Protocol No: ARV-471-BC-201

An Open-Label, Randomized, Non-Comparative Phase 2 Study of ARV-471 or Anastrozole in Post-Menopausal Women With ER+/HER2– Breast Cancer in the Neoadjuvant Setting

Statistical Analysis Plan

Version: Draft 3.0

Date: 15 November 2024

SIGNATURE PAGE

[redacted]

15-Nov-2024

[redacted]

Date

Arvinas Estrogen Receptor, Inc (Arvinas)

[redacted]

15-Nov-2024

Date

Caidya

Table of Contents

MODIFICATION HISTORY

DRAFT VERSION HISTORY			
Draft 0.1	09Jan2023	[redacted]	The first draft based on Original Protocol dated on 27 May 2022
Draft 0.1	27Jan2023		Update based on Amendment #1 dated on 09 Jan 2023 and comments from internal reviewer
Draft 0.2	10Mar2023		Update based on Arvinas comments
Draft 0.3	17Apr2023		* Accept Arvinas updates and Caidya updates in draft 0.2 * Remove the summary for BOR and ORR, add summary for radiographic response per mRECIST in primary tumor during Cycle 6 * Update based on Arvinas comments on TFL shells
Draft 0.4	24Apr2023		Correct Typo
Final 1.0	25Apr2023		N/A
Draft 1.1	16Jan2024		Update based on Arvinas comments on dryrun TFLs
Draft 1.2	24May2024		Update based on Arvinas comments and new requests
Final 2.0	03June2024		Accept the updates in version 1.2 and make minor updates based on Arvinas comments
Draft 2.1	06Sep2024		Update CI round rules and baseline definition Add Estimands in the document
Draft 2.2	11Oct2024		Update based on the comments on dryrun #2 draft: * Update the definition of subgroups – derivation will be from primary target lesion(s) and laboratory data instead of IRT * Add summary for participants with Tumor Biopsies at each visit, medical history, absolute dose intensity, relative dose intensity, subgroup analysis for change of tumor size by baseline tumor size category

		[redacted]	* Add additional plots for KI-67 at surgery, ER AQUA Score, PR H-score * Update Concomitant Medications and TEAE definition
Draft 2.3	14Nov2024		Accept the updates in version 2.2 and the edits by Arvinas in version 2.2 Update based on the comments on dryrun #2 final: * update 'MedDRA 24.0' to 'MedDRA 27.0 or higher' * Tornado plot for treatment emergent adverse events with Grade 3 or higher by Preferred Term * Add imputation for PR H-score post-baseline value of 0 for the derivation of log transform analysis
Final 3.0	15Nov2024		Accept update in 2.3

ABBREVIATIONS

AE	adverse event
ALT	alanine aminotransferase
Alk Phos	alkaline phosphatase
AST	aspartate aminotransferase
AUC	area under the curve
BCS	breast conserving surgery
BID	twice daily
BP	blood pressure
CBR	clinical benefit response
CCCA	complete cycle cell arrest
CI	confidence interval
Cmax	maximum observed concentration
Cmin	minimum observed concentration
CRF	case report form
CTCAE	Common Terminology Criteria for Adverse Events
Ctrough	trough concentration
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
EDC	electronic data capture
ER	estrogen receptor
HER2	human epidermal growth factor receptor 2
IHC	immunohistochemistry
ISH	in situ hybridization
LSM	least square means
MedDRA	Medical Dictionary for Regulatory Activities
mPEPI	modified Pre-Operative Endocrine Prognostic Index
MRI	magnetic resonance imaging
NA	not applicable
NCI	National Cancer Institute
NET	neoadjuvant endocrine therapy
ORR	objective response rate
pCR	pathologic complete response
PD	pharmacodynamics(s)
PK	pharmacokinetic(s)
PR	partial response
PT	preferred term
QTc	corrected QT
QTcF	corrected QT (Fridericia method)
mRECIST	modified Response Evaluation Criteria in Solid Tumors
SAE	serious adverse event
SAP	statistical analysis plan
SD	Stable Disease
SOC	standard of care

t1/2	terminal elimination half-life
Tbili	total bilirubin
TEAE	treatment-emergent adverse event
Tmax	time to maximum concentration
TRAE	treatment-related adverse event
ULN	upper limit of normal

1 INTRODUCTION

The objective of this document is to detail the statistical methodology to be used in the summary and the final statistical analysis of clinical study protocol ARV-471-BC-201: "An Open-Label, Randomized, Non-Comparative Phase 2 Study of ARV-471 or Anastrozole in Post-Menopausal Women With ER+/HER2– Breast Cancer in the Neoadjuvant Setting".

This SAP is based on Protocol dated on 09 Jan 2023 and Case Report Forms (CRFs) dated on 23 Aug 2023.

2 STUDY DESIGN

This is a Phase 2, open-label, randomized, non-comparative, proof of concept study of ARV-471 or anastrozole in participants with ER+/HER2– breast cancer amenable to definitive surgical resection. The main goal of this study is to evaluate the biological activity of ARV-471 and anastrozole, respectively.

Participants will be randomized in a 2:1 manner to receive treatment on one of two treatment arms for approximately 5.5 months:

- Arm A: ARV-471 200 mg orally, daily and continuously until day before surgical resection (no later than C6D18 + 14 days)
- Arm B: anastrozole 1 mg orally, daily and continuously until day before surgical resection (no later than C6D18 + 14 days)

Stratification will occur based on the following features of the participant's breast cancer:

- Size of primary breast tumor (T-stage): ≤ 2 cm, > 2 to < 5 cm, or ≥ 5 cm.
- Ki-67 score (assessed locally): < 20% or ≥ 20%

Participants will have a screening biopsy, an on-treatment biopsy on C1D15 (+ 5 days), and surgical resection approximately 5.5 months after starting treatment (C6D18 ± 14 days). Participants will return for follow up 30 days (+ 7 days) after definitive surgical resection. After surgery, participants will receive SOC radiation and systemic therapy (chemotherapy, endocrine therapy, etc.) in accordance with local practice guidelines per the treating physician's discretion. No participant should take study drug dispensed for the trial after surgical resection, and no study drug should be dispensed after surgical resection.

2.1 Study Objectives, Endpoints, and Estimands

2.1.1 Study Objectives and Endpoints

Objective	Endpoints
Primary	
Evaluate the effects of ARV-471 and anastrozole, respectively, on Ki-67 expression in tumors after 2 weeks of treatment	Percent change in Ki-67 expression between baseline and C1D15 tumor biopsies
Secondary	

Evaluate the safety and tolerability of ARV-471 and anastrozole, respectively	Incidence of all adverse events, serious adverse events, and adverse events leading to study drug discontinuation
Evaluate the clinical and pathological response of ARV-471 and anastrozole, respectively	Pathologic stage, pathologic complete response (pCR)rate, and modified Pre-operative Endocrine Prognostic Index (mPEPI) score at the time of surgical resection (C6D18 ± 14 days); rates of breast conserving surgery (BCS); radiographic response of the primary tumor based on breast imaging during cycle 6; caliper-based response on C6D1
Exploratory	
Evaluate the effects of ARV-471 and anastrozole, respectively, on CCCA after 2 weeks of treatment	CCCA (Ki67 ≤2.7%) rates at C1D15
Evaluate ER degradation of ARV-471	Percent change in estrogen receptor (ER) protein levels between baseline and C1D15
Evaluate the effects of ARV-471 and anastrozole, respectively, on Ki-67, and ER degradation by ARV-471 in tumors at the time of surgical resection.	Changes in ER and Ki-67 expression between baseline and Cycle 6 surgical tumor samples; Rates of CCCA in the Cycle 6 surgical samples.
Explore additional biomarkers that may be associated with the effects of ARV-471 in tumor tissue	Additional biomarkers may include, but are not limited to, PgR expression, [redacted]
Correlate exposure of ARV-471 with ER reduction	Correlate population PK model-derived PK parameters (AUC, Cmin, Cmax) with ER reduction or other response parameters

2.1.2 Estimands

2.1.2.1 Primary Estimands

The primary estimand of this study is defined as the percent change in Ki-67 expression between baseline and C1D15 tumor biopsies observed from each Arm, respectively. Descriptive statistics will be provided to evaluate the effects of ARV-471 and anastrozole, respectively, on Ki-67 expression in tumors after two weeks of treatment. No comparisons between the treatment arms are planned.

