cutoff Date: DDMMMYYYY	rtf. Generated on DDMM	MYYYY:HH:MM:SS						

TESARO Inc. Confidential									Page 1 of x	
Protocol No: XXXXX Listing 16.2.6.1C Investigator Assessment of Response (Safety Population in the Extension Phase)										
TREATMENT:	<nirapari< td=""><td>B TABLET or</td><td>NIRAPARIB CAPSU</td><td>LE&gt;</td><td></td><td></td><td></td><td></td><td></td></nirapari<>	B TABLET or	NIRAPARIB CAPSU	LE>						
Patient Number	Visit	Date	Rel Day [1]	Overall Response						
				NE: <reason></reason>						
[1] Relative to first dose during the Extension Phase. Source: Program: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX										

TESARO I	nc.		Confid	lential						Page 1 of x
Protocol	No: XXXXX		Ticting	16 2 7	1 7					
		Adverse Eve	ents (Safety Popul	ation i	n the Sta	age 1 PK 1	Phase)			
							,			
Treatment	Sequence: <sta< td=""><td>ge 1 &amp; 2: TABLET/CAPSULE</td><td>or CAPSULE/TABLET</td><td>&gt; or <st< td=""><td>age 3: E</td><td>ASTED/FED</td><td>or FED/FAS</td><td>STED&gt; or &lt;</td><td>Extension:</td><td>NIRAPARIB</td></st<></td></sta<>	ge 1 & 2: TABLET/CAPSULE	or CAPSULE/TABLET	> or <st< td=""><td>age 3: E</td><td>ASTED/FED</td><td>or FED/FAS</td><td>STED&gt; or &lt;</td><td>Extension:</td><td>NIRAPARIB</td></st<>	age 3: E	ASTED/FED	or FED/FAS	STED> or <	Extension:	NIRAPARIB
TABLET or	NIRAPARIB CAPS	SULE>, as applicable								
			Start Date:Time				Action			
	Dosing Period/	Adverse Event	(Rel Day [1])		SAE/		Taken on	Other		
Patient 1	Niraparib	MedDRA Preferred Term	End Date (Rel		Reason		Study	Action	Relation-	
Number	Treatment	System Organ Class	Day [1])	TEAE?	[2]	Severity	Treatment	Taken	ship	Outcome
		*****	yyyy-mm-dd [x]	Y	Ν	Grade 1				Recovered/
	Period 1/	*****	yyyy-mm-dd [x]							Resolved
(	Capsule	******								
		XXXXXXXXXXXXXXX	yyyy-mm-dd [x]	Y	Ν	Grade 1				Recovered/
	Period 2/		yyyy-mm-dd [x]							Resolved
	Tablet									
	PK Safety FU									
[1] Relat [2] Reaso 4 = Requi	ive to the date n for SAE: 1 = res or prolongs	e of first dose in PK Phas Result in death; 2 = Life a hospitalization; 5 = Con	e. threatening; 3 = genital abnormali	Result ty/birth	in persi 1 defect;	stent or 6 = Othe	significant r medically	: disabili / importan	ty/incapaci t event.	ty;
				~ .	1 551					
Source: P Data Extr	rogram: XXXXXX act Date: DDMM	MYYYY, Data Cutoff Date:	XXXXXXXXXX.TTI. DDMMMYYYY	Generate	ed on DDM	1MMYYYY:HH	:MM:SS			
Data Enti	ace bace. Dbin	milli, baca cacoli bace.	DDIMMITIT							
Repeat fo	r:									
Listing 1	6.2.7.1B Advers	se Events (Safety Populati	on in the Stage 2	PK Phas	se)					
[Add time	for start date									
Listing 1	6.2.7.1C Advers	se Events (Safety Populati	on in the Extensi	on Phase	e)					
Listing 1	6.2.7.1D Advers	se Events (Safety Populati	on in the Stage 3	PK Phas	se)					
[Programm	ing Notesl									
• Stad	ge 3: Treatment	Sequence will be Fasted/I	Fed and Fed/Fasted	d.						
• Stad	- ge 3: Column 2:	- Dosing Period/Treatment -	- Treatment should	d be Nir	aparib F	ASTED or	Niraparib F	ED.		
• Ev+/	angion Phago. D	o not need column for Dos	ing Period/Trootm					-		

- Extension Phase: Do not need time with start/stop dates.
- Extension Phase: Footnote: [1] Relative to first dose during the Extension Phase.
- Extension Phase: Add column for Dose at Onset of AE.

