Title: A Phase 2, Randomized, Open-Label, 3-Arm Study of Relacorilant in Combination with Nab-Paclitaxel for Patients with Recurrent Platinum-Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

NCT number: NCT03776812

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STATISTICAL ANALYSIS PLAN (SAP)
STUDY CORT125134-552

Title	**A Phase 2, Randomized, Open-Label, 3-Arm Study of Relacorilant in Combination with Nab-Paclitaxel for Patients with Recurrent Platinum-Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer**
Study Protocol	CORT125134-552
Phase	2
Investigational Product	Relacorilant (CORT125134)
Indication	Ovarian Cancer
Protocol Version	Amendment 2
Protocol Version (date)	23 October 2019
Sponsor	Corcept Therapeutics Incorporated 149 Commonwealth Drive Menlo Park, California 94025 USA (650) 327-3270
IND Number	[redacted]
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Confidentiality Statement

APPROVAL SHEET

STATISTICAL ANALYSIS PLAN

CORT125134-552: A Phase 2, Randomized, Open-Label, 3-Arm Study of Relacorilant in Combination with Nab-Paclitaxel for Patients with Recurrent Platinum-Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Reviewed and Accepted at Corcept Therapeutics by

[redacted]

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LIST OF ABBREVIATIONS

Abbreviation	Definition
AE	Adverse event
AUC	Area under the concentration-time curve
BoR	Best overall response
C_{max}	Maximum concentration
C_{min}	Minimum concentration within a dose interval
CA-125	Cancer antigen 125
CEA	Carcinoembryonic antigen
CI	Confidence interval
CR	Complete response
DoR	Duration of response
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	Electronic case report form
EDC	Electronic data capture
EOT	End of Treatment
EQ-5D-5L/VASc	EuroQoL 5 Dimensions, 5 Levels
FACT NFOSI-18	Functional Assessment of Cancer Therapy Ovarian Symptom Index-18
GCIG	Gynecologic Cancer Intergroup
G-CSF	Granulocyte colony-stimulating factor
GR	Glucocorticoid receptor
MedDRA	Medical dictionary for regulatory affairs
NCI CTCAE	National Cancer Institute Common Terminology Criteria for Adverse Events
ORR	Objective response rate
OS	Overall survival
PD	Disease progression (progressive disease per RECIST v1.1)
PFS	Progression-free survival
PK	Pharmacokinetic(s)
PRO	Patient-reported outcomes
PROMIS	Patient-Reported Outcomes Measurement Information System
PR	Partial response

QoL	Quality of life
RECIST	Response evaluation criteria in solid tumors
SAE	Serious adverse event
SAP	Statistical analysis plan
SD	Stable disease
$t_{1/2}$	Apparent terminal elimination half-life
t_{lag}	Latest time after dosing before the first quantifiable concentration
T_{max}	Time to maximum concentration
T_{min}	Time of minimum concentration in a dose interval
TEAE	Treatment-emergent adverse event
TLF	Tables, listings, and figures
V_{ss}	Apparent oral volume of distribution at steady state
WHODD	World health organization drug dictionary

1 INTRODUCTION

This statistical analysis plan (SAP) contains definitions of analysis populations and endpoints, outlines the timing of statistical analyses, and provides a comprehensive description of statistical analyses to be implemented to assess the clinical efficacy and safety of protocol CORT125134-552, Amendment 2, dated 23 October 2019: A Phase 2, Randomized, Open-Label, 3-Arm Study of Relacorilant in Combination with Nab-Paclitaxel for Patients with Recurrent Platinum-Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.

2 STUDY OVERVIEW

This is a Phase 2, open-label, randomized, 3-arm study to evaluate the efficacy, safety, PK, pharmacodynamics, PRO, and QoL of continuous and intermittent dosing of relacorilant in combination with nab-paclitaxel compared with nab-paclitaxel alone.

The study population is women with recurrent ovarian, primary peritoneal, or fallopian tube cancer following at least one treatment, and which is resistant and/or refractory to platinum-based chemotherapy, including the following histological subtypes:

- High-grade serous carcinoma
- Carcinosarcoma
- Endometrioid carcinoma

Screening procedures will be performed within the 28 days prior to the first dose of study treatment.

Eligible patients will be randomized 1:1:1 to one of the following 3 treatment arms. Patient randomization will be stratified by treatment-free interval from most recent taxane (relapse within 6 months vs. >6 months) and presence of ascites (yes vs. no).

- Arm A (continuous relacorilant): relacorilant starting at 100 mg, administered orally, once daily every day in combination with nab-paclitaxel 80 mg/m^2 on Days 1, 8, and 15 of each 28-day cycle.
- Arm B (intermittent relacorilant): relacorilant 150 mg, administered orally, once daily on the day before (excluding Cycle 1, Day -1), the day of, and the day after nab-paclitaxel, in combination with nab-paclitaxel 80 mg/m^2 on Days 1, 8, and 15 of each 28-day cycle.
- Arm C (comparator): nab-paclitaxel 100 mg/m^2 on Days 1, 8, and 15 of each 28-day cycle.

Study treatment will start on Cycle 1, Day 1 in all treatment arms.

Tumor assessments will be conducted using computerized tomography (CT) with contrast or magnetic resonance imaging (MRI) scans of the chest, abdomen, and pelvis. A baseline tumor scan (prior to initiating therapy) is required within 28 days prior to the first dose of study treatment and then every 8 weeks (±7 days) from Cycle 1, Day 1 until unequivocal PD is documented, including in patients who prematurely discontinue therapy. Tumor response will be assessed by the Investigator or local radiologist using RECIST v1.1. Radiographic scans will be quality checked, anonymized and stored centrally.

CA-125 will be assessed within 14 days prior to the first dose of study treatment and then every 4 weeks from Cycle 1, Day 1 for the first 12 months of study treatment. CA-125 response will be determined according to GCIG criteria.

Tumor response will be assessed by RECIST v1.1, as described above. A combined response endpoint incorporating RECIST v1.1 and GCIG criteria will also be reported.

Patients will remain on study treatment until unequivocal PD as determined by the Investigator, unmanageable toxicity, or patient refusal, or until meeting other criteria for discontinuation of study treatment. Patients will be seen approximately 30 days after the last dose of relacorilant or nab-paclitaxel, whichever is latest, for a 30-Day Follow-up Visit.

Patients who discontinue treatment at any time will continue to be followed for survival information (i.e., the date and cause of death) and subsequent treatment information (i.e., name[s] of subsequent therapy regimen[s], dates of initiation and completion, PD on subsequent therapy and response to subsequent therapy) during the Long-Term Follow-up.

For patients who discontinue treatment before unequivocal PD, subsequent treatment information will be collected at the same time as radiographic tumor assessments (i.e., every 8 weeks) until unequivocal PD. After PD, they will be followed every 3 months for the remainder of the Long-Term Follow-up.

For patients with PD, or for patients who decline further radiographic tumor assessments, survival and subsequent treatment information will be collected every 3 months after the last dose of study treatment. Long-Term Follow-up will continue until the end point of death, the patient is lost to follow-up, or other study exit criteria are met (see Protocol Section 4.4.2).

Patients in Arm C (comparator) who experience unequivocal PD per RECIST v1.1 will be given the opportunity to receive relacorilant in combination with nab-paclitaxel after discussion with the Medical Monitor. Tumor assessments at the time of PD on nab-paclitaxel will be considered the End of Treatment (EOT) assessment for comparator-only treatment and Baseline for combination therapy. If more than 28 days have passed since the date of PD and Cycle 1 Day 1 of the Crossover, then a new baseline radiographic tumor assessment will need to be obtained prior to initiating crossover treatment. Tumor assessments will then be performed every 8 weeks (±7 days) from the first dose of relacorilant until PD. CA-125 will be assessed within 14 days of the first dose of relacorilant and assessed every 4 weeks for the first 12 months. Study procedures will be performed according to the schedule for the Treatment Phase; assessments for the Arm C EOT visit and Crossover Cycle 1, Day 1 visit may be combined into one visit for patients in Arm C who crossover from nab-paclitaxel to combination treatment (relacorilant 100 mg, administered orally, once daily every day starting on Cycle 1, Day 1; in combination with nab-paclitaxel 80 mg/m^2 on Days 1, 8, and 15 of each 28-day cycle).

Safety, pharmacokinetics (PK), patient-reported outcomes (PRO), quality of life (QoL), and pharmacodynamic profiles will also be assessed in the three dosing regimen arms.

This SAP will be developed and approved prior to database lock and data analysis. Any deviations from the SAP will be documented as such in the clinical study report.

The analysis of PFS, the primary endpoint, will be conducted when approximately 135 PFS events have been observed. An interim analysis of OS will be performed after 135 PFS events have occurred. An additional OS analysis will be performed when at least 120 OS events have occurred, which will be used for the purpose of final OS reporting.

An Independent Data Monitoring Committee (IDMC) will monitor safety during the study on a regular basis. The committee will operate independently from the Sponsor and the Investigators as described in the IDMC charter.

Production and quality control of statistical analyses and accompanying tables, listings, and figures (TLFs) will be the responsibility of [redacted], with appropriate oversight by Corcept Therapeutics Biometrics team.

3 STUDY OBJECTIVES

For all efficacy objectives and corresponding endpoints listed below, assessment for response and disease progression are according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 as assessed by the Investigator or local radiologist, unless otherwise noted.

Primary:
To evaluate progression-free survival (PFS) in patients treated with intermittent or continuous regimens of relacorilant in combination with nab-paclitaxel compared with patients treated with nab-paclitaxel alone.