Treatments: ARV-471 (Arm A) and anastrozole (Arm B)

Population: post-menopausal women with newly diagnosed and treatment naïve ER+/HER2– breast cancer that is amenable to definitive surgical resection. Participants must also have tumor that is at least 1.5 cm by imaging due to biopsy requirements for this study. The primary analysis regarding Ki-67 expression will be performed in all enrolled participants who received at least one dose of study treatment and had evaluable Ki-67 measurements from baseline and C1D15 visits.

Variable: the log-transformed Ki-67 after approximately two weeks of treatment as a percentage of the baseline value, ie, the ratio between the Ki-67 measurements obtained from C1D15 visit and baseline.

Intercurrent events: only participants with evaluable Ki-67 results from baseline and C1D15 visits will be included in the primary analysis. No participants will be censored or excluded due to any reasons other than missing Ki-67 data.

Population-level summary: the log-transformed percentage Ki-67 will be modelled using a GLM. Refer to Protocol Section 9.3.2 and the SAP for more details.

2.1.2.2 Secondary Estimands

There are no key secondary endpoints defined for this study. No estimands are defined for any of the secondary or exploratory endpoints.

2.2 Sample Size Considerations

There are no plans for formal comparisons between ARV-471 and anastrozole. No power calculations are needed. Approximately 150 participants will be randomized to the two treatment arms in 2:1 ratio (100 participants to the ARV-471 arm and 50 participants to the anastrozole arm). These numbers were chosen to provide meaningful information about the primary endpoint, ie, changes (on-treatment C1D15 vs baseline) in Ki-67 expression levels after approximately 2 weeks of treatment with ARV-471 and anastrozole, respectively.

Table 1 and Table 2 provide a list of probable scenarios demonstrating the width of the CIs for the primary endpoint under the assumption that 80% (ie, n=120) of the randomized participants will provide valid Ki-67 measurements from both their baseline and C1D15 visits. Table 2 indicates that the width of the 80% CIs of the mean percentage Ki-67 after 2 weeks of treatment by ARV-471 will not exceed 14% and the width of the 95% CIs will not exceed 21.6% if the mean percentage of the corresponding baseline values after 2 weeks of treatment ranges from approximately 20% to 40%. The planned sample size will provide estimates for the treatment effect in terms of the reduction of Ki-67 with reasonable precision.

Table 1 Confidence Intervals for Mean Percentage of Baseline Value in Ki-67 After Two Weeks

Number of participants/arm [a]	Mean percentage Ki-67 in two weeks [b]	SD of log-transformed percent change in Ki-67 [c]	80% CI [d]	95% CI [d]
100 (80 evaluable)	20%	1.0	(17.3%, 23.1%)	(16.0%, 25.0%)
	30%		(26.0%, 34.7%)	(24.0%, 37.5%)
	40%		(34.6%, 46.2%)	(32.0%, 50.0%)
	20%	1.2	(16.8%, 23.8%)	(15.3%, 26.1%)
	30%		(25.2%, 35.7%)	(23.0%, 39.2%)
	40%		(33.6%, 47.6%)	(30.6%, 52.2%)
50 (40 evaluable)	20%	1.0	(16.3%, 24.6%)	(14.5%, 27.5%)
	30%		(24.4%, 36.9%)	(21.8%, 41.3%)
	40%		(32.5%, 49.2%)	(29.1%, 55.1%)

Number of participants/arm [a]	Mean percentage Ki-67 in two weeks [b]	SD of log-transformed percent change in Ki-67 [c]	80% CI [d]	95% CI [d]
	20%	1.2	(15.6%, 25.6%)	(13.6%, 29.4%)
	30%		(23.4%, 38.4%)	(20.4%, 44.0%)
	40%		(31.2%, 51.2%)	(27.3% 58.7%)

a. Approximately 100 participants will be enrolled to the ARV-471 arm with 80 participants providing valid Ki-67 data. Approximately 50 participants will be enrolled to the anastrozole arm with 40 participants providing valid Ki-67 data.
b. Percentage Ki-67 in two weeks is defined as the ratio between Ki-67 reported from C1D15 visit and baseline respectively.
c. Ki-67 measurements are assumed to follow a log-normal distribution. The CIs are generated using the quantiles of the standard normal distribution on the log scale. Various values for the SD of the log-transformed Ki-67 percent change are provided to mimic the variability reported in the coopERA study (Hurvitz 2022).
d. The CIs are presented in the original percentage scale through exponential-transformation of the CIs generated using the log-transformed Ki-67 data.

Table 2 Confidence Intervals for the Ratio Between the Mean Percentage of Baseline Values for Ki-67 Observed from ARV-471 and Anastrozole Arms (Ki-67 Evaluable Participants N=120)

Mean percentage Ki-67 with ARV-471 [a]	Mean percentage Ki-67 with anastrozole [a]	SD of log-transformed percentage Ki-67 [b]	Difference of mean percentage Ki-67 (anastrozole – ARV-471)	80% CI for the ratio of mean percentage Ki-67 [c]	95% CI for the ratio of mean percentage Ki-67 [c]
20%	30%	1.0	10%	(1.17, 1.93)	(1.02, 2.20)
30%	40%			(1.71, 1.04)	(0.91, 1.96)
20%	30%	1.2		(1.11, 2.02)	(0.95, 2.38)
30%	40%			(0.99, 1.80)	(0.84, 2,11)
20%	28%	1.0	8%	(1.09, 1.80)	(0.95, 2.05)
30%	38%			(0.99, 1.63)	(0.86, 1.86)
20%	28%	1.2		(1.04, 1.89)	(0.88, 2.22)
30%	38%			(0.94, 1.71)	(0.80, 2.01)
20%	25%	1.0	5%	(0.97, 1.60)	(0.85, 1.83)
30%	35%			(0.91, 1.50)	(0.80, 1.71)
20%	25%	1.2		(0.93, 1.69)	(0.79, 1.98)
30%	35%			(0.86, 1.57)	(0.74, 1.85)

a. Assume the relative reduction in Ki-67 attributed to ARV-471 exceeds the reduction attributed to anastrozole by 5%, 8% and 10% respectively in various scenarios.
b. Assume the same SD for the log- transformed percent change in Ki-67 in either arm.
c. The ratio is defined as the mean percentage Ki-67 with anastrozole divided by the mean percentage Ki-67 with ARV-471. A ratio above unity (1) is in favor of ARV-471.

3 ANALYSIS SETS

For purposes of analysis, the following analysis sets are defined.

Analysis Set	Description
Full Analysis Set	All enrolled participants who were randomized. Participants are analyzed according to the treatment they have been randomized to.

Safety Analysis Set	All enrolled participants who receive at least 1 dose of study intervention.
Ki-67 Evaluable Set	All enrolled participants who were randomized and received at least one dose of study treatment and had evaluable Ki-67 measurements other than '0' or '< 1' from baseline and evaluable Ki-67 measurements from C1D15 visits.
Pharmacodynamic/ Biomarker Analysis Set(s)	The Pharmacodynamic/Biomarker analysis population is defined as all enrolled participants with at least 1 of the Pharmacodynamic/ Biomarkers evaluated at pre and/or post dose.
PK Concentration Analysis Set	The PK Concentration Analysis Set includes all participants in the Safety Analysis Set who have at least one plasma concentration (including those below the limit of quantification) for ARV-471, or ARV-473.

4 GENERAL CONSIDERATIONS

4.1 Programming Environment

All analyses will be conducted using SAS© version 9.4 or later.

4.2 General Statistical Methods

The statistical analyses will be presented for the different analysis sets as defined in Section 3.

4.2.1 Analysis Groups

The summary will be presented as ARV-471 200 mg, anastrozole 1 mg, and overall.

4.2.2 Descriptive Summaries

In general, numerical variables will be summarized using descriptive statistics, displaying the number of participants in the respective analysis group, the number of participants with data, mean, standard deviation, median, minimum (min) and maximum (max).

Categorical variables will be summarized by using frequency counts and percentages. In addition, the number of participants with missing values will be displayed. Unless otherwise specified, the denominators used for calculating sample proportions will be the number of participants for each level of the analysis group defined above in the specified statistical analysis set (or a subset of the statistical analysis set under use).

Statistical methods for efficacy endpoints are described in section 10.2.

4.2.3 Presentation Conventions

Means and medians will be presented by 1 additional decimal place and standard deviation will be presented by 2 additional decimal places than the standard presentation level of the respective data. Minimum and maximum values will be presented using the same number of decimal places as the original data. Confidence limits will be presented by 1 additional decimal place than corresponding point estimates.