TESARO In	TESARO Inc. Confidential Page 1 of x									
Protocol	Protocol No: XXXXX Listing 16.2.8.1.1A									
	Hematology Results in the PK Phase (Safety Population in the Stage 1 PK Phase)									
			51							
Treatment TABLET or	Sequence: <stag NIRAPARIB CAPSU</stag 	e 1 & 2: LE>, as a	TABLET/CA applicable	PSULE or CAPSULE	C/TABLET>	or <stage 3:="" fa<="" td=""><td>STED/FED or FE</td><td>D/FASTED&gt; or &lt;</td><td>Extension: NIRAPARIB</td></stage>	STED/FED or FE	D/FASTED> or <	Extension: NIRAPARIB	
Patient Number	Parameter (unit)	Visit	Rel Day [1]	Sample date/time	Result	Change from baseline	Normal range	Out of range flag	Clinically significant flag	
					XX.X	XX.X	xx.x - xx.x			
[1] Relat Scheduled the Exten Source: P Data Extr	[1] Relative to the date of first dose in the PK Phase. Scheduled and unscheduled visits through the extension screening phase or through study discontinuation for those not continuing in the Extension Phase, are included. Visits related to the extension screening phase are not included. Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY									
• If re	ng Notes]: equired for reada	bility,	move 'Pati	ent Number' int	o Header 1	row after 'Trea	tment Sequence'			
Repeat for	:	wiiicy,			o neuder i	ow areer frea	emerre bequerree	•		
Listing 16	.2.8.1.1B Hemato	logy Resi	ults (Safet	ty Population in	the Stag	e 2 PK Phase)				
Listing 16	.2.8.1.1C Hemato	logy Resi	ults (Safe	ty Population in	the Exte	nsion Phase)				
Listing 16	.2.8.1.1D Hemato	logy Resi	ults Throug	gh the PK End of	Treatmen	t Visit (Safety	Population in	the Stage 3 P	K Phase)	
Listing 16	.2.8.1.2A Chemis	try Resul	lts (Safety	Y Population in	the Stage	1 PK Phase)				
Listing 16	.2.8.1.2B Chemis	try Resul	lts (Safety	y Population in	the Stage	2 PK Phase)				
Listing 16	.2.8.1.2C Chemis	try Resul	lts (Safety	y Population in	the Exten	sion Phase)				
Listing 16	.2.8.1.2D Chemis	try Resul	lts Through	n the PK End of	Treatment	Visit (Safety	Population in t	the Stage 3 PK	Phase)	
Listing 16.2.8.1.3A Urinalysis Results (Safety Population in the Stage 1 PK Phase)										
Listing 16.2.8.1.3B Urinalysis Results (Safety Population in the Stage 2 PK Phase)										
Listing 16	Listing 16.2.8.1.3C Urinalysis Results (Safety Population in the Extension Phase)									
[Programmi • Footr Listing 16	ng Notes For Extended for Extended for Extended for the second se	ension Ph ve to fir ysis Resu	nase Tables st dose du ults Throug	s]: rring the Extens gh the PK End of	ion Phase. Treatmen	t Visit (Safety	Population in	the Stage 3 P	K Phase)	

TESARO Inc.	RO Inc. Confidential									
Protocol No: XX	XXXX									
Listing 16.2.8.1.4C										
	Liver Function Tests - Potential Hy's Law Cases (Safety Population in the Extension Phase)									
TREATMENT: <nif< td=""><td>APARIB TABLE</td><td>T or NIRAPARIB CAPS</td><td>ULE&gt;</td><td></td><td></td><td></td><td></td></nif<>	APARIB TABLE	T or NIRAPARIB CAPS	ULE>							
	Laboratory Analyte (result/xULN)									
Patient Number	Visit	Sample Collection Date	Day [1]	ALT (U/L)	AST (U/L)	Total Bilirubin (umol/L)	ALP (U/L)			
		DDMMMYYYY		150/3.3	100/2.7	40/2.3	100/0.7			
ATD-alkaling ph	arphatara M		naforaço A	ST-accortate amir	otransforaço III N-11	ppor limit of pormal				
ABF-AIRAIINE phosphalase. ABT-AIANINE AMINOTRANSIERASE. AST-ASPARTATE AMINOTRANSIERASE. ULN=upper limit of normal.										
[1] Relative to first dose during the Extension Phase.										
Source: Program: XXXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY										

[Programming Notes]

Include all visits for any Patients with ALT or AST >3×ULN with bilirubin >2×ULN and ALP <2×ULN at any time in Extension Phase.