Secondary:

Efficacy

- To evaluate objective response rate (ORR) in patients with measurable disease at Baseline treated with intermittent or continuous regimens of relacorilant in combination with nab-paclitaxel compared with patients treated with nab-paclitaxel alone.
- To evaluate duration of response (DoR) in patients treated with intermittent or continuous regimens of relacorilant in combination with nab-paclitaxel compared with patients treated with nab-paclitaxel alone.
- To assess response according to cancer antigen 125 (CA-125) using Gynecologic Cancer Intergroup (GCIG) criteria. A combined response endpoint based on both RECIST v1.1 and GCIG criteria will also be reported.
- To evaluate PFS rate at 6 and 12 months in patients treated with intermittent or continuous regimens of relacorilant in combination with nab-paclitaxel compared with patients treated with nab-paclitaxel alone.
- To evaluate overall survival (OS) in patients treated with intermittent or continuous regimens of relacorilant in combination with nab-paclitaxel compared with patients treated with nab-paclitaxel alone.
- To evaluate PFS, ORR, DoR and best overall response (BoR) in patients who receive continuous relacorilant in combination with nab-paclitaxel following progression on nab-paclitaxel (Crossover).
- To assess response according to CA-125 using GCIG criteria in those patients who crossover to continuous relacorilant + nab-paclitaxel. A combined response endpoint based on both RECIST v1.1 and GCIG criteria will also be reported for Crossover patients.

Safety

- To assess the safety of relacorilant treatment in combination with nab-paclitaxel.
- To model the exposure-toxicity and exposure-response of relacorilant and nab-paclitaxel in each treatment arm to recommend a dosing regimen of relacorilant in combination with nab-paclitaxel for further development.

Pharmacokinetics

- To assess the pharmacokinetics (PK) of relacorilant and nab-paclitaxel following intermittent or continuous treatment regimens of relacorilant in combination with nab-paclitaxel compared with nab-paclitaxel alone.

Exploratory

Pharmacodynamics / Biomarkers

- To assess the relationship between baseline characteristics of patients that respond to intermittent or continuous treatment regimens of relacorilant in combination with nab-paclitaxel and patients treated with nab-paclitaxel alone.
- To assess pharmacodynamic effects of intermittent or continuous treatment regimens of relacorilant in combination with nab-paclitaxel and patients treated with nab-paclitaxel alone.

Patient-Reported Outcomes and Quality of Life

To describe changes from Baseline of PRO and QoL scores in the study population and to describe differences across treatment arms.

4 STUDY ENDPOINTS

4.1 Primary Endpoint

Progression free survival: the time from randomization until the date of first documented PD by RECIST v1.1 (as determined by the Investigator at the local site) or death due to any cause, whichever occurs first.

4.2 Secondary Endpoints

Efficacy

- ORR: proportion of patients with measurable disease at Baseline who attain complete response (CR) or partial response (PR) by RECIST v1.1 (confirmation not required).
- DoR: time from when response (CR or PR) was first documented to first objectively documented PD or death (whichever occurs first).
- BoR: the best response recorded from the date of randomization until PD/recurrence (or death).
- CA-125 response will be assessed per GCIG criteria (Rustin 2011) defined as ≥50% reduction in CA-125 from a pre-treatment sample and maintained for ≥28 days in patients with a pretreatment sample that is at least twice the upper limit of the reference range within 2 weeks before starting the treatment. In addition, patients who have a CA-125 response and whose CA 125 level falls to within the reference range will be classified as CA-125 complete responders.
- Combined response according to RECIST v1.1 + GCIG criteria. Response will be reported separately and combined for RECIST 1.1 and CA-125/GCIG criteria.
- Progression-free rate (proportion of patients who have not progressed) at 6 and 12 months
- PFS, ORR, DoR, BoR in patients who crossover to treatment with continuous relacorilant in combination with nab-paclitaxel from the time of PD (Baseline for combination therapy) on nab-paclitaxel alone.
- Overall survival: time from randomization to death by any cause.

Safety

The safety of each treatment group will be assessed by evaluating:

- Study drug exposure
- Exposure-toxicity and exposure-response of relacorilant and nab-paclitaxel
- Incidence of adverse events (AEs), serious AEs (SAEs), treatment-related AEs, AEs by severity, deaths
- Discontinuations of treatment and study withdrawal due to AEs
- Dose interruptions and reductions due to AEs
- Change from Baseline in clinical laboratory tests
- Change from Baseline in vital signs (including blood pressure, heart rate)

- Change from Baseline in physical examination
- Use of growth factors
- Change from Baseline in ECOG performance status

Pharmacokinetics

- Primary PK parameters of relacorilant and nab-paclitaxel estimated from intensive PK sampling on Cycle 1, Day 15 will be assessed.

4.3 Exploratory Endpoints

Pharmacodynamics

Baseline assessment of:

- Tumor immunohistochemistry: GR and immune markers such as [redacted]
- RNA analyses from circulating cells and tumor, where feasible
- Cancer antigens, such as CA-125, CA15-3, CA19-9 and/or carcinoembryonic antigen (CEA)
- Cytokines

Change from Baseline of:

- Tumor immunohistochemistry: GR and immune markers such as [redacted]
- RNA analyses from circulating cells and tumor, where feasible
- Cancer antigens, such as CA-125, CA15-3, CA19-9 and/or CEA
- Cytokines

Descriptive statistics will be presented for all the biomarker endpoints. Additional exploratory biomarker analyses of these and other assessments may be conducted and described in a separate Biomarker SAP.

Patient-Reported Outcomes and Quality of Life

Changes from Baseline of PRO and QoL assessments scores using the Functional Assessment of Cancer Therapy Ovarian Symptom Index-18 (FACT NFOSI-18) and EuroQoL 5 Dimensions, 5 Levels (EQ-5D-5L/VASc) scales and Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function-Short Form score will be assessed.

5 SAMPLE-SIZE CONSIDERATIONS

The assumed median PFS is 3.8 months in the nab-paclitaxel alone arm (Arm C) and 5.4 and 6.8 months, respectively, in Arm B and Arm A. For the comparison between Arm C and Arm A, 91 PFS events will provide approximately 79% power for a 2-sided log-rank test at a 0.05 significance level to detect a hazard ratio [HR]=0.56. Assuming an exponential distribution of PFS, this corresponds to an increase in median PFS from 3.8 months in Arm C to 6.8 months in Arm A. For the comparison between Arm C and Arm B, 92 PFS events will provide approximately 39% power for a 2-sided log-rank test at a 0.05 significance level to detect a HR=0.7. Assuming an exponential distribution of PFS, this corresponds to an increase in median PFS from 3.8 months in Arm C to 5.4 months in Arm B. A total of approximately 177 patients will need to be randomized (1:1:1 ratio), assuming approximately 10% drop-out in each study arm. The total accrual duration is expected to be 24 months, with expected study duration of 43 months.

Assuming a median survival of 13.3 months in the control group, and 16.6 and 17.4 months in Arms B and A, respectively, approximately 120 OS events can be expected to be observed during the 43 months of study duration. This will provide 33% global power for the comparison of time to OS among the 3 treatment arms.

6 ANALYSIS POPULATIONS

6.1 Intent-To-Treat Population

Intent-to-Treat Population (ITT) will include all randomized patients, analyzed according to the randomized treatment arm. This population will be used for analysis of the primary endpoint of PFS as well as all secondary efficacy endpoints.

6.2 Safety Analysis Population

Safety Analysis Population (SAF) will include all randomized patients who receive at least one dose of study treatment, analyzed according to the treatment actually received. This population will be used for all safety endpoints. Safety analysis population in the crossover period will include all patients in arm C who chose to crossover after progression to combination treatment of relacorilant and nab-paclitaxel. The experience of patients in crossover period will be summarized separately from the primary treatment period.

6.3 Pharmacokinetic Analysis Population

Pharmacokinetics Analysis Population (PKA) will be all patients in the SAF who have PK data collected and available for analysis. Summary tables for PK parameters will be based on this set of patients.

7 DEFINITIONS, COMPUTATIONS AND CONVENTIONS

The statistical principles applied in the design and planned analyses of this study are consistent with International Council for Harmonisation (ICH) E9 guidelines (ICH 1998) and Guidance for Industry Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics (2007). All statistical analyses detailed in this SAP will be conducted using SAS version 9.4 or higher.

7.1 Definitions

Study day for efficacy: Study day for efficacy will be calculated in reference to the date of randomization (study day 1). For assessments conducted on or after the randomization date, study day is calculated as (assessment date – randomization date + 1). For assessments conducted before the randomization date, study day is calculated as (assessment date – randomization date). There is no study day 0.

Study day for safety: Study day for safety will be calculated in reference to the date of the first dose of study drug. For assessments conducted on or after the date of the first dose of study drug, study day will be calculated as (assessment date=date of first dose of study drug + 1). For assessments conducted before the date of the first dose of study drug, study day is calculated as (assessment date – date of first dose of study drug). There is no study day 0.

Treatment-emergent period: The treatment-emergent period is defined as the period of time from the date and time of the first dose of study drug through 30 days after the last dose of study drug. The treatment-emergent period will be used in the summaries of treatment-emergent adverse events (TEAEs).

Baseline and postbaseline value: Unless otherwise specified, a baseline value will be defined as the most recent value prior to the first dose of study treatment (relacorilant or nab-paclitaxel, whichever occurs earliest) including PRO, QoL and baseline characteristics. In addition, pre-treatment C1D1 values could serve as baseline. A postbaseline value is defined as an assessment obtained after the first dose of study drug.