If not otherwise stated, percentages will be presented to 1 decimal place. However, when the percentage (or estimated proportion) is 100% exactly, no decimal place will be shown, whereas a presented 100.0% implies that the percentage is in the half-open interval [99.95%, 100%). The number of decimal places may be adjusted, e.g., if the above default choices may lead to misinterpretation of the presented data.

If the number of participants in a category is 0, then percentage will not be displayed, and only a count of 0 will be shown. However, structural zeros (e.g., when the count is deemed to be 0 before obtaining actual data), missing data or inapplicable/unevaluable summaries will be presented as −, NA or NE.

In listings, data will be sorted by study part, arm, and participant. When appropriate by visit, scheduled timepoint or other identifiers for sequence or type of observation.

4.3 Covariates and Strata

The stratification factors include Size of primary breast tumor (≤ 2 cm, >2 to < 5 cm, or ≥ 5 cm) and Baseline Ki-67 local score (< 20% vs ≥ 20%).

4.4 Subgroups

The primary endpoint will be presented for subgroups defined by the following criteria that will be derived from primary target lesion(s) and laboratory data instead of IRT:

- Size of primary breast tumor (T-stage): ≤ 2 cm, >2 to < 5 cm, or ≥ 5 cm
- Baseline Ki-67 score (assessed locally): < 20% vs ≥ 20%
- Baseline Ki-67 score (assessed centrally): < 20% vs ≥ 20%

Other factors will be considered if the observed data imply potential findings of clinical interest.

4.5 Multiple Comparison/Multiplicity

This is a Phase 2 proof of concept study designed to generate data informing future studies about ARV-471. There are no plans for formal comparisons or hypotheses testing. There is no need for Type I error control. Descriptive statistics (including point estimates and two-sided CIs) will be provided for all parameters of interest. For information purposes, all the 2-sided CIs will be reported on both 80% and 95% confidence levels.

5 DEFINITIONS & DATA HANDLING CONVENTIONS

5.1 Study Day, Duration, and Study Periods

5.1.1 Study Day

Day 1 will be the date corresponding to the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.

Unless otherwise specified, day is the primary time unit for derived time and durations. Derived time units include week=7 days, month=30.436875 days, and (Gregorian) year=365.2425 days=12 months. Thus, 1 month and 4 weeks are considered different.

5.1.2 Duration

Unless otherwise specified, duration of time is defined from the starting day through the ending day, inclusive of both boundary days.

5.2 Analysis Visit Windows

Participant visits will be presented according to the nominal visit as obtained upon the eCRF. All values will be included in the participant data listings.

5.3 Baseline and Change from Baseline

The baseline value is defined to be the last non-missing assessment on/before the date of the first ARV-471/anastrozole dose. In case the randomized subject does not receive any treatment, the baseline will be the last assessment on/before the date of randomization. Change from baseline (CFB) calculations for a treatment window assessment will be the applicable treatment window assessment minus the baseline assessment. If either the treatment window assessment value or the baseline value is/are missing, then CFB will be set to missing for descriptive analysis purposes, unless otherwise specified.

5.4 Missing Data

5.4.1 Partial or Missing Dates and Time

The incomplete dates (e.g., start and/or stop dates of AE, concomitant medication) will be assumed as the most conservative value possible. In general, unless the available parts of the partial date preclude an AE to be treatment-emergent, the AE will be considered treatment-emergent; similarly, unless the available parts of the partial date exclude a medication to be concomitant, the medication will be considered as a concomitant medication.

For example, if the start date has a missing day value, the first day of the month will be imputed for study day computations, etc. If day is missing for an end date, the last day of the month will be imputed. If the start date has a missing month value, the first month of the year will be imputed for study day computations, etc. If month is missing for an end date, the last month of the year will be imputed. For determination of treatment-emergent status, the start date will be imputed as the date of the first dose of study drug, unless there is clear evidence (through comparison of partial dates/times) to suggest otherwise.

Date imputation will only be used for computational purposes such as treatment-emergent status, etc. Actual data values, as they appear in the original eCRFs, will be presented in the participant data listings. Non-monotone partial dates (e.g., day and month are non-missing but year is missing) need to be queried and resolved before DBL.

5.4.2 Other Missing Values

Every effort will be made to obtain the required data at each scheduled evaluation from all participants who have been enrolled. In general, missing data will not be imputed and the data will be analyzed as they are recorded.

6 STUDY POPULATION AND DISPOSITION

6.1 Analysis Sets

The number and percentage of participants in each analysis set as defined in Section 3 will be summarized using the Full Analysis Set as described in Section 4.2.1.

Corresponding data listing will be provided using the Full Analysis Set.

6.2 Participant Disposition

The number and percentage of the following will be summarized using the Enrolled Participants /Ki-67 Evaluable Set as described in Section 4.2.1, including:

- Completed Treatment per Protocol
- ARV-471/Anastrozole early discontinuation
- Reason for ARV-471/Anastrozole early discontinuation
  - Disease Progression per Response Criteria
  - Clinical Progression
  - Withdrawal of Consent
  - Significant non-compliance
  - Pregnancy
  - Death
  - Adverse Event
  - Study Terminated by Sponsor
  - Lost to Follow-up
  - Other
- Completed study per Protocol
- Study early discontinuation
- Reason for study early discontinuation
  - Withdrawal of Consent
  - Study Terminated by
  - Sponsor
  - Lost to Follow-up
  - Death
  - Other

Disposition of participants will be provided in a data listing using the Full Analysis Set.

Additionally, the number of participants with Tumor Biopsies (including Ki-67 and PgR636, etc.) at Screen/Cycle 1 day 15/ Cycle 6 day 18/Unscheduled will be summarized. The number and percentage of participants with the tested result or uninterpretable per test per visit will be summarized.

6.3 Protocol Deviations

Protocol Deviation Management version: 1.0 dated 04 Jan 2023 (by Translational Research In Oncology) defined the study specific procedures and responsibilities for managing Protocol Deviations. Protocol Deviation severity includes minor, major or critical. The deviations will be categorized as:

- Informed Consent
- IMP/NIMP

- Protocol Compliance
- Safety
- ICH/GCP

All protocol deviations in each arm will be summarized by severity and categories. Protocol Deviation will also be listed in the Full Analysis Set.

7 DEMOGRAPHICS AND DISEASE CHARACTERISTICS

7.1 Demographics and Baseline Characteristics

The following demographic characteristics will be summarized using Full Analysis Set and Ki-67 Evaluable Set as described in Section 4.2.1:

- Age (as reported in EDC) (n, mean, SD, minimum, maximum)
- Sex (female)
- Age group (age ≥ 60, or age < 60)
- Race (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or other Pacific Islander, White, Other, Unknown)
- Ethnicity (Hispanic or Latino, not Hispanic or Latino, not reported)
- Weight (kg) at baseline (n, mean, SD, minimum, maximum)
- Height (cm) at baseline (n, mean, SD, minimum, maximum)
- ECOG Status (0, 1)
- Size of primary breast tumor (T-stage) (≤ 2 cm, >2 to < 5 cm, or ≥ 5 cm)
- Post-menopausal reason (Prior bilateral oophorectomy, Age >= 60 years, Age < 60 and amenorrheic for at least 12 months and FSH/estradiol in the postmenopausal range)

Demographic characteristics will also be provided in a data listing using the Full Analysis Set.

7.2 Disease Staging and Disease Characteristics

The following disease staging and disease characteristics will be summarized using the Full Analysis Set and Ki-67 Evaluable Set described in Section 4.2.1:

- Time since initial diagnosis (months), defined as time from the date of initial diagnosis to the date of first ARV-471/anastrozole dose (n, mean, SD, minimum, maximum)
- Time since current staging (months), defined as time from the date of current staging to the date of first ARV-471/anastrozole dose (n, mean, SD, minimum, maximum)
- Primary diagnosis (ER+ HER2- Breast Cancer)
- Stage at initial diagnosis (Stage 0, Stage IA, Stage IB, Stage IIA, Stage IIB, Stage IIIA, Stage IIIB, Stage IIIC, Stage IV, Unknown)
- Disease stage at screening (Stage 0, Stage IA, Stage IB, Stage IIA, Stage IIB, Stage IIIA, Stage IIIB, Stage IIIC, Stage IV, Unknown)
- Primary tumor at initial diagnosis (TX , T0, Tis, T1mi, T1a, T1b, T1c, T2, T3, T4a, T4b, T4c)
- Primary tumor at screening (TX , T0, Tis, T1mi, T1a, T1b, T1c, T2, T3, T4a, T4b, T4c)