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TESARO Inc. Protocol No: XXXXX

## Listing 16.2.8.2A Vital Signs (Safety Population in the Stage 1 PK Phase)

Treatment Sequence: <Stage 1 & 2: TABLET/CAPSULE or CAPSULE/TABLET> or <Stage 3: FASTED/FED or FED/FASTED> or <Extension: NIRAPARIB TABLET or NIRAPARIB CAPSULE>, as applicable

Patient Number	Visit	Assessment Date	Rel Day [1]	Height (cm)	Weight (kg)	Temperature (°C)	Pulse (beats/min)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)

[1] Relative to the date of first dose in the PK Phase. Data is listed only when the vital sign assessment was performed.

Repeat for:

Listing 16.2.8.2B Vital Signs (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.2C Vital Signs (Safety Population in the Extension Phase)

[Programming Notes For Extension Phase Tables]:

• Footnote: [1] Relative to first dose during the Extension Phase

Listing 16.2.8.2D Vital Signs Through the PK End of Treatment Visit (Safety Population in the Stage 3 PK Phase)

TESARO Inc. Confidential										
Protocol No: XX	XXX			Listing 16.2.8.3A						
ECG Results (Safety Population in the Stage 1 PK Phase)										
			Hee Repares (bareey	roparación in che beage i na mabe,						
Treatment Seque TABLET or NIRAE	ence: <s PARIB CA</s 	tage 1 & 2: PSULE>, as a	TABLET/CAPSULE or CAPSUI pplicable	LE/TABLET> or <stage 3:="" fasted="" fed="" or=""> or <extension:< td=""><td>: NIRAPARIB</td></extension:<></stage>	: NIRAPARIB					
Patient										
Number	Visit	Date	Rel Day [1]	ECG Interpretation						
<pre>[1] Relative to the date of first dose in the PK Phase. NCS = Not Clinically Significant, CS = Clinically Significant. Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY</pre>										
Repeat for:										

Listing 16.2.8.3B ECG Results (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.3C ECG Results (Safety Population in the Extension Phase)

Listing 16.2.8.3D ECG Results (Safety Population in the Stage 3 PK Phase)

[Programming Notes For Extension Phase Tables]:

• Footnote: [1] Relative to first dose during the Extension Phase
TESARO Inc.	Page 1 of x								
Protocol No: XXXX	Protocol No: XXXXX								
Listing 16.2.8.4A									
	ECOG Performance Status (Safety Population in the Stage 1 PK Phase)								
Treatment Sequence	e: <stage &="" 1="" 2<="" td=""><td>: TABLET/CAPSULE or CAPSULE/TABLET&gt;</td><td>&gt; or <stage 3:="" c<="" fasted="" fed="" td=""><td>or FED/FASTED&gt; or <extension: niraparib<="" td=""></extension:></td></stage></td></stage>	: TABLET/CAPSULE or CAPSULE/TABLET>	> or <stage 3:="" c<="" fasted="" fed="" td=""><td>or FED/FASTED&gt; or <extension: niraparib<="" td=""></extension:></td></stage>	or FED/FASTED> or <extension: niraparib<="" td=""></extension:>					
TABLET or NIRAPAR	IB CAPSULE>, as	applicable	-						
	-	-							
Patient									
Number	Visit	Assessment Date	Rel Day [1]	Performance Status					
[1] D. J. L		hala is the prophere path is list							
[1] Relative to the date of first dose in the PK Phase. Data is listed only when the ECOG Performance Status assessment was performed.									
ECUG = Eastern cooperative Uncology Group:									
U-ruity active, able to carry on all pre-ulsease performance without restriction									
2-Ambilatory and canable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours									
3=Canable of only limited self-care, confined to bed or chair more than 50% of waking hours									
4=Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair									
Source: Program: XXXXXXXXXXXXXXXXXXX. Output: xxxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS									
Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY									

Repeat for:

Listing 16.2.8.4B ECOG Performance Status (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.4C ECOG Performance Status (Safety Population in the Extension Phase)

[Programming Notes For Extension Phase Tables]:

• Footnote: [1] Relative to first dose during the Extension Phase

Listing 16.2.8.4D ECOG Performance Status Through the PK End of Treatment Visit (Safety Population in the Stage 3 PK Phase)