Baseline values for tumor assessment and CA-125 marker will be collected within 14 days of start of study treatment.

Baseline and postbaseline value for safety analyses: Unless otherwise specified, a baseline value for safety analyses is defined as the last value before the date/time of first dose of study drug for laboratory tests, vital sign assessments, and electrocardiogram (ECG) data. A postbaseline value for safety analyses is defined as a measurement taken after the date/time of first dose of study drug. If multiple values are present for the same date, the average of these values will be used in the summaries by visit, and the worst toxicity grade will be used in the summaries of toxicity grade by laboratory tests.

Last dose date: Date of the last nonzero dose from the drug administration electronic case report form (eCRF).

Baseline for crossover from nab-paclitaxel: For patients in Arm C (comparator) who crossover to continuous relacorilant in combination with nab-paclitaxel, the tumor assessments at the time of PD on nab-paclitaxel will be considered the final tumor assessment for comparator-only treatment and baseline for combination therapy. If more than 28 days have passed since the date of PD and Cycle 1Day 1 of the Crossover, then a new baseline radiographic tumor assessment will need to be obtained prior to initiating crossover treatment. CA-125 measured within 14 days of starting combination treatment will serve as the baseline value for this subgroup of crossover patients.

7.2 Reporting Conventions

Unless otherwise specified, the following conventions will be applied to all analyses:

- Mean and median values will be formatted to 1 more decimal place than the measured value. Standard deviation values will be formatted to 2 more decimal places than the measured value; minimum and maximum values will be presented to the same number of decimal places as the measured value.
- Percentages will be rounded to 1 decimal place. Number and percentage values will be presented as xx (xx.x%).
- Listings will be sorted for presentation in order of treatment group, patient identifier (ID), and date of procedure or event.
- Analysis and summary tables will have the analysis population sample size (i.e., number of patients).
- Laboratory data will be reported using standard international (SI) units; as local laboratories are used for this study, conversion factors from conventional units will be listed in the clinical study report.
- 1 inch = 2.54 cm.
- Time-to-event or duration of event endpoints will be based on the actual date the radiograph was obtained rather than the associated visit date.
- Hazard ratios and odds ratios will be rounded to 2 decimal places.
- For by-visit observed data analyses, percentages will be calculated based on the number of patients with nonmissing data as the denominator unless otherwise specified.
- For time-to-event right-censored data, the summary statistics and descriptions will include Kaplan-Meier plots and/or life tables.
- For other continuous endpoints, the summary statistics will include mean, standard deviation, median, and range (minimum and maximum).
- For categorical endpoints, the summary statistics will include frequency counts and percentages.
- Confidence intervals (CIs), when presented, will generally be constructed at the 95% level. For binomial variables, exact methods will be employed unless otherwise specified.
- P-values will be rounded to 4 decimal places. P-values that round to 0.0000 will be presented as ‘<0.0001’ and p-values that round to 1.000 will be presented as ‘>0.9999’.

- Medical history and adverse events will be coded using the Medical Dictionary for Regulatory Activities (MedDRA version 21.1. Adverse event severity will be evaluated using the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE v.5.0).
- Prior therapies and concomitant medications will be coded using the World Health Organization (WHO) Drug Dictionary and summarized by Anatomical Therapeutic Chemical (ATC) therapeutic subgroup and preferred drug names.

7.3 Conventions for Dates

Conventions for calculations with dates are as follows:

- Dates will be stored as numeric variables in the SAS analysis files and reported in DDMMMYYYY format (i.e., the Date9. datetime format in SAS).
- Dates recorded in comment fields will not be imputed or reported in any specific format.
- Intervals that are presented in weeks will be transformed from days to weeks by using the following conversion formula, and rounding to 1 decimal place:
  - WEEKS = DAYS / 7
- Intervals that are presented in months will be transformed from days to months by using the following conversion formula, and rounding to 1 decimal place:
  - MONTHS = DAYS / 30.4375

Detailed rules for imputation of missing/partially missing dates for adverse events, prior/concomitant medications/procedures, and primary cancer diagnosis are provided in Section 12.1.

7.4 Treatment Group Presentation

Patient disposition, protocol deviations, demographics and baseline characteristics, medical history, prior medications and procedures, and efficacy data summaries will be presented by randomized treatment group. Unless otherwise specified, safety data summaries will be presented by the actual treatment received.

7.5 Handling of Missing Data

Unless stated otherwise in sections below, missing data will not be replaced with imputed values.

Missing dates or partially missing dates will be imputed conservatively for adverse events and prior/concomitant medications/procedures. Specific rules for handling of missing or partially missing dates for date of birth, adverse events, prior/concomitant medications/procedures, and diagnosis of ovarian cancer are provided in Appendix 1.

7.6 Visit Windows

Visit windows are defined in Section 12.2.

8 TIMING OF ANALYSES

8.1 Primary Analysis

The analysis of PFS, the primary endpoint, will be conducted when approximately 135 PFS events have been observed. An interim analysis of OS will be performed after 135 PFS events have occurred. An additional OS analysis will be performed when at least 120 OS events have occurred, which will be used for the purpose of final OS reporting.

9 STATISTICAL METHODS

9.1 Patient Disposition

Patient populations will be summarized by treatment group for all patients randomized and will include the number and percentage of patients in the ITT, safety, and PKA populations.

Disposition summaries will present number of patients enrolled, number treated, and among those treated, number who completed and discontinued treatment. Primary reason for discontinuation of treatment, including any of the following, will be summarized:

- Disease progression
- Adverse event(s)
- Investigator decision
- Patient withdrawal of consent for treatment
- Patient withdrawal of consent from study
- Protocol non-compliance
- Patient died
- Unknown/lost to follow-up
- Other

Counts and percentages of patients who complete the study and those who discontinue for any of the following reasons will also be calculated:

- Adverse events
- Death
- Lost to follow-up
- Physician decision
- Pregnancy
- Protocol-defined disease progression
- Study terminated by Sponsor
- Patient non-compliance/Protocol violations
- Withdrawal of consent

9.2 Protocol Deviations

Protocol deviations will be categorized as important or other according to the protocol deviation specification document. Important protocol deviations that occur during the study will be summarized by deviation category for all patients in the ITT population by treatment group as randomized. A by-patient listing of all deviations will be provided.

Patient eligibility including inclusion and exclusion criteria that were not met at randomization will be summarized for all patients in the ITT population.

9.3 Demographic Characteristics

The following patient characteristics collected for the ITT Population will be presented in data listings and summarized by treatment regimen and overall:

- Age at informed consent (continuous and categorical variable: <50, ≥50 to <65, ≥65) will be summarized
- Sex
- Of childbearing potential (Yes/No)
- Ethnicity
- Race
- Geographic region: North America (United Stated and Canada), Europe (xxx)

9.4 Disease Characteristics and Previous Therapies

Medical and Oncology History:

All medical history verbatim terms will be coded using the MedDRA version 21.1 and ordered by system organ class (SOC) and preferred term (PT). At each level of summation (SOC, PT), patients reporting more than one medical condition will be counted only once.

Study-Specific Disease History: For each patient, date and stage of initial diagnosis, primary site of disease (ovarian, fallopian tube, or peritoneal), histologic features and grade, and current extent and location of disease will be listed. A summary table will summarize these disease history characteristics by treatment arm and overall.

Prior Procedures/Surgeries for Ovarian, Fallopian Tube, or Peritoneal Cancer: All previous procedures or surgeries for ovarian, fallopian tube or peritoneal cancer will be listed by date of procedure. By treatment arm and overall, number of patients reporting at least one prior procedure/surgery will be summarized. Additional characteristics summarized will include whether primary debulking, or interval debulking surgery with neoadjuvant therapy were performed, outcomes, as well as any debulking surgeries performed for recurrent disease.

Prior Anticancer Therapy for Ovarian, Fallopian Tube, or Peritoneal Cancer: All prior anticancer therapies received, and whether ongoing, will be listed by date of first dose. A summary table will be provided by treatment arm and overall for number of patients reporting at least one prior anticancer therapy, previous treatment-free, platinum-free, and taxane-free intervals, therapy type, mode of administration of chemotherapy, best response achieved, and reason for discontinuation of therapy (toxicity, disease progression, or Other) and related information.

Prior Radiotherapy for Ovarian, Fallopian Tube, or Peritoneal Cancer: A listing will display all entries for prior radiotherapies received by date of first dose. Patients who received at least one prior radiotherapy for ovarian, fallopian tube, or peritoneal cancer, its site, administrative setting, and total dose will be summarized by treatment arm and overall.

9.5 Medical History

Non-Cancer Medical History: As noted on the eCRF, a complete medical history, including any clinically significant medical conditions, will be collected during Screening and presented in a listing and summary table. Verbatim terms will be coded using the MedDRA version 21.1 and ordered by system organ class (SOC) and preferred term (PT). At each level of summation (SOC, PT), patients reporting more than one medical condition will be counted only once.

Medical History for Non-Ovarian, Non-Fallopian Tube, Non-Peritoneal Cancer: History of any other cancer(s) including type, stage at original diagnosis, and whether metastatic will be listed and summarized.

Prior Procedures/Surgeries, Anticancer Therapy, and Radiotherapy for Non-Study Related Cancers: Information collected on any prior procedures/ surgeries, anticancer therapy, and radiotherapy for other cancer(s) will be identical to that for study-specific cancer and presented in data listings and summary tables as described above.