- Imaging modality for primary tumor at screening (CT, MRI, Ultrasound, Mammogram)
- Regional lymph node at initial diagnosis (cNX, cN0, cN1, cN2a, cN2b, cN3a, cN3b, cN3c)
- Regional lymph node at screening (cNX, cN0, cN1, cN2a, cN2b, cN3a, cN3b, cN3c)
- Distant metastasis at initial diagnosis (M0, M1, Unknown)
- Distant metastasis at screening (M0, M1, Unknown)
- Histopathological classification at initial diagnosis (In-Situ Carcinoma, Invasive Ductal Carcinoma, Invasive Lobular Carcinoma, Invasive Mixed Ductal and Lobular Breast Carcinoma, Invasive Carcinoma NOS, Invasive Adenocarcinoma NOS, Tubular Carcinoma, Invasive Mucinous Adenocarcinoma, Other)
- Histopathological classification at screening (In-Situ Carcinoma, Invasive Ductal Carcinoma, Invasive Lobular Carcinoma, Invasive Mixed Ductal and Lobular Breast Carcinoma, Invasive Carcinoma NOS, Invasive Adenocarcinoma NOS, Tubular Carcinoma, Invasive Mucinous Adenocarcinoma, Other)
- Histopathological grade at initial diagnosis (Grade 1, Grade 2, Grade 3, Grade X)
- Histopathological grade at screening (Grade 1, Grade 2, Grade 3, Grade X)
- Planned type of breast surgery (Breast conserving surgery, Mastectomy)

The disease staging and disease characteristics will be listed using Full Analysis Set.

7.3 Disease Staging at Post-Surgery

The number and percentage of subjects with the following disease staging at post-surgery will be summarized using the Full Analysis Set and Ki-67 Evaluable Set described in Section 4.2.1:

Pathologic Tumor - ypT, n(%)

- ypTx
- ypT0
- ypTis
- ypT1mi
- ypT1a
- ypT1b
- ypT1c
- ypT2
- ypT3
- ypT4a
- ypT4b
- ypT4c

Multiple Foci of Residual Tumor?, n(%)

- Yes
- No

Pathologic Lymph Nodes - ypN, n(%)

- ypNX
- ypN0
- ypN0(i+)
- ypN0(mol+)

- ypN1
- ypN1mi
- ypN1a
- ypN1b
- ypN1c
- ypN2
- ypN2a
- ypN2b
- ypN3
- ypN3a
- ypN3b
- ypN3c

Distant Metastasis (M), n(%)

- M0
- pM1
- Unknown

Lymphatic Vascular Invasion Classification, n(%)

- Present
- Not Present
- Unknown

The disease staging at post-surgery will be listed using Full Analysis Set.

7.4 Molecular Biology of Disease at Baseline

The molecular biology of disease - HER2 status, Ki67, Estrogen receptor, Progesterone receptor at baseline will be summarized using the Full Analysis Set and Ki-67 Evaluable Set:

- Perform of HER2 status, Ki67, Estrogen receptor, Progesterone receptor (Yes, No)
- Sample site of HER2 status, Ki67, Estrogen receptor, Progesterone receptor (Breast, Lymph Node, Other)
- HER2 analytical method (IHC, ISH)
- HER2 analytical result (0, 1+, 2+, 3+, Positive, Negative, Unknown)
- % of Tumor cells with Ki67 (assessed locally) (n, mean, SD, minimum, maximum, < 20% vs ≥ 20%)
- % of Tumor cells with Ki67 (assessed centrally) (n, mean, SD, minimum, maximum, < 20% vs ≥ 20%)
- % of Tumor cells with Estrogen receptor (n, mean, SD, minimum, maximum, < 10% vs ≥ 10%)
- % of Tumor cells with Progesterone receptor (n, mean, SD, minimum, maximum, < 1% vs ≥ 1%)

The molecular biology of disease will be listed using Full Analysis Set.

7.5 Prior Cancer Related Surgery/Biopsy

The following prior cancer related surgery/biopsy characteristics will be summarized descriptively using Full Analysis Set as described in Section 4.2.1:

- Any prior surgery/biopsy related to the disease under trial (Yes)

- Procedure (Sentinel node biopsy, Axillary sampling, Fine needle aspiration, Core needle biopsy, Other)
- Procedure location (Breast, Lymph node, Other)
- Laterality (Left, Right, Bilateral, Not applicable)
- Time since most recent surgery/biopsy (months), defined as time from the most recent date of surgery to the date of first ARV-471/Anastrozole dose (n, mean, SD, minimum, maximum)

7.6 Medical History

Medical histories are coded according to Medical Dictionary for Regulatory Activities (MedDRA version 27.0 or higher) and will be classified as system organ class and preferred terms.

The number and percentage of participants will be summarized according to system organ class and preferred terms. If a participant has more than one disease within a system organ class and/or preferred terms the participant will be counted only once per system organ class or preferred terms.

The medical history will be listed using the Full Analysis Set.

8 PROTOCOL-REQUIRED DRUG EXPOSURE AND COMPLIANCE

The dosing data for ARV-471 and Anastrozole be summarized descriptively using the Safety Analysis Set as described in Section 4.2.1.

The follow exposure parameters for ARV-471 and Anastrozole will be derived separately and will be summarized with n. mean, sd, median, min, max:

- **Duration of treatment** (week) is defined as the time from the date of first dose to the date of last dose
- **Cumulative dose** (mg) is the sum of 'Actual total daily dose' × (End date- Start date+1) per record
- **Absolute Dose Intensity** (mg/week) is defined as (Cumulative Dose (mg)/(Duration of Treatment (week).
- **Relative Dose Intensity** (%) is defined as (Absolute Dose Intensity (mg/week))/ (Initial Planned Weekly Dose (mg/week). ARV-471 Initial Planned Weekly Dose (mg/week) is 1400 mg/week (200*7). Anastrozole Initial Planned Weekly Dose (mg/week) is 7 mg/week (1*7).
- **Total planned dose** (mg) is the sum of 'Planned total daily dose' × (End date- Start date+1) per record
- **Compliance** is 100*(Cumulative dose/Total planned dose)
- Number of compliant patients (with compliance >= 80% - <= 120%).

The number and percentage of participants with dose discontinued, dose interrupted, dose reduced, dose increased, reasons for the action taken (Adverse event, Participant missed/Skipped dose, Medication error, Other) will be presented. All dosing data (including

the above derived dosing parameters) will also be presented in a data listing using the Safety Analysis Set.

9 PRIOR AND CONCOMITANT THERAPIES

Full Analysis Set will be used to list diagnostic and medical procedures.

9.1 Prior and Concomitant Medications

Prior and concomitant medications and on-study anti-cancer therapy will be coded according to WHO-Drug B3 Global version September 2024 or most current version with Anatomical Therapeutic Chemical (ATC) Classification System and preferred names (PN). Prior medications include the medications that are ended before Day 1. Concomitant medications include the medications that are used/started on/after Day 1 and within 30 days from the last administration of the study intervention (ie, study drug treatment or surgical resection, whichever occurs last).

The number and percentage of participants with prior medication or concomitant medications will be summarized by ATC level 2 category and preferred name will be summarized using the Full Analysis Set as described in Section 4.2.1. If a participant received more than 1 drug within an ATC2 or PN, the participant will be counted only once for this ATC2 and PN.

Prior and concomitant medications and on-study anti-cancer therapy will also be provided in a data listing using the Full Analysis Set.

10 EFFICACY ANALYSES

10.1 Assessment

10.1.1 Tumor Biopsies

Tumor samples for Ki67, estrogen receptor (ER), and PD endpoints will be collected at screening, C1D15 (+ 5 days), surgical resection (after approximately 5.5 months of treatment). Ki-67 expression will be measured by IHC. ER expression will be measured by quantitative immunofluorescence. These analyses will be done in a blind manner at the **central laboratories**.

10.1.2 Radiographic Imaging

Radiographic imaging (eg, breast ultrasound, breast MRI with contrast, and/or mammogram) will be performed at screening, C4D1 (± 7 days), and within 7 days prior to surgical resection. Tumor responses are assessed based on mRECIST criteria by Investigator. The overall tumor response per visit includes Complete Response (CR), Partial Response (PR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE).

10.1.3 Physical Exam

Caliper based measurements of the primary breast tumor will be performed during physical exam at screening, day 1 of cycle 1~cycle 6, and C6D18 prior to the surgery.

10.1.4 Local Pathological Assessments

Local pathological assessments of the tissue include surgical resection (performed after approximately 5.5 months of treatment) for surgical procedure (Breast Conserving Surgery (BCS), Mastectomy), post-surgery pathologic stage (ypT and ypN stage), and post-surgery pathologic response (Pathological Complete Response (pCR), Pathological Partial Response (pPR), No Response (NR)).