TESARO Inc. Confidential						Page 1 of x			
Protocol No: XXXXX									
Listing 16.2.8.5A									
Baseline Physical Examination Findings (Safety Population in the Stage 1 PK Phase)									
Treatment Sequence: <stage &="" 1="" 2:="" capsule="" or="" tablet=""> or <stage 3:="" fasted="" fed="" or=""> or <extension: niraparib<="" td=""></extension:></stage></stage>									
TABLET or NIRA	PARIB CAPSU	LE>, as applicable							
Patient			Rel						
Number	Visit	Date Performed	Day [1]	Body System	Status	Abnormality Description			
[1] Relative to the date of first dose in the PK Phase.									
Source, Brogram, VVVVVVVVVVVVVVVVVVVVVVVVVVVVVVVVVVVV									
Data Extract Date · DDMMMYYYY. Data Cutoff Date · DDMMMYYYY									
···· ···· , ···· ····									

Repeat for:

Listing 16.2.8.5B Baseline Physical Examination Findings (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.5C Baseline Physical Examination Findings (Safety Population in the Extension Phase)

Listing 16.2.8.5D Baseline Physical Examination Findings (Safety Population in the Stage 3 PK Phase)

[Programming Notes For Extension Phase Tables]:

• Footnote: [1] Relative to first dose during the Extension Phase.

TESARO Inc Protocol N	c. No: XXXXX	Confidential						
	Listing 16.2.8.6A							
Pregnancy Test (Safety Population in the Stage 1 PK Phase)								
Treatment Sequence: <stage &="" 1="" 2:="" capsule="" or="" tablet=""> or <stage 3:="" fasted="" fed="" or=""> or <extension: niraparib<br="">TABLET or NIRAPARIB CAPSULE&gt;, as applicable</extension:></stage></stage>								
Patient Number	Visit	Was Pregnancy Test Performed?	Date of Test	Rel Day [1]	Туре	Result		
[1] Relative to the date of first dose in the PK Phase. Scheduled and unscheduled visits through the Extension Screening Phase or through study discontinuation for those not continuing in the Extension Phase, are included. Visits related to the Extension Screening Phase are not included. Source: Program: XXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY								

Repeat for:

Listing 16.2.8.6B Pregnancy Test (Safety Population in the Stage 2 PK Phase)

Listing 16.2.8.6C Pregnancy Test (Safety Population in the Extension Phase)

[Programming Notes For Extension Phase Tables]:

• Footnote: [1] Relative to first dose during the Extension Phase

Listing 16.2.8.6D Pregnancy Test (Safety Population in the Stage 3 PK Phase)

TESARO I	nc.			Confider	itial	Ра	ge 1 of x		
Protocol No: XXXXX							-		
Listing 16.2.9.2D									
Listing of COVID-19 Assessments and Symptom Assessments for Patients with COVID-19 Adverse Events									
(Safety Population in the Stage 3 PK Phase)									
Treatment Sequence. <stage 1.="" 2.="" 3.="" fasted="" fed.="" fed.<="" or="" period="" td=""></stage>									
readmente bequence. Notage 5. reriou 1. rested of FED, reriou 2. rested of FED/									
					COVID-19 Test				
Patient	Treatment	Adverse	AE	COVID-19 Case	Performed/ Test	Assessments and			
Number	Period (State)	Event	Start Date	Diagnosis [1]	Date/ Results	Symptom Assessments	Result		
XXXX	1 (FASTED)	Coronavirus	2020-04-16	Suspected	Yes/	Travel to Location with Community	No		
		infection		-	2020-04-17/	Transmission [2]			
					Indeterminate				
						Visited Health Care Facility [2]	No		
						Contact with COVID-19	Unknown		
						Confirmed/Probable Case [2]			
						Medication Taken to Treat COVID-19	Yes		
						Fever	Yes		
						Cough	Yes		
						Shortness of Breath	Yes		
						Sore Throat	No		
						Loss of Appetite	No		
						Nausea	No		
						Vomiting	No		
						Diarrhea	No		
						Abdominal Pain	No		
						Fatigue	No		
						Loss of Smell	No		
						Loss of Taste	No		
						Asymptomatic	No		
						Home Quarantined/Isolated	Unknown		
	2 (FED)								
AE=Adverse event. [1] COVID-19 Case Diagnosis is based on WHO Definition as of DDMMMYYYY. [2] Within 14 days prior to symptom onset. Source: Program: XXXXXXXXXXXXXXXXXXXXX. Output: xxxxxxxxx.rtf. Generated on DDMMMYYYY:HH:MM:SS Data Extract Date: DDMMMYYYY, Data Cutoff Date: DDMMMYYYY									

[Programming Notes]

The COVID-19 AE terms include: Asymptomatic COVID-19, Coronavirus infection, COVID-19, COVID-19 pneumonia, Suspected COVID-19. Note that the number of COVID-19 AE terms may change.