Prior Cancer Panel/Molecular Profiling Results: Analysis will be described in the Biomarker SAP.

History of tobacco and alcohol use: Patient history of tobacco and alcohol use as noted on the Demographics eCRF during Screening will be listed and summarized by treatment arm and overall.

9.6 Concomitant Medications and Subsequent Therapies

Any concomitant medication used by patients will be recorded on eCRF. Indication for use, whether taken for medical history or AE, start and end date, ongoing, dose, dose formulation, frequency, and route of administration will be noted. Medications are considered concomitant if exposure occurs during the treatment-emergent period. A patient reporting use of the same medication more than once will be counted once in the calculation of the number and percentage of patients who received that medication.

The imputation rules for missing start and end date of a concomitant medication are described in Appendix 1.

Verbatim terms from the eCRF will be mapped to Anatomical/Therapeutic Chemical (ATC) drug class (level 4) and generic drug names using the WHODD Global B3 September 2018 coding dictionary.

For each treatment arm, a listing will display all entries for medications received by a patient, ordered by “Start date”. The listing will display the recorded term from the eCRF and, the ATC level 2 class (therapeutic subgroup) and the preferred/generic drug name.

A summary table will be organized to display the therapeutic subgroup (level 2) and preferred/generic drug name. It will include counts and percentages of patients who reported using at least one medication in each therapeutic subgroup by treatment arm and overall.

A data listing will be provided for all concomitant procedures and/or surgeries.

Concomitant radiotherapy, blood transfusions, and subsequent anticancer therapies received will be listed and summarized by treatment arm and overall.

9.7 Extent of Exposure and Study Drug Compliance

All recorded information on oral dosing of relacorilant, including whether taken during fasting, any dose reductions and related reason, actual dose, any dose interruption and discontinuation during the cycle and end date, as well as drug accountability will be presented in a data listing by date of administration.

A separate data listing and summary table will present data collected on nab-paclitaxel administered via an IV infusion. Body surface area, whether dose reduced prior to infusion and reason, volume of prepared and administered dose, actual dose administered, whether infusion was interrupted and reason, and discontinuation will be included.

A table by treatment arm and overall will provide summary statistics on the following:

Number of Cycles of Treatment: The number of cycles for each study drug will be presented based on the last visit when the patient received treatment.

Duration of Exposure: The duration of exposure for each study drug will be presented in days and calculated as the date of last dose of study drug minus the date of the first dose of study drug, plus one.

Total Dose Received: The total dose received for each study drug will be the sum of the actual dose administered for the duration of exposure. For subjects where their dose received is either zero or missing, a received dose of zero is included in the total dose received derivation.

Total Dose Expected: The total dose expected is calculated for each study drug. The expected study drug dosing schedule is as follows:

For Arm A patients relacorilant is expected to be taken daily starting at Cycle1 Day 1. Nab-paclitaxel is expected to be taken on Day 1, 8, and 15 of each cycle.

For Arm B patients, relacorilant is expected to be taken on Day 1, 2, 7, 8, 9, 14, 15, 16, and 28 of each cycle. Nab-paclitaxel is expected to be taken on Day 1, 8, and 15 of each cycle.

For Arm C nab-paclitaxel is expected to be taken on Day 1, 8, and 15 of each 28-day cycle.

The expected drug dosing schedule is used in combination with the actual date and dose of study drug administration to calculate the total dose expected. A subject will have expected dose calculations based on all days within a cycle as determined by the earliest start date and the latest end date within a given cycle. For subjects where their dose received is either zero or missing, an associated expected dose is included in the total dose expected derivation.

The planned dose for relacorilant will reflect the allowed dose titrations for patients on Arm A. For patients who escalate to 125 mg and then again for patients who escalate to 150 mg the planed dose will be escalated as well. If a patient goes down a level on the next cycle, for example from 125 mg to 100 mg the planned dose will reflect 100 mg for this cycle and

following cycles. If there are reductions lower than 100, the planned dose remains at 100 mg. For Arm B, the planned dose should always be 150 mg.

Relative Dose Intensity: Relative dose intensity is calculated for each study drug as the total dose received divided by the total dose expected, multiplied by 100.

Due to risk of neutropenia, all patients in Arm A (continuous relacorilant), Arm B (intermittent relacorilant), and the crossover will receive prophylactic G-CSF. Patients in Arm C (comparator) will receive G-CSF as per the Investigator's standard practice.

Patients who are at high risk for neutropenia in Arm C will also receive prophylactic G-CSF. Prophylactic G-CSF will consist of at least one injection of G-CSF the day after the nab-paclitaxel infusion. Patient use of G-CSF factors will be listed and summarized by treatment arm and overall.

9.8 Efficacy Analyses

The ITT analysis population will be used to address the primary as well as secondary efficacy objectives of the study. Disease response and progression assessed according to RECIST v1.1 by the Investigator or local radiologist will provide the basis for efficacy endpoints.

Additionally, the GCIG criteria for definitions of response and progression in ovarian cancer clinical trials (Rustin 2011) will be employed for select outcomes, as calculated using CA-125 local laboratory results.

At all scheduled visits, data recorded for target, non-target, and new lesions, and Investigator response assessment will be presented in by-patient listings. Summary tables and figures will be provided for endpoints as described in the following sections.

Stratified analyses will use the same stratification factors that were used to stratify the randomization schedule as documented in IVRS/IWRS. The stratification factors include the following:

Treatment-free interval from most recent taxane (relapse within 6 months vs. greater than 6 months)

Presence of ascites (yes vs. no).

9.8.1 Multiplicity Adjustment for Efficacy Analyses

The Hochberg procedure to control the familywise error rate will be used for hypothesis testing. The two hypotheses of group A vs. placebo and group B vs. placebo will be tested simultaneously to maintain the overall two-sided alpha level of 0.05.

In accordance with the Hochberg procedure decision rules: The resulting p-values for the two tests will be ordered from largest to smallest. If the larger p-value is <0.05, then all p-values are <0.05 and all null hypotheses will be rejected. Otherwise, if the smaller p-value is <0.025 (the adjusted alpha-level for the Hochberg procedure), then that null hypothesis is rejected. This rule

applies to the current case of k=2 hypotheses only. In the general case, the adjusted alpha-level is determined by the formula: α/k, where k is the number of the test being performed.

9.8.2 Primary Efficacy Endpoint

Progression-Free Survival (PFS) is defined as the time from date of randomization to the date of first documented PD by RECIST v1.1 (as determined by the Investigator at the local site) or death due to any cause, whichever occurs first.

PFS (months) = (earliest date of progression, death, or censoring – date of randomization + 1)/30.4375

All events of disease progression or death will be counted regardless of whether the event occurred while the patient was on study drug or had previously discontinued treatment. Patients who do not experience disease progression or death before the analysis cutoff date will be censored at the date of last adequate tumor assessment. Censoring will also be applied to patients with a disease progression event or death that occurs after two or more consecutively missed tumor assessments (no scans within 119 days of progression). Date of censoring for these patients will be based on the last tumor assessment prior to missing the assessments. Censoring rules are summarized in Table 1.

Table 1 Censoring Rules for the Primary Analysis of PFS

Censoring Categories	Date of Censoring
Patients who did not have baseline or postbaseline tumor assessments and did not die on or before the data cutoff date	Randomization date
Patients who did not have documented progression as determined by the Investigator and did not die on or before the data cutoff date	Date of the last adequate tumor assessment on or before the data cutoff date
Patients who did not have documented progression as determined by the Investigator on or before initiation of a new anticancer therapy and did not die on or before the data cutoff date	Date of the last adequate tumor assessment on or before initiation of a new anticancer therapy and on or before the data cutoff date
Patients who had 2 or more consecutive missed scheduled tumor assessments immediately prior to disease progression	Date of the last adequate tumor assessment without evidence of disease progression before the 2 missed tumor assessments and on or before the data cutoff date
Patients who did not have documented progression as determined by the Investigator and died more than 119 days from most recent tumor assessment.	Date of the last adequate tumor assessment on or before the data cutoff date

If a patient meets the criteria for more than 1 censoring rule, PFS will be censored at the earliest censoring date.

9.8.2.1 Primary Analysis

Hazard ratios for patients in treatment Arms A and B versus the reference Arm C, 2-sided 95% confidence intervals (CIs), and P-values will be obtained via stratified Cox proportional hazards models that includes treatment as a covariate and are stratified by stratification variables used at randomization.

The log-rank test, stratified by stratification variables used at randomization, will be used to compare treatment Arms A and B versus Arm C.

Conclusions about whether at least one of the combination therapies is truly different from the comparator arm will be drawn from Hochberg's step-up procedure, as described in Section 9.8.1.

Survival across treatment arms will also be graphically displayed in Kaplan-Meier plots.

9.8.2.2 Sensitivity Analyses

A sensitivity analysis of PFS to assess the impact of postbaseline anticancer therapies will be performed. For this analysis, PFS is defined as the time from randomization until the date of progression as determined by the Investigator, initiation of a new anticancer therapy, or death due to any cause, whichever occurs first.

Additionally, a sensitivity analysis of PFS to assess the impact of treatment discontinuation for any reason will be performed. For this analysis, patients who discontinue treatment before radiographic progression as determined by the Investigator or death will be considered to have a PFS event at the time of the study treatment discontinuation. PFS is defined as the time from randomization until the date of progression as determined by the Investigator, study treatment discontinuation for any reason, or death due to any cause, whichever occurs first.