10.2 Definitions of Efficacy Endpoints

10.2.1 Ki-67 Percentage at C1D15 (Primary)

The tumor biopsies Ki-67 expression (%) at baseline and C1D15 will be collected. The endpoint is the ratio between the Ki-67 measurements obtained from C1D15 visit and baseline, which will be derived as = log(Ki-67 at C1D15) - log(Ki-67 at baseline) and the treatment effects will be back transformed. The percentage change of Ki67 from baseline at C1D15 will be derived as = 100 × (% Ki67 at C1D15 - % Ki67 at baseline)/% Ki67 at baseline.

If the value at C1D15/surgery is reported as “0”, “<1”, or other special characters will be imputed as ‘0.1” with % as unit.

10.2.2 ER Percentage at C1D15

The tumor biopsies ER expression will be reported with AQUA score (absolute quantification score in arbitrary units) at baseline and C1D15.The endpoint is the percentage change of ER expression obtained from C1D15 visit and baseline, which will be derived as = 100 × (ER AQUA score at C1D15 - ER AQUA score at baseline)/ ER AQUA score at baseline.

10.2.3 pCR Rate

Post-Surgery Pathological Response will be reported as Pathological Complete Response (pCR), Pathological Partial Response (pPR), No Response (NR). Additionally, pCR will also be programmatically derived according to the definition in the protocol using Disease Staging – Post-Surgery data: pCR is defined as no invasive cancer in the breast and sampled axillary lymph nodes following completion of neoadjuvant systemic therapy (ie, Pathologic Tumor - ypT = ypT0 or ypTis, and Pathologic Lymph Nodes – ypN = ypN0 in the current AJCC staging system). pCR rate is the proportion of participants with pCR, which are either determined by site pathologist or derived based on EDC data.

10.2.4 mPEPI Score and mPEPI0 Rate

Modified Pre-operative Endocrine Prognostic Index (mPEPI) score will be derived from factors assigned a numerical score following Neoadjuvant endocrine treatment (NET) according to the following table (Ellis 2008, Sanati 2015). The factors include Ki67 expression in the surgical specimen, pathologic tumor size, and lymph node status. Total mPEPI score (mPEPI_T) per participant is the sum of mPEPI score of each factor. mPEPI0 rate is the proportion of participants achieving mPEPI_T 0 after treatment (before surgery).

Pathology, biomarker status	**mPEPI Score**
Pathological tumor size	
T1/2	0
T3/4	3
Node status	

Pathology, biomarker status	mPEPI Score
Negative	0
Positive	3
Ki67 level (centrally)	
0%–2.7%	0
>2.7%–7.3%	1
>7.3%–19.7%	1
>19.7%–53.1%	2
>53.1%	3

10.2.5 Breast Conserving Surgery (BCS) Rate

Breast conserving surgery (BCS) Rate is the proportion of participants receiving breast conserving surgery.

10.2.6 Radiographic Response per mRECIST in Primary Tumor during Cycle 6

The percentage of subjects with Complete Response (CR), Partial Response (PR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE) per mRECIST at Cycle 6 (before surgery) will be calculated.

Percentage change of target lesions and target lesion (primary tumor) from baseline at each visit and the best percentage change of target lesions and target lesion (primary tumor) from baseline will be summarized.

10.2.7 Caliper-Based Response

The percentage change from the baseline of the primary breast tumor in physical exam will be calculated by visit. The best percentage change from baseline, Caliper-based response, which is maximum percentage decrease or minimum percentage increase if there is no decrease per participant.

10.2.8 CCCA Rate

Complete cycle cell arrest (CCCA) at Week 2/surgery is defined as Ki67 score ≤ 2.7%. CCCA rate is the proportion of participants achieving CCCA at Week 2 (or C1D15)/surgery.

10.3 Analysis of Efficacy Variables

All efficacy data and the derived endpoints will be listed. The endpoints will be analyzed below.

10.3.1 Ki-67 Percentage at C1D15 (Primary)

Analysis of Ki-67 reduction will be based on Ki-67 Analysis Set.

The log-transformed Ki-67 after approximately 2 weeks of treatment as a percentage of the baseline value, ie, the ratio between the Ki-67 measurements obtained from C1D15 visit and baseline, will be modelled using a GLM, with both derived stratification factors (ie, baseline Ki-67 score (local laboratory and central laboratory) and the tumor size) and treatment as covariates, or with treatment as only covariate Treatment effects for each arm will be summarized using the LSM and their two-sided 80% CI and 95% CI on the log scale. In addition, for easier interpretation of the data, the treatment effects will be back transformed

and expressed as the geometric means and their CIs on the original percentage scale by treatment arm.

LSM difference between two arms and its two-sided 80% CI and 95% CI will be calculated on the log scale. The treatment effects will be back transformed and expressed as the geometric means and their CIs on the ratio of original percentage scale.

The calculation will use Ki-67 score from central laboratory.

Same analysis will be performed for the Ki-67 Percentage at surgery using Full Analysis Set.

Spider plot for individual Ki-67 value at C1D15 and Surgery, Box plot for Ki-67 percentage change from baseline at C1D15 and Surgery will be presented.

10.3.2 Binary or Categorical Endpoints

Analysis of these parameters will be based on Full Analysis Set. The participants without post baseline assessment will be considered as Not Evaluable in Post-Surgery Pathological Response and Radiographic Response per mRECIST and counted in denominator.

The number and percentage of participants with Post-Surgery Pathological Response and Radiographic Response per mRECIST during Cycle 6 will be summarized. pCR rate, mPEPI rate, BCS rate, and CCCA rate will be computed by treatment arm along with the 80% CI and 95% CI using Wilson method.

Odds ratios of CCCA rate and mPEPI rate between the treatments adjusted for the stratification factors through the Cochran-Mantel-Haenszel method will be provided along with their 80% CIs and 95% CIs.

The number and percentage of participants with Post-Surgery Disease Staging will be summarized using both Full Analysis Set and Ki-67 Analysis Set.

10.3.3 Primary Tumor Assessments

Caliper-based primary breast tumor size in physical exam and its percentage change from baseline at each visit will be summarized with n, mean, sd, median, min, max using Full Analysis Set. Caliper-based response is the best percentage change from baseline (maximum percentage decrease or minimum percentage increase if there is no decrease per participant), which will be presented with n. mean, sd, median, min, max and Waterfall Plot.

Sum of target lesion and primary target lesion at each visit will be calculated separately. The size and its percentage change from baseline at each visit will be summarized with n. mean, sd, median, min, max using Full Analysis Set. The best percentage change from baseline (maximum percentage decrease or minimum percentage increase if there is no decrease per participant) will be presented in with n. mean, sd, median, min, max and Waterfall Plot.

A spider plot for the percentage change of target lesion from baseline will be presented.

10.3.4 ER AQUA Score Percentage at C1D15 and Surgery

ER AQUA score reduction will be analyzed using Full Analysis Set with Normalized AQUA score from Navigate transfer at screen and C1D15/Surgery. The percentage change of ER AQUA score from baseline will be analyzed using a GLM, with both derived stratification factors (ie, baseline Ki-67 score (from central lab only) and the tumor size) and treatment as covariates, or with treatment as only covariate. Treatment effects for each arm and difference

between two arms will be summarized using the LSM and their two-sided 80% CI and 95% CI. Additionally, the percentage change of log-transformed ER AQUA score from baseline will be analyzed using a GLM with treatment as only covariate. Treatment effects for each arm and difference between two arms will be summarized using the LSM and their two-sided 80% CI and 95% CI. The treatment effects will be back transformed and expressed as the geometric means and their CIs on the ratio of original scale. Baseline values of 0 are not imputed and the participants will be excluded in the summary. Post-baseline value of 0 will be imputed as 0.1 for the derivation of log transform analysis.

10.3.5 PR H-score Percentage at C1D15 and Surgery

PR (progesterone receptor) H-score (H-score = (SCORE_1)*1 + (SCORE_2)*2 + (SCORE_3)*3) reduction will be analyzed using Full Analysis Set with PgR636 assessment at screen and C1D15/Surgery. If a value includes a special character such as "<" or ">", the value after the special character will be used for the derivation of H-score. Baseline values of 0 are not imputed and the participants will be excluded in the summary. Post-baseline value of 0 will be imputed as 0.1 for the derivation of log transform analysis.