A third sensitivity analysis will look at clinical progressions in addition to radiographic progressions. In this analysis, patients who progress clinically as determined by the Investigator will be considered to have a PFS event. In this analysis, PFS is defined as the time from randomization until the date of clinical or radiographic progression as determined by Investigator, or death due to any cause, whichever occurs first. Censoring rules described in Table 1 will apply.

9.8.3 Secondary Efficacy Endpoints

Each secondary efficacy endpoint will be evaluated at the 2-sided 0.05 level of significance without adjustment for multiplicity of testing. P-values from secondary and exploratory tests will be considered descriptive.

Progression-Free Rate at 6 and 12 months: The proportion of patients who are progression-free (as defined above) at 6 and 12 months will be summarized for each treatment arm and overall using Kaplan-Meier estimates.

Objective Response Rate: By-treatment summary tables will include distribution of the response outcomes at each assessment visit. ORR is defined as the proportion of patients with measurable

disease at Baseline who achieve a complete response (CR) or partial response (PR) by RECIST v1.1 (confirmation not required).

The stratified Cochran-Mantel-Haenszel method at a two-sided 0.05 significance level will be used for hypothesis testing of ORR by Investigator between treatment groups A and C, and B and C. An unstratified p-value will also be provided as a sensitivity analysis. Point estimates of ORR, the difference in response rates between treatment groups A and C, and B and C, and the two-sided 95% CIs for the point estimates and the differences will be provided using exact methods.

Best Overall Response: For each patient, BoR will be derived from all Investigator assessments recorded from the date of randomization to PD or death. BoR rates will be summarized by the number and percentage of patients within each response category (CR, PR, stable disease, PD, or not evaluable) for the ITT population.

Waterfall plots will visually illustrate the maximum percent change in the target lesions' longest diameter measured on the response axis, with vertical bars representing the BoR of CR, PR, SD, or PD.

Duration of Response: DoR is defined as the time from the date of first documented CR or PR until first observation of PD or death due to any cause, whichever is earlier and will be assessed only in patients who have a response at any time on study. Patients who do not experience PD and are alive as of the analysis cutoff date will be censored at the date of last adequate tumor assessment. Censoring rules in Table 1 will be applied as well.

DOR (months) = (earliest date of progression, death, or censoring – date of first documented objective response + 1)/30.4375

Estimates of median DoR with 95% CIs will be computed for each treatment arm using the Kaplan-Meier method. Kaplan-Meier graphs will visually display DoR by treatment arm.

Overall Survival: Date and cause of death, along with any post-therapy information, will be collected for all patients, including those who discontinue treatment, at 3-month intervals starting from the date of progression to death, loss to follow-up, or study termination by Sponsor. For patients who withdraw consent, public records will be searched for survival status as allowed per local laws.

OS is defined as the time from the date of randomization to the date of death due to any cause. If a patient has not died before the analysis cutoff date, OS will be censored at the date of last contact on or before the data cutoff date. The date a patient was last known to be alive before the data cutoff date is described in Section 12.3.

Median, 25th and 75th percentiles of OS, in months, with 95% CIs will be summarized and plotted graphically by treatment arm and overall using the Kaplan-Meier method. The HR and the two-sided 95% CI will be estimated using a stratified Cox regression model with treatment as a covariate. The log-rank test, stratified by stratification variables used at randomization, will be

used to compare treatment Arms A and B versus Arm C. The resulting p-value will be considered descriptive.

OS (months) = (earliest date of death or censoring – date of randomization + 1)/30.4375

An evaluation of OS will be performed at the time of the primary analysis after 135 PFS events have occurred. An additional OS analysis will be performed when at least 120 OS events have occurred, which will be used for the purposes of final OS reporting.

Disease Response via RECIST 1.1 and GCIG Criteria

Disease response in this study will primarily be evaluated via RECIST v1.1. The GCIG criteria (Rustin 2011) for definition of response in ovarian cancer clinical trials will also be utilized for determining efficacy. Patients in the ITT population who have an initial CA-125 level of at least twice the upper limit of the reference range within 2 weeks before starting treatment will be considered eligible and evaluable for the GCIG response criteria. Results will be presented separately and combining one or both criteria for RECIST v1.1 and CA-125 response.

CA-125 Response: Patients without initial measurable disease either because no measurable disease is evident on radiological imaging or because appropriate imaging was not performed may be evaluated using the GCIG criteria. A 50% or greater reduction in CA-125 from a pre-treatment sample that is confirmed and maintained for at least 28 days will be defined as a CA-125 response. The date when CA-125 level is first reduced by 50% will be the date of CA-125 response. Patients who achieve a CA-125 response and whose CA-125 level falls within the reference range will be classified as CA-125 complete responders.

To calculate response per GCIG criteria, an intent-to-treat analysis will be used that includes all randomized patients with an initial CA-125 level of at least twice the upper limit of the reference range as eligible and evaluable. In addition, as a separate analysis, those patients who have a CA-125 response and whose CA-125 level falls to within the reference range can be classified as CA-125 complete responders. In Table 2 and Table 3 where CA-125 is stated as normalized or normal, means within the reference range.

Evaluation of Best Overall Response in Patients without Initial Measurable Disease and Evaluable by CA-125 (GCIG)

CA-125 may be used to evaluate response in patients without initial measurable disease either because no measurable disease is evident on radiological imaging or because appropriate imaging has not been performed as demonstrated in Table 2.

Table 2 Evaluation of Best Overall Response in Patients Without Initial Measurable Disease and Who are Evaluable by CA-125 (GCIG)

CA-125	Nontarget Lesions [a]	New Lesions	Overall Response	Best Response for This Category Also Requires
Response and Normalized	CR	No	CR	Confirmed and maintained for at least 28 days
Response	Non-PD	No	PR	
Normalized but no response	Non-CR/Non-PD	No	SD	
Non-PR/non-PD	Non-PD	No	SD	
PD	Any	Yes or No	PD	
Any	PD [b]	Yes or No	PD	
Any	Any	Yes	PD	

Abbreviations: CR, Complete response; PD, progressive disease; PR, partial response; SD, stable disease.
[a] Nontarget lesions include ascites and peritoneal thickening, which are not measurable according to RECIST.
[b] Unequivocal progression in nontarget lesions may be accepted as disease progression.

Evaluation of Best Overall Response in Patients with Initial Measurable Disease and Who are Also Evaluable by CA-125 (GCIG)

A report that combines both CA-125 and RECIST v1.1 criteria is likely to include patients who are measurable by one or both of the criteria and who may have events at different time points. It should be determined according to Table 3. In patients who have measurable disease by both criteria, the date of response will be the date of the earlier of the two events if this approach to combined response reporting is to be used. In the combined assessment of CA-125 and RECIST v1.1 response, the following algorithm applies when determining the best overall response. If patients have progressive disease (PD) according to RECIST v1.1 within 28 days of CA-125 response, they are classified as having PD. If the PD according to RECIST v1.1 occurs more than 28 days from the CA-125 response, they are classified as having partial response. Patients whose best response according to RECIST v1.1 is stable disease but who have a CA-125 response are classified as CA-125 responders.

Table 3 Best Overall Response in Patients with Measurable Disease and Who are also Evaluable by CA-125 (GCIG)

Target Legion [a]	Nontarget [b]	New Lesion	CA-125	Best Overall Response
CR	CR	No	Normal	CR
CR	Non-CR Non-PD	No	Not PD	PR
CR	CR	No	PR but not normal	PR
CR	NE	No	PR	PR
PR	Non-PD or NAE	No	Not PD	PR
NAE	Non-PD	No	PR	PR
PD or New >28 days from CA-125 PR [c]			PR	PR
SD	Non-PD	No	PR	PR
SD	Non-PD or NAE	No	Not PR and not PD	SD
PD or New ≤28 days From CA-125 PR [c]			PR	PD
PD	Any	Yes or No	Any	PD
Any	PD	Yes or No	Any	PD
Any	Any	Yes	Any	PD
Any	Any	Yes or No	PD	PD

Abbreviations: CA-125, cell surface antigen 125; CR, Complete response; NE, Not evaluated; NAE, not all evaluated; PD, progressive disease; PR, partial response; SD, stable disease.

[a] Target lesions include up to 5 measurable lesions (2 per organ) as defined by RECIST v1.1.

[b] Nontarget lesions include ascites and peritoneal thickening which are not measurable according to RECIST v1.1.

[c] Patients who have a CA-125 response that occurs more than 28 days from PD according to RECIST v1.1 are considered a PR, according to best response, but PD if the RECIST v1.1 PD is within 28 days of CA-125 response.

Reporting of Response According to both RECIST v1.1 and CA-125 (GCIG) Criteria

In this study, responses will be reported separately for both tumor response per RECIST v1.1 and CA-125 response per GCIG. A combined response endpoint based on both RECIST v1.1 and GCIG will also be reported. Tumor response will be assessed by the Investigator or local radiologist using RECIST v1.1. CA-125 response and the combined response will be derived based upon local CA-125 results.

Assessment in Crossover Patients

Efficacy endpoints of PFS, ORR, BOR, DOR, and disease response assessment as per RECIST v1.1 and the GCIG criteria described above from the time of PD (Baseline for combination therapy) on nab-paclitaxel alone will be reported separately for the subset of crossover patients who were in Arm C and Crossover to Arm A.