The percentage change of PR H-score from baseline will be analyzed using a GLM with treatment as only covariate. Treatment effects for each arm and difference between two arms will be summarized using the LSM and their two-sided 80% CI and 95% CI. Additionally, the percentage change of log-transformed PR H-score from baseline will be analyzed using a GLM with treatment as only covariate. Treatment effects for each arm and difference between two arms will be summarized using the LSM and their two-sided 80% CI and 95% CI. The treatment effects will be back transformed and expressed as the geometric means and their CIs on the ratio of original scale. For the log transformation, observed 0 will be converted to 0.1 for calculation.

Spider plot for individual PR H-score at C1D15 and Surgery, Box plot for PR H-score percentage change from baseline at C1D15 and Surgery will be presented.

10.3.6 Subgroup Analyses

Summaries of the primary endpoint will be presented for subgroups defined by the following criteria:

- Size of primary breast tumor (T-stage): ≤ 2 cm, >2 to < 5 cm, or ≥ 5 cm
- Baseline Ki-67 score (assessed locally): < 20% vs ≥ 20%
- Baseline Ki-67 score (assessed centrally): < 20% vs ≥ 20%

Other factors will be considered if the observed data imply potential findings of clinical interest. Results of the primary analysis will be reported within each subgroup.

11 SAFETY ANALYSES

All safety analyses will be performed on the Safety Analysis Set.

11.1 Adverse Events

Adverse events (AE) will be coded using MedDRA 27.0 or higher and graded according to the NCI-CTCAE 5.0.

Summaries of AEs will be based on treatment-emergent AEs (TEAEs). A TEAE is an AE that emerges or worsens (ie increase in CTCAE grade) on/after the first dose of ARV-471/Anastrozole to 30 days from the last administration of the study intervention (ie, study drug treatment or surgical resection, whichever occurs last). TEAE summaries will be presented by System Organ Class (SOC) and Preferred Term (PT). Although AEs may be reported more than once for a PT or SOC in a participant, each participant will only be counted once per SOC and PT.

An overview of Treatment Emergent Adverse Events (TEAEs), including number and percent of participants who had any TEAE, TEAE related to study drug, serious TEAEs, serious TEAEs related to study drug, TEAE leading to drug withdrawn, TEAEs leading to drug interrupted, TEAEs leading to dose reduced, TEAE related to study drug leading to drug withdrawn, TEAEs related to study drug leading to drug interrupted, TEAEs related to study drug leading to dose reduced, TEAEs ≥ grade 3 in severity, TEAEs related to study drug ≥ grade 3 in severity, TEAE leading to death.

Number and percentages of participants with TEAEs will be presented by SOC and PT in the following summaries:

- TEAEs
- TEAEs related to study drug
- TEAEs with grade 3 or higher
- TEAEs with grade 3 or higher related to study drug
- Serious TEAEs
- Serious TEAEs to study drug
- TEAEs leading to drug withdrawn
- TEAEs related to study drug leading to drug withdrawn
- TEAEs leading to drug interrupted
- TEAEs related to study drug leading to drug interrupted
- TEAEs leading to dose reduced
- TEAEs related to study drug leading to dose reduced
- TEAEs leading to death

Number and percentages of participants with TEAEs will be presented by PT in the following summaries:

- TEAEs
- TEAEs related to study drug
- Serious TEAEs
- Serious TEAEs to study drug

Tornado plots for treatment emergent adverse events in >= 5% subjects of any arm by Preferred Term and with Grade 3 or higher by Preferred Term will be presented.

Number and percentages of participants with TEAEs will be presented by SOC, PT and maximum CTCAE grade in the following summaries:

- TEAEs
- TEAEs related to study drug
- Serious TEAEs
- Serious TEAEs to study drug

Number and percentages of participants with MedDRA SMQ for Torsade de Pointes will be presented by PT and maximum CTCAE grade. PTs include Electrocardiogram QT interval abnormal, Electrocardiogram QT prolonged, Long QT syndrome, Long QT syndrome congenital, Torsade de pointes, Ventricular tachycardia, Arrhythmic storm, Cardiac arrest, Cardiac death, Cardiac fibrillation, Cardio-respiratory arrest, Electrocardiogram repolarization abnormality, Electrocardiogram U wave inversion, Electrocardiogram U wave present, Electrocardiogram U-wave abnormality, Loss of consciousness, Seizure, Sudden cardiac death, Sudden death, Syncope, Ventricular arrhythmia, Ventricular fibrillation, Ventricular flutter, Ventricular tachyarrhythmia.

Participant listings will be provided for participants with all AEs.

11.2 Deaths

The reason of subject death will be summarized using Safety Analysis Set. Death information will be provided in a listing.

11.3 Vital Signs

Vital signs parameters with abnormal clinically significant will be provided in a data listing.

11.4 Clinical Laboratory

For lab values in the form of <x, ≤x, below lower quantification limit, etc., the value will be imputed as x/2 or half of the lower quantification limit for the purpose of numerical descriptive summary. For lab values in the form of >x, ≥x, above upper quantification limit, etc., the value will be imputed as x or upper quantification limit for the purpose of numerical descriptive summary. When such imputation occurs, footnotes will be presented to clarify the imputation rule. The original lab values will be presented in data listings.

The Laboratory test value and change from baseline for continuous parameters over hematology tests, chemistry tests, coagulation tests will be summarized using descriptive statistics (n, mean, SD, median, minimum, maximum) by visit.

The value of hematology tests, coagulation tests, and chemistry tests will be graded with CTCAE 5.0. Shift of hematology tests, coagulation tests, and chemistry tests from baseline CTCAE grade to the worst postbaseline CTCAE grade will be presented. If a parameter includes both hypo- and hyper- CTCAE grade derivation, hypo- and hyper- will be tabulated separately. If the baseline is not CTCAE gradable (e.g., AST increase), the baseline measurement will be categorized as low/normal/high according to reference ranges.

Laboratory hematology, chemistry, coagulation, and urinalysis will be provided in data listings.

11.5 12-Lead Electrocardiogram

Triplicate 12-lead ECGs include Heart Rate, PR Interval, QRS Duration, QT Interval, QTcB Interval (Bazette's), QTcF Interval (Fridericia's). The mean of each parameter per visit will be used to summary. The value and change from baseline at each visit/timepoint will be summarized using descriptive statistics (n, mean, standard deviation, median, minimum, and maximum). If a parameter is tested only one time, the value will be used for summary directly.

The number and percentage of participants in the following QTcB and QTcF categories will also be summarized:

- QTcB/QTcF at Baseline
  - QTcB/QTcF >450 msec
  - QTcB/QTcF >480 msec
  - QTcB/QTcF >500 msec
- QTcB/QTcF Worst Post-Baseline
  - QTcB/QTcF >450 msec
  - QTcB/QTcF >480 msec
  - QTcB/QTcF >500 msec
- QTcB/QTcF Worst Change from Baseline
  - >30 msec
  - >60 msec

All ECG data (scheduled or unscheduled) will be displayed in a data listing.

11.6 Eastern Cooperative Oncology Group (ECOG) Performance Status

All ECOG scores will be provided in a data listing.

12 OTHER ANALYSES

12.1 Pharmacokinetics

Pharmacokinetic blood samples from participants receiving ARV-471 may be collected at pre-dose, 1 hour (± 15 min) post-dose, 2 hours (± 15 min) post-dose, 4 hours (± 30 min) post-dose on Cycle 2 Day 1, pre-biopsy on Cycle 1 Day 15, and pre-surgery on Cycle 6 Day 18. The plasma concentrations of ARV-471 and ARV-473 of individual participants will be presented by listings and summarized.

The plasma concentrations of ARV-471 and ARV-473 on Cycle 2 Day 1 will be summarized by time-point using PK analysis set. The following concentration data on Cycle 2 Day 1 should be flagged and excluded from summary.

a. Pre-dose samples are collected after dosing time.
b. Post-dose samples are collected out of time window.
c. Received ARV-471 dose is different from the planned dose

Correlation of population PK model-derived PK parameters (AUC, Cmin, Cmax) with ER reduction or other response parameters may be explored. The analysis plan and report may be provided separately.

12.2 Pharmacodynamics

Exploratory analyses include evaluation of the effects of ARV-471 and anastrozole, respectively, on Ki-67, and ER degradation by ARV-471 in tumors at the time of surgical resection. Changes in ER and Ki-67 expression between baseline and Cycle 6 surgical tumor samples as well as rates of CCCA in the cycle 6 surgical samples will be summarized for the full analysis set. The ER changes will be reported as a percentage change from baseline and derived as: 100 x (ER AQUA at surgery – ER AQUA at baseline)/ER AQUA at baseline. The Ki67 changes will be reported as a percentage change from baseline and derived as: 100 x (% Ki67 at surgery - % Ki67 at baseline)/% Ki67 at baseline. Treatment effects for each arm will be summarized using the LSM and their two-sided 80% CI and 95% CI.