9.8.4 Exploratory Efficacy Endpoints

Exploratory Pharmacodynamic/Biomarkers Analyses

During this study, with the consent of patients, biological samples (e.g. blood, plasma, serum, or tumor tissue) will be obtained either for analysis during the study or future analysis. These samples will be used to develop a better understanding of the mechanisms of both treatment response (predictive biomarkers) and disease processes (prognostic biomarkers) and ultimately to identify which patients have a high probability to benefit from treatment with relacorilant and those who do not.

A central laboratory will conduct tests using a variety of techniques (e.g. immunohistochemistry and DNA/RNA analysis). Pharmacodynamic assays may be performed to correlate results of biomarker assessments to the physiological effects of relacorilant.

Pharmacodynamic/biomarker endpoints may include, but not limited to, analysis of baseline assessment and change from Baseline of:

- Tumor immunohistochemistry: Glucocorticoid receptor (GR) and immune markers such as [redacted]
- RNA analyses from circulating cells and tumor, where feasible.
- Cancer antigens such as CA-125, CA15-3, CA19-9 and/or carcinoembryonic antigen (CEA).
- Cytokines

Data listings will be provided for whether archival or recent (pre-treatment) tumor biopsy, optional paired tumor biopsies, and blood samples were obtained, the date of collection, as well as additional information recorded on the eCRFs.

Descriptive statistics will be presented for all the biomarker endpoints. Additional exploratory biomarker analyses of these and other assessments may be conducted and described in a separate Biomarker document.

Patient-Reported Outcomes and Quality of Life Assessment. Health-related PRO and QoL will be assessed in the Safety population using three standard and validated instruments. Baseline measures will be collected prior to the first dose of relacorilant or nab-paclitaxel, whichever is earlier, at the Screening visit. Patient response to the questions "Do you expect to have side effects?" (Y/N), and "Do you expect to have benefit" (Y/N) will also be collected at this visit to gauge any potential bias that could influence PRO/QoL assessments in this open label study.

Post-baseline assessments will be made every other cycle starting with Cycle 2 Day 1, End of Treatment visit, and 30-day follow-up visit. Patients will be asked to complete the Functional Assessment of Cancer Therapy Ovarian Symptom Index 18 (FACT NFOSI-18) (Jensen et al. 2011) first, followed by EuroQoL 5 Dimensions (EQ-5D-5L/VASc) (EuroQoL Group 1990), and Patient-Reported Outcome Measurement Information System (PROMIS) Physical Function (Cella et al. 2007, Rose et al. 2008, Rose et al. 2014).

FACT NFOSI-18: Patient responses to the 18 items of the instrument will be scored to obtain an overall and four subscale scores, with lower scores indicating greater symptom burden. Possible ranges for the calculated scores would be:

- Overall: 0 – 72
- Disease-Related Symptoms – Physical: 0 – 36
- Disease-Related Symptoms – Emotional: 0 – 4
- Treatment Side Effects: 0 – 20
- Function/Well-Being: 0 – 12

A data listing will include patient responses to all items reported at scheduled visits, as well as derived overall and subscale scores.

Descriptive statistics (mean, standard deviation, 95% CI, median, range) of the observed scores at Baseline, post-baseline visits, and change from Baseline will be summarized at each time point by treatment arm and overall for each subscale and overall.

Overall and within each subscale, mean change in scores between the groups will be assessed, using a linear mixed model for repeated measures (MMRM) analysis using mixed effects model that considers the scores at each assessment point up to 6 months or PD, whichever is later. Crossover assessments will be excluded. When a patient has a missing scheduled assessment, it will be imputed with an unscheduled assessment or EOT assessment which is within one month of the scheduled timepoint, if available. All other unscheduled assessments will not be included. The remainder of the EOT assessments will be summarized in the EOT visit for the summary statistics outputs. To aid in convergence for the MMRM analysis, only those visits up to and including C6D1 will be used in the model.

The variables in the model will be treatment, visit, treatment-by-visit, with baseline used as a covariate and adjusted for patient response to the two bias questions at the Screening visit. The MMRM model will include patients within treatment arms as random effects. An unstructured covariance structure will be used to model within-patient error. In case of convergence issues, the following covariance structures will be used until the convergence criteria is met, in this order: unstructured covariance, heterogeneous compound symmetry, compound symmetry. The Kenward and Roger method for calculating the denominator degrees of freedom for tests of fixed effects will be used.

Mean change in scores in treatment arms A and B versus the reference arm C and arm A versus B, with 95% CIs and P values (considered descriptive) will be reported.

EQ-5D-5L: The five dimensions of this instrument, mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, along with a visual analog score for overall health will be assessed at designated visits. Patients will respond to each dimension on a 5-level Likert-type scale and also quantitatively rate their overall health from 0 to 100, with 0 indicating the worst health imagined. Based on preferences identified by the US general population, a weighted index value will be calculated from patient responses to the 5 dimensions (v Hout B, Janssen MF, et al. 2012).

Patient responses recorded at each visit as well as the derived index score will be included in a data listing.

By treatment arm, a summary table will present health profile results as the proportion of patients reporting problems at each level for each dimension at baseline and follow-up visits.

A linear mixed model for repeated measures (MMRM) analysis using mixed effects model controlling for bias questions will be constructed to obtain mean differences in the weighted index value and visual analog score for patients in each of treatment arms A and B versus the reference arm C and arm A versus B. Associated 95% CIs and P values (considered descriptive) will also be presented. Crossover assessments will be excluded. When a patient has a missing scheduled assessment, it will be imputed with an unscheduled assessment or EOT assessment which is within one month of the scheduled timepoint, if available. All other unscheduled assessments will not be included. The remainder of the EOT assessments will be summarized in the EOT visit for the summary statistics outputs. To aid in convergence for the MMRM analysis, only those visits up to and including C6D1 will be used in the model.

The variables in the model will be treatment, visit, treatment-by-visit, with baseline used as a covariate and adjusted for patient response to the two bias questions at the Screening visit. The MMRM model will include patients within treatment arms as random effects. An unstructured covariance structure will be used to model within-patient error. In case of convergence issues, the following covariance structures will be used until the convergence criteria is met, in this order: unstructured covariance, heterogeneous compound symmetry, compound symmetry. The Kenward and Roger method for calculating the denominator degrees of freedom for tests of fixed effects will be used.

PROMIS Physical Function: Self-reported measure of physical capability, including functioning of upper extremities (dexterity), lower extremities (walking or mobility), central regions (neck, back), as well as instrumental activities of daily living such as running errands, will be obtained at scheduled visits.

A single Physical Function capability score will be calculated from the 47 items of the instrument. Response to each question, which could range from 1 to 5, will be summed for determining a total raw score. The final score will be represented by the raw score converted into a standardized T-score with a mean of 50 and a standard deviation of 10. Thus, a T-score of 60 would imply physical functioning one standard deviation better than average and a T-score of 40 would indicate physical functioning one standard deviation below average.

Data recorded at each visit, as well as the calculated Physical Function score, will be presented in a by-subject listing.

Mean score at Baseline, post-baseline visits, and change from Baseline will be summarized by treatment arm and overall.

A linear mixed-model-for -repeated-measures (MMRM) analysis using mixed effects model as described above will provide estimates of mean differences in the Physical Function of patients in each of the treatment arms A and B versus the comparator arm C as well as arm A versus B

over time. Crossover assessments will be excluded. When a patient has a missing scheduled assessment, it will be imputed with an unscheduled assessment or EOT assessment which is within one month of the scheduled timepoint, if available. All other unscheduled assessments will not be included. The remainder of the EOT assessments will be summarized in the EOT visit for the summary statistics outputs. To aid in convergence for the MMRM analysis, only those visits up to and including C6D1 will be used in the model.

The variables in the model will be treatment, visit, treatment-by-visit, with baseline used as a covariate and adjusted for patient response to the two bias questions at the Screening visit. The MMRM model will include patients within treatment arms as random effects. An unstructured covariance structure will be used to model within-patient error. If case of convergence issues, the following covariance structures will be used until the convergence criteria is met, in this order: unstructured covariance, heterogeneous compound symmetry, compound symmetry. The Kenward and Roger method for calculating the denominator degrees of freedom for tests of fixed effects will be used.

Healthcare utilization: Health care facility use, emergency department visits and inpatient hospital services over last two months will be summarized by treatment arm and presented in by-subject listing.

Time to second progression: The time to second progression (PFS2) will be defined as time from randomization to progression on subsequent anticancer therapy or death due to any cause, whichever occurs first. PFS2 analysis will be performed in the ITT population. Patients alive and for whom a second objective disease progression has not been observed should be censored at the last time known to be alive and without second objective disease progression. Censoring rules for PFS2 are described in Table 4.

Table 4 Censoring Rules for PFS2

Censoring Rules	Date of Censoring
Patients with no postbaseline assessments	Date of randomization.
Patients who had no first documented disease progression per RECIST 1.1 or death on study before data cutoff date	Date of the last tumor assessment before data cutoff date
Patients who had a documented first disease progression on study but did not continue with a subsequent anticancer therapy	Date of treatment discontinuation or date of the last tumor assessment before data cutoff date, whichever comes last
Patients who did not have a second documented disease progression on subsequent anticancer therapy before data cutoff	Date of the last available tumor assessment on or before the analysis data cutoff date or date of discontinuation of treatment, whichever comes last
Patients who started subsequent anticancer treatment but had no further tumor assessment information	Date of the start date of subsequent anticancer therapy

Censoring Rules	Date of Censoring
Patients who initiate a new anticancer therapy after start of subsequent anticancer therapy without evidence of a second documented disease progression	Date of the discontinuation of subsequent anticancer therapy or the analysis data cutoff date, whichever comes first

Kaplan-Meier methods will be used for calculating the median time to second progression in each treatment arm. A 2-sided 95% CI will be provided for this estimate.

Summary statistics for duration on subsequent therapy will also be reported.

Duration on subsequent therapy (months) = (end date – start date + 1)/30.4375

9.8.5 Subgroup Analyses

Additional sub-group analyses will be conducted including

- BRCA1/BRCA2 somatic or germline deleterious mutation vs. no BRCA1/BRCA2 mutation of clinical significance for the primary efficacy analysis of PFS,
- 1 prior line vs. 2 prior lines vs. 3 prior lines vs. 4 prior lines of therapy,
- prior Bevacizumab vs no prior Bevacizumab and
- prior PARP inhibitor (Olaparib, Rucaparib, Niraparib) vs no prior PARP inhibitor.

The subgroup analyses will use stratified log rank test and median time to PFS will be estimated for each subgroup by treatment using Kaplan-Meier method and the 95% CI will be calculated. The HR and the 95% CI will be estimated using a stratified Cox regression model. If there are convergence problems the analysis will be unstratified.

9.9 Pharmacokinetic and Pharmacokinetic/Pharmacodynamic Exposure/Safety Analyses

Intensive PK sampling will occur on Cycle 1 Day 15 and will consist of a total of 5 samples collected at the following time points: pre-dose (0 hour), 1, 2, 4, and 6 hours post-dose. The plasma concentrations of relacorilant and nab-paclitaxel will be assessed in the PKA population. The following, noncomprehensive list includes examples of PK parameters that will be calculated where possible and appropriate, by standard non-compartmental methods, for relacorilant and/or nab-paclitaxel:

- % AUC_{ex}: Proportion of $AUC_{0-\infty}$ estimated by extrapolation after t_z as a percentage.
- λ_z: Apparent terminal rate constant.
- AUC_{0-24h}: AUC values from time 0 to 24 hours post-dose.
- $AUC_{0-\infty}$: AUC values from time 0 extrapolated to infinity.
- AUC_{last}: AUC values from time 0 to time of last measurable concentration.
- C_{max}: Maximum concentration.
- C_{24}: Concentration at 24 hours post dose.
- T_{max}: Time to maximum concentration.

- T_{last}: Time after dosing of the last quantifiable concentration.

PK parameters listed above may be excluded or additional PK parameters may be calculated as warranted. PK parameters will be listed and summarized by treatment arm using descriptive statistics.

Additionally, exploratory pharmacokinetic/pharmacodynamic analyses will be conducted to evaluate the potential relacorilant and nab-paclitaxel exposure response relationships for efficacy and safety.

9.10 Safety Analyses

All safety analyses will be performed on the SAF population. Data collected on study drug exposure, adverse events, deaths, clinical lab assessments, concomitant medications and therapies, physical examination, vital signs, 12-lead ECG, ECOG performance status will be presented in data listings and summary tables.

9.10.1 Adverse Events

Adverse events will be collected immediately following signing of informed consent and will continue until 30 days after the last dose of relacorilant or nab-paclitaxel, whichever is latest. An abnormal laboratory value that leads to a dose modification or patient withdrawal from the study will be recorded as an AE. Events that occur after the first dose of either study treatment and up to and including 30 days after administration of the last dose of either or prior to the first dose of the crossover treatment (combination relacorilant and nab-paclitaxel), whichever occurs first will be considered treatment-emergent adverse events (TEAEs). Adverse events reported more than 30 days after the last dose of study treatment will be considered post-treatment AEs. The treatment emergent adverse events definition for the cross over period is applicable to subjects on arm C who chose to crossover after progression and consists of events which occur after initiation of crossover treatment and up to 30 days after administration of the last dose of either treatments in the crossover period. TEAEs during the crossover period will be summarized separately from the primary treatment period.

For this study, attributes of AEs that must be assigned by the Investigator will include description of event, dates of onset and resolution, severity, relationship to study treatment, seriousness criteria if applicable, and action taken.

Incidence of AEs will be listed and summarized using the Medical Dictionary for Regulatory Activities (MedDRA) version 21.1 by system organ class and preferred term. A hierarchical listing will display the MedDRA system organ classes represented in the data, and within each system organ class, the listing will display each unique preferred term ordered alphabetically. At each level of summation of system organ class and preferred term, patients reporting more than one AE will only be counted once. Similarly, multiple incidences of the same AE for each patient will be reported only once at the maximum severity. If relationship to study drug is missing, the adverse event will be counted as related. Adverse event listings will show missing relationship as missing.

All AEs, whether treatment-emergent or not, will be listed by treatment arm and individual patient, including dates of onset and resolution, whether ongoing, serious, NCI-CTCAE toxicity grade, action taken, outcome, and relationship to study treatment Serious TEAEs and TEAEs that lead to discontinuation of relacorilant, TEAEs that lead to discontinuation of nab-paclitaxel will be listed separately. Serious AEs occurring during Screening will be presented in a listing along with safety narratives.

By treatment arm and overall, summary tables will be provided for all TEAEs, Grade 3 or greater TEAEs, serious TEAEs, treatment related TEAEs, TEAEs leading to discontinuation of relacorilant or nab-paclitaxel, and TEAEs leading to dose reduction or interruption of relacorilant or nab-paclitaxel.

9.10.1.1 Identified Risks and General Safety Topics

Neutropenia is an Identified Risk. Analysis methods are described in Section 9.10.1.

9.10.2 Deaths

All deaths, date and primary cause, whether they occurred during treatment or after 30-day follow-up, and whether an autopsy report is available will be listed and summarized.

9.10.3 Clinical Laboratory Tests

Screening Hepatitis B and C serologies and HIV, CA-125, and other clinical laboratory tests for safety (hematology, chemistry, coagulation, urinalysis) will be performed according to the study schedule, data processed by local laboratories, and entered directly into the EDC by site users. Table 5 lists all laboratory variables evaluated during the study. All results and normal ranges will be presented in data listings.

Table 5 Clinical Laboratory Variables Evaluated During the Study

Hematology	Serum Chemistry	Urinalysis (dipstick)
Red blood cell count	Sodium	Bacteria
Hemoglobin	Potassium	Blood
Hematocrit	Calcium	Urobilinogen
Platelet count	Chloride	Nitrites
White blood cell count (WBC)	Phosphorus [a]	Color
WBC with 5-part differential:	Magnesium [a]	Clarity
Neutrophils	Serum creatinine	pH
Lymphocytes	Total bilirubin	Specific gravity
Monocytes	Albumin	Ketones
Eosinophils	Alkaline phosphatase	Protein
Basophils	Aspartate aminotransferase	Glucose
	Alanine aminotransferase	Bilirubin
Coagulation	Glucose, document whether fasting or non-fasting	Leukocyte esterase
International normalized ratio		**Hormone**
Activated partial thromboplastin time	Blood urea nitrogen	Serum or urine human chorionic gonadotropin, if applicable
Prothrombin time	Bicarbonate	
Tumor Markers	Total protein	**Pharmacodynamic**
Cancer antigen 125	**Other [b]**	See Table 12 in the protocol for details.
	HIV immunoassay [c]	
	Hepatitis B/C serology [d]	

[a.] Magnesium and phosphorus at Screening and Day 1 of each cycle only.
[b.] Must be confirmed as negative prior to randomization and first dose of study drug.
[c.] 4th generation immunoassay that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen.
[d.] Serologic assays for hepatitis B surface antigen (HBsAg), antibody to hepatitis B core antigen (anti-HBc), antibody to hepatitis B surface antigen (anti-HBs), and anti-hepatitis C antibodies.

For safety lab panels, summaries of actual values and change from Baseline will be presented by treatment arm and overall at each assessment time point. Change from Baseline will be calculated as the post-baseline minus the baseline measurement. If either value is missing, the observation will not be included in the summary statistics.

For parameters that can be graded using NCI-CTCAE v5.0, shift tables that summarize counts and percentages of patients by severity grade at Baseline and worst post-baseline result will also be constructed.

Results from a serum or urine pregnancy test for patients of childbearing potential, performed prior to start of study treatment and subsequently every 12 weeks, will be listed.

9.10.4 Vital Signs and Weight

At designated visits, vital signs will be recorded and will include weight, systolic and diastolic blood pressure, resting heart rate, body temperature, and respiratory rate. A listing of all vital signs will be provided. Additionally, data will be summarized by treatment arm and overall, using descriptive statistics at Baseline, each study evaluation, and change from Baseline to evaluation. Change from Baseline will be calculated as the post-baseline minus the baseline measurement. If either value is missing, the observation will not be included in the summary statistics.

9.10.5 Electrocardiograms

At Screening and EOT visits, 12-lead ECG data, obtained in triplicate, will be classified as normal, abnormal but not clinically significant, or abnormal and clinically significant by the Investigator or qualified designee. All recorded results will be included in a listing, and results averaging the triplicate reading at screening and end of study will be summarized for each treatment arm as an absolute value and change from Baseline.

9.10.6 ECOG Performance Status

ECOG performance status assessed at Screening and subsequent study visits will be included in a data listing. Patient performance status will also be summarized by treatment arm and overall for each numeric grade at baseline and change from Baseline.

9.10.7 Physical Examination

Confirmation of a physical examination, including date of assessment, will be listed for each scheduled time point.

10 CHANGES FROM PROTOCOL IN STUDY CONDUCT OR STATISTICAL ANALYSIS PLAN

The protocol described the sample-size estimation methods incorrectly as using a one-sided test. This SAP corrected the section describing the sample-size calculation methods to indicate the test used is 2-sided.