Complete cycle cell arrest (CCCA) at surgical resection is defined as Ki67 score ≤ 2.7%. CCCA rate is the proportion of participants achieving CCCA at surgical resection.

Any additional explorative pharmacodynamics analysis if needed will be described in a separate plan.

13 SCHEDULE OF ANALYSES

The final analysis will take place when all participants discontinue the study.

14 REFERENCES

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Protocol No: ARV-471-BC-201

An Open-Label, Randomized, Non-Comparative Phase 2 Study of ARV-471 or Anastrozole in Post-Menopausal Women With ER+/HER2– Breast Cancer in the Neoadjuvant Setting

Table and Figure Shells

Author: [redacted]

SAP Version: v3.0

Table and Listing Shell Version: v2.0

SIGNATURE PAGE

[redacted]

15-Nov-2024

[redacted]

Date

Arvinas Estrogen Receptor, Inc (Arvinas)

[redacted]

15-Nov-2024

Date

Caidya

INTRODUCTION

The following are mock table and listing shells. These represent the format of the analysis tables that will be programmed for this project. These are based on the statistical analysis plan (SAP) for study ARV-471-BC-201.

Statistical results are represented with placeholders such as “xxx.x.” These placeholders will be populated with results when the tables are programmed based on the data.

These shells are in Microsoft Word, whereas the programmed tables are developed with SAS. Very minor differences in appearance should be expected between these shells and the programmed tables, although the general layout and format of the programmed tables will be consistent with these shells.

TABLE OF CONTENTS

REVISIONS

Date	Brief Description
10March2023	First draft 0.1
17April2023	Updates based on Arvinas comments
24April2023	Accept updates in Version 0.2 and correct some typo
15Jan2024	Add more TFL shells based on Arvinas comments on dryrun TFLs
24May2024	Add additional TFL shells based on Arvinas comments and new requests
03June2024	Accept the updates in version 0.4
24June2024	Update Baseline definition
02October2024	Update based on Arvinas' comments on dryrun #2 draft
11October2024	Update based on Arvinas' replies on the Caidya's updates and meeting discussion on 08OCT2024: * Update the definition of subgroups – derivation will be based on EDC and lab data instead of IRT * Add summary for participants with Tumor Biopsies at each visit, medical history, absolute dose intensity, relative dose intensity, subgroup analysis for change of tumor size by baseline tumor size category * Add additional plots for KI-67 at surgery, ER AQUA Score, PR H-score * Update Concomitant Medications and TEAE definition
14November2024	* Accept changes in version 1.2 * Update based on Arvinas' comments on dryrun #2 Final: add Grade 3 or higher panel in Figure 14.3.2.8; update footnotes or contents text for more details; Renumbering the listings
15November2024	Accept Changes in version 1.2

GLOBAL CONVENTIONS

Format and Ordering of Groups

Columns in summary tables will be ordered as follow:

ARV-471 200 mg N=XX n (%)	Anastrozole 1 mg N=XX n (%)	Total N=XXX n (%)

"Total" column in some efficacy tables will be removed if it is not necessary.

General Display Conventions

Summary tables and subject data listings will be in landscape format. Table titles will be centered.

Sorting Conventions

For MH summaries, Primary System Organ Classes (SOCs) will be ordered descending count for All Subjects and Preferred Terms (PTs) will be ordered by descending count for All Subjects or alphabetically for PTs with the same count for All Subjects.

For AE summaries, Primary SOCs will be ordered descending count for All Subjects and PTs will be ordered by descending count for all subjects

Display of Continuous Statistics

Means and medians will be shown to one more decimal place and the standard deviation will be shown to two more decimal that the source data values. In cases where variables are derived and have floating point values (no fixed number of decimal places), an appropriate level of precision will be determined based on the context.

Statistics that cannot be derived will be shown as a dash ("-") in summary tables.

Two-Sided confidence intervals are displayed with a format such as "(xx.x, xx.x)." If a confidence interval cannot be produced due to insufficient data, then a dash ("-") will be shown in place of the entire confidence interval.

Display of Percentages

The following conventions apply for percentages:

- Percentages will be displayed to one decimal place unless otherwise specified
- No percentage will be shown if the corresponding count is 0
- Percentages that are exactly equal to 100% will be displayed as “100%”
- Percentages that round down to 0.0% will be displayed as “<0.1%”
- Percentages that round up to 100.0% will be displayed as “>99.9%”

Percentages are shown in parentheses after the corresponding count such as “25 (5.2)” where extra spaces are included after the left parenthesis to ensure that decimal places for all percentages align within the same column.

Display of P-Values

Unless otherwise noted, p-values will be displayed as follows:

- P-values between 0.0001 and 0.9999 will be displayed in the format “0.xxxx”
- P-values that are exactly equal to 1 will be displayed as “1.0000”
- P-values <0.0001 will be displayed as “<0.0001”
- P-values >0.9999 and not exactly equal to 1 will be displayed as “>0.9999”

P-values that are descriptive and not associated with a formal test of hypothesis will not be flagged based on statistical significance. The following note will be shown in the table:

```
Note: P-values are for descriptive purposes and are not evaluated for statistical significance.
```

Unless otherwise noted, p-values that are statistically significant will be flagged with an asterisk. The table footnote is dependent on the setting, but the following example footnote is appropriate for many settings:

```
* Statistically significant at the 0.05 level.
```

Display of Dates in Subject Data Listings

Dates will be shown as follows:

- DDMMMYYYY for complete dates
- MMMYYYY for dates with only a month and year
- YYYY for dates with only a year

Partial dates are not imputed for subject data listings even if such dates are imputed for statistical algorithms. Relative day (if shown) is only derived for complete dates.

Display of Time in Subject Data Listings

Time will be shown as follows:

- HH:MM for complete time
- HH for time with only hours

Partial time is not imputed for subject data listings.

Display of Missing Values in Subject Data Listings

For subject data listings, missing numeric values will be shown as a dash (“-”). Missing character values will be shown as blanks.

Table 14.1.1.1 Summary of Analysis Sets
Analysis Set: Full Analysis Set

Analysis Set	ARV-471 200 mg N=XXX n (%)	Anastrozole 1 mg N=XX n (%)	Total N=XXX n (%)
Full Analysis Set [1]	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Safety Analysis Set [2]	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Ki-67 Evaluable Set [3]	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Pharmacodynamic/Biomarker Analysis Set [4]	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
PK Concentration Analysis Set [5]	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

[1] Full Analysis Set is defined as all enrolled participants who were randomized.
[2] Safety Analysis Set is defined as all enrolled participants who receive at least 1 dose of study intervention.
[3] Ki-67 Evaluable Set is defined as all enrolled participants who were randomized and received at least one dose of study treatment and had evaluable Ki-67 measurements other than '0' or '< 1' from baseline and evaluable Ki-67 measurements from C1D15 visits.
[4] Pharmacodynamic/Biomarker Analysis Set is defined as all enrolled participants with at least 1 of the Pharmacodynamic/Biomarkers evaluated at pre and/or post dose.
[5] PK Concentration Analysis Set includes all participants in the Safety Analysis Set who have at least one plasma concentration (including those below the limit of quantification) for ARV-471, or ARV-473.
Source: Listing 16.2.1.1.
Date of data extraction: DDMMMYYYY; Date of Creation: DDMMMYYYY. (add this footnote in all TFLs)

Programming Note:

Table 14.1.1.2 Summary of Participants with Tumor Biospsy
Analysis Set: Full Analysis Set

Test: Ki-67

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
At Screen, N'	XXX	XXX	XXX
With result, n (%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Uninterpretable, n (%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
At Cycle 1 Day 15, N'	XXX	XXX	XXX
With result, n (%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Uninterpretable, n (%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
At Cycle 6 Day 18, N'	XXX	XXX	XXX
With result, n (%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Uninterpretable, n (%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
At Unscheduled, N'	XXX	XXX	XXX
With result, n (%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Uninterpretable, n (%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

Note: N' is the number of participants at the visit. It is the denominator of the visit.
Source: Listing 16.2.6.5.
Date of data extraction: DDMMMYYYY; Date of Creation: DDMMMYYYY. (add this footnote in all TFLs)

Programming Note:
Repeat the table for each test on a new page. "Test: Progesterone Receptor"

Table 14.1.2.1
Summary of Disposition and Discontinuation
Analysis Set: Enrolled Participants

	ARV-471 200 mg N=XXX n (%)	Anastrozole 1 mg N=XX n (%)	Total N=XXX n (%)
Number of Enrolled Participants, N'			XXX
Number of Screen Failures, N'			XX
Number of Eligible Participants not Randomized, N'			XX
Number of Participants Randomized (Full Analysis Set),N	XXX	XX	XXX
Never Dosed	X(XX.X)	X(XX.X)	X(XX.X)
Completed Treatment per Protocol	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ARV-471/Anastrozole Early Discontinuation	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Reason for ARV-471/Anastrozole Early Discontinuation			
Disease Progression per Response Criteria	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Clinical Progression	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Withdrawal of Consent	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Significant non-compliance	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Pregnancy	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Death	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Adverse Event	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Study Terminated by Sponsor	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Lost to Follow-up	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Other	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Completed Study per Protocol	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Study Early Discontinuation	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Reason for Study Early Discontinuation			
Withdrawal of Consent	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Study Terminated by Sponsor	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Lost to Follow-up	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Death	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Other	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

Note: Enrolled Participants included all subjects who signed the Informed Consent.
Note: Column N and percentage are based on the number of subjects in Full Analysis Set.
Source: Listing 16.2.1.2.
Date of data extraction: DDMMMYYYY; Date of Creation: DDMMMYYYY.

Repeat the following table with Table 14.1.2.1 shell

Table 14.1.2.2
Summary of Disposition and Discontinuation
Analysis Set: Ki-67 Evaluable Set

Table 14.1.3
Summary of Protocol Deviation
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XX n (%)	Anastrozole 1 mg N=XX n (%)	Total N=XXX n (%)
Number of Subjects with Any Protocol Deviation	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Informed Consent	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
IMP/NIMP	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Protocol Compliance	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Safety	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ICH/GCP	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
<insert>			
Number of Subjects with Major or Critical Protocol Deviation	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Informed Consent	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
IMP/NIMP	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Protocol Compliance	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Safety	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ICH/GCP	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
<insert>			
Number of Subjects with Minor Protocol Deviation	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Informed Consent	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
IMP/NIMP	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Protocol Compliance	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Safety	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ICH/GCP	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
<insert>			

Source: Listing 16.2.2.
Date of data extraction: DDMMMYYYY; Date of Creation: DDMMMYYYY.

Table 14.1.4.1
Summary of Demographic Characteristics
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Sex, n(%)			
Female	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Age (years)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Age Group, n(%)			
≥ 60 Years	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
< 60 Years	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Race [1], n(%)			
American Indian or Alaskan Native	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Asian	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Black or African American	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Native Hawaiian/Other Pacific Islander	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
White	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Other	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Unknown	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Ethnicity, n(%)			
Hispanic or Latino	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Not Hispanic or Latino	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Not Reported	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Weight (kg) at Baseline			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Height (cm) at Baseline			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

ECOG Status at Baseline, n(%)			
0	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Size of Primary Breast Tumor (T-stage), n(%)			
≤ 2 cm	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
>2 to < 5 cm	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
≥ 5 cm	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Post-menopausal Reason, n(%)			
Prior bilateral oophorectomy	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Age >= 60 years	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Age < 60 years and amenorrhoeic for at least 12 months and FSH/estradiol in the postmenopausal range	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

[1] Multiple race might be reported.
Source: Listing 16.2.4.1.
Date of data extraction: DDMMMYYYY; Date of Creation: DDMMMYYYY.

Repeat the following table with Table 14.1.4.1 shell

Table 14.1.4.2
Summary of Demographic Characteristics
Analysis Set: Ki-67 Evaluable Set

Table 14.1.5
Summary of Medical History by System Organ Class and Preferred Term
Analysis Set: Full Analysis Set

System Organ Class Preferred Term	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Patients with Medical History, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class #1			
Preferred Term #1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #2	xx (xx.x)	xx (xx.x)	xx (xx.x)
<insert>	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class #2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #2	xx (xx.x)	xx (xx.x)	xx (xx.x)
<insert>	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Medical history was coded with MedDRA version 27.0.
Note: Subjects are counted once per Preferred Term and once per System Organ Class.
Sources: Listing 16.2.4.2.

Programming notes:

Table 14.1.6.1
Summary of Disease Staging and Disease Characteristics
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Time since Initial Diagnosis (months)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Time since Current Staging (months)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Primary Diagnosis: ER+ HER2- Breast Cancer, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Disease Stage at Initial Diagnosis, n(%)			
Stage 0	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Stage IA	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Stage IB	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Stage IIA	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Stage IIB	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Stage IIIA	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Stage IIIB	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Stage IIIC	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Stage IV	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Unknown	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Disease Stage at Screening, n(%)			
Stage 0	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Stage IA	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Stage IB	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Stage IIA	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Stage IIB	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Stage IIIA	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Stage IIIB	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Stage IIIC	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Stage IV	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Unknown	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

Primary Tumor at Initial Diagnosis, n(%)			
TX	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T0	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Tis	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T1mi	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T1a	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T1b	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T1c	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T3	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T4a	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T4b	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T4c	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Primary Tumor at Screening, n(%)			
TX	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T0	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Tis	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T1mi	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T1a	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T1b	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T1c	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T3	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T4a	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T4b	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
T4c	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Imaging Modality for Primary Tumor at Screening, n(%)			
CT	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
MRI	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Ultrasound	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Mammogram	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Regional Lymph Node at Initial Diagnosis, n(%)			
cNX	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
cN0	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
cN1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
cN2a	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
cN2b	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
cN3a	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
cN3b	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
cN3c	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

Regional Lymph Node at Screening, n(%)			
cNX	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
cN0	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
cN1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
cN2a	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
cN2b	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
cN3a	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
cN3b	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
cN3c	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Distant Metastasis at Initial Diagnosis, n(%)			
M0	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
M1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Unknown	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Distant Metastasis at Screening, n(%)			
M0	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
M1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Unknown	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Histopathological Classification at Initial Diagnosis, n(%)			
In-Situ Carcinoma	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Invasive Ductal Carcinoma	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Invasive Lobular Carcinoma	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Invasive Mixed Ductal and Lobular Breast Carcinoma	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Invasive Carcinoma NOS	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Invasive Adenocarcinoma NOS	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Tubular Carcinoma	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Invasive Mucinous Adenocarcinoma	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Other	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Histopathological Classification at Screening, n(%)			
In-Situ Carcinoma	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Invasive Ductal Carcinoma	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Invasive Lobular Carcinoma	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Invasive Mixed Ductal and Lobular Breast Carcinoma	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Invasive Carcinoma NOS	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Invasive Adenocarcinoma NOS	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Tubular Carcinoma	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Invasive Mucinous Adenocarcinoma	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Other	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

Histopathological Grade at Initial Diagnosis, n(%)			
Grade 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 3	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade X	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Histopathological Grade at Screening, n(%)			
Grade 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 3	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade X	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Planned Type of Breast Surgery, n(%)			
Breast conserving surgery	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Mastectomy	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

Note: Time since initial diagnosis (months) is defined as time from the date of initial diagnosis to the date of first ARV-471/anastrozole dose. Time since current staging (months) is defined as time from the date of current staging to the date of first ARV-471/anastrozole dose.
Source: Listing 16.2.4.3 and Listing 16.2.4.4.
Date of data extraction: DDMMMYYYY; Date of Creation: DDMMMYYYY.

Programming Note:

Repeat the following table with Table 14.1.6.1 shell

Table 14.1.6.2
Summary of Disease Staging and Disease Characteristics
Analysis Set: Ki-67 Evaluable Set

Table 14.1.7.1
Summary of Disease Molecular Biology at Baseline
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
HER2 Status, Performed, n(%)			
Yes	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
No	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Sample Site of HER2 Status, n(%)			
Breast	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Lymph Node	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Other	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
HER2 Analytical Method, n(%)			
Immunohistochemistry (IHC)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
In Situ Hybridization (ISH)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
HER2 Analytical Result, n(%)			
0	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
1+	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
2+	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
3+	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Positive	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Negative	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Unknown	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Ki67, Performed, n(%)			
Yes	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
No	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Sample Site of Ki67, n(%)			
Breast	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Lymph Node	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Other	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
% of Tumor Cells with Ki67 (Local)			
n	xxx	xx	Xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

< 20%, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
≥ 20%, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
% of Tumor Cells with Ki67 (Central)			
n	xxx	xx	Xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
< 20%, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
≥ 20%, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Estrogen Receptor, Performed