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12 APPENDIX

12.1 Imputation of Missing/Partially Missing Dates

Missing data will not be imputed unless otherwise specified.

For safety analyses, incomplete date of last dose of study drug and incomplete start date of a new antitumor treatment that are missing the day of the month, the 15th of the month will be used to impute the missing data. When imputing partial last dose dates, the last assessment date and death date will be taken into consideration. This imputation rule will be used to determine the treatment-emergent period.

Adverse Events and Concomitant Medications

The imputation rule for the safety analyses will be used to address the issues with partial dates. The imputed dates will be used to determine the treatment-emergent period. For adverse events with a partial date, available date parts (year, month, and day) of the partial date will be compared with the corresponding date components of the start date and end date of the treatment-emergent period to determine if the event is treatment emergent. When in doubt, the adverse event will be considered treatment emergent by default. The following rules will be applied to impute partial dates for adverse events:

If start date of an adverse event is partially missing, impute as follows:

- If both month and day are missing and year = year of treatment start date, then set to treatment start date
- If both month and day are missing and year ≠ year of treatment start date, then set to January 01
- If day is missing and month and year = month and year of treatment start date, then set to treatment start date
- If day is missing and month and year ≠ month and year of treatment start date, then set to first of the month
- If only year is missing or start date is completely missing, set to treatment start date as long as adverse event end date is not before treatment start date

If end date of an adverse event is partially missing, impute as follows:

- If both month and day are missing, then set to December 31
- If only day is missing, then set to last day of the month
- If only year is missing or end date is completely missing, do not impute

When the start date or end date of a medication is partially missing, the date will be imputed to determine whether the medication is prior or concomitant (or both). The following rules will be applied to impute partial dates for medications:

If start date of a medication is partially missing, impute as follows:

- If both month and day are missing, then set to January 01
- If only day is missing, then set to the first of the month

If end date of a medication is partially missing, impute as follows:

- If both month and day are missing, then set to December 31
- If only day is missing, then set to last day of the month

If only year is missing or start date or end date of a medication is completely missing, do not impute.

Primary Cancer Diagnosis

If the diagnosis date of primary cancer is partially missing, the following rules will be applied to impute partial dates:

- If both month and day are missing and year = year of treatment start date, then set to treatment start date.
- If both month and day are missing and year ≠ year of treatment start date, then set to December 31.
- If day is missing and month and year = month and year of treatment start date, then set to treatment start date.
- If day is missing and month and year ≠ month and year of treatment start date, then set to the last day of the month.

12.2 Visit Windows

Visit windows will be used to associate assessments with a scheduled visit for summarizing data by visit.

Study visits will align with nab-paclitaxel infusion days during the Treatment Phase. Screening hematology and chemistry laboratory tests can be used for the Cycle 1, Day 1 values if collected within 48 hours of the first dose of study treatment. For all other visits, hematology and chemistry should be performed within the prior 24 hours (relative to the study visit/nab-paclitaxel infusion).

If more than one assessment occurs within a given visit window, the assessment closest to the target date will be used in summaries for the given visit.

The Follow-up Visit should be performed 30 days (±3 days) after the patient receives their final dose of relacorilant or nab-paclitaxel, whichever is latest.

The Long-term follow-up assessments should be done every 3 months (±7 days) until the endpoint of death, the patient is lost to follow-up, or until study termination by Corcept.

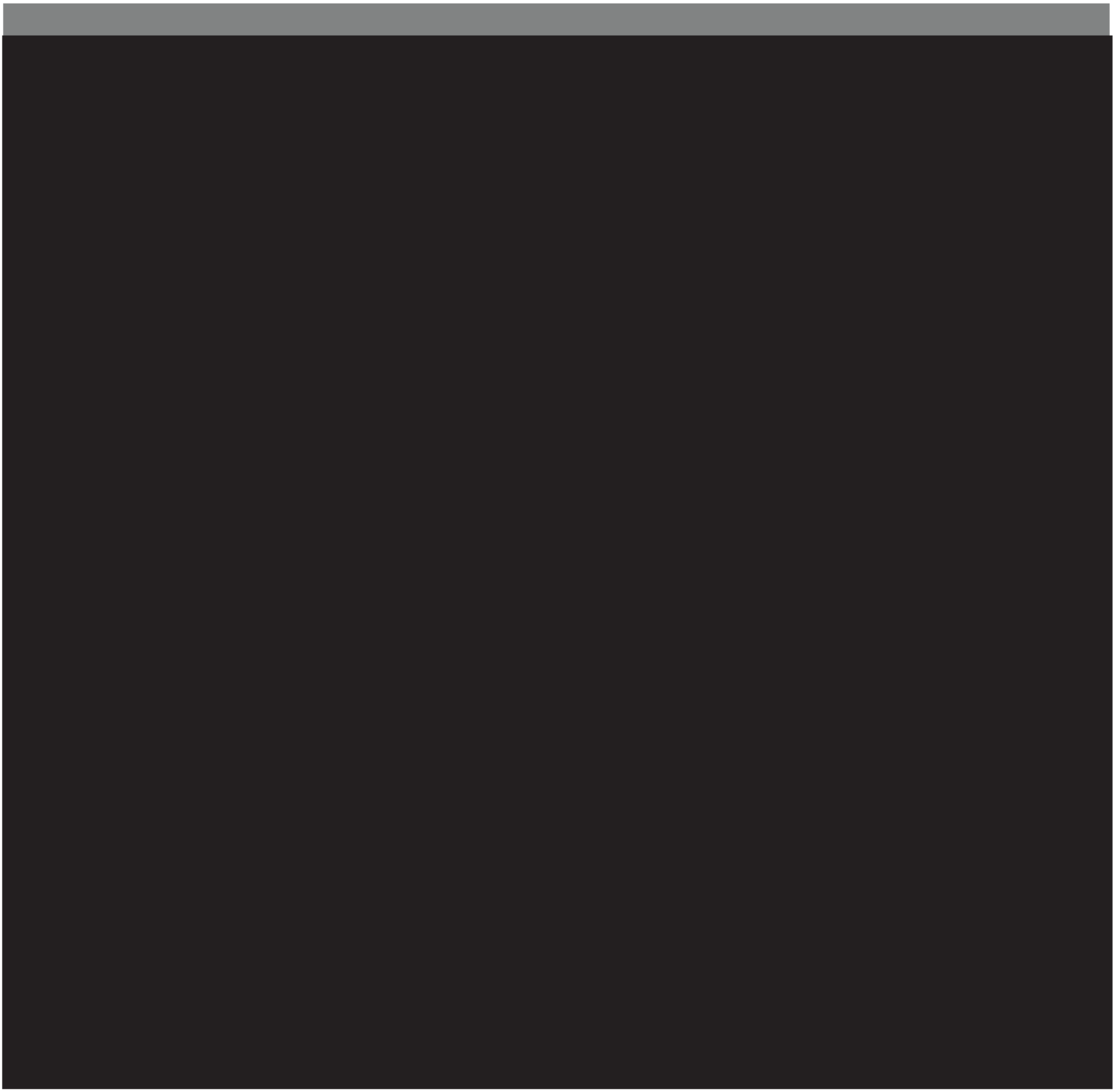
A serum or urine pregnancy test for female patients of childbearing potential will be performed prior to the first dose of study treatment (48-hour window from the first dose of study treatment) and then every 12 weeks ±7 days.

Tumor assessments will be performed within 28 days prior to the first dose of study treatment and then every 8 weeks (±7 days) from Cycle 1, Day 1 irrespective of treatment delays until unequivocal disease progression is documented, including in patients who prematurely discontinue therapy. The same method should be used for each assessment for a particular patient.

12.3 Overall Survival

For the overall survival analysis, deaths that occur on or before the data cutoff date will be considered an event. Data from patients who do not die on or before the data cutoff date will be censored at the last contact date. The last contact date will be derived as follows:

Source Data	Conditions
Date of randomization	No condition
Last contact date/last date patient known to be alive from Long-Term Follow-Up eCRF	Use if patient status is reported to be alive Do not use if patient status is reported unknown
End of study	Not lost to follow up
Start/end dates of postbaseline antineoplastic therapy	Nonmissing medication/procedure term
Start/end dates from drug administration record	Nonmissing dose. Doses of 0 are allowed.
End of treatment date from the End of Treatment eCRF	No condition
Tumor assessment (RECIST v1.1) date	Evaluation is marked as done.
Laboratory/PK collection dates	Sample collection marked as done.
Vital signs date	At least 1 nonmissing parameter value
ECOG performance status date	Nonmissing ECOG performance status
Start/end dates of adverse events	Nonmissing verbatim term
Physical examination	At least 1 nonmissing parameter value
ECG	At least 1 nonmissing parameter value



In Person Signer Events	Signature	Timestamp
Editor Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	2/19/2021 11:50:44 AM
Certified Delivered	Security Checked	2/19/2021 2:55:14 PM
Signing Complete	Security Checked	2/19/2021 2:55:37 PM
Completed	Security Checked	2/23/2021 10:58:38 AM

Payment Events	Status	Timestamps

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Browsers (for SIGNERS):	Internet Explorer 6.0?, Mozilla FireFox 1.0, NetScape 7.2 (or above)
Email:	Access to a valid email account
Screen Resolution:	800 x 600 minimum
Enabled Security Settings:	•Allow per session cookies •Users accessing the internet behind a Proxy Server must enable HTTP 1.1 settings via proxy connection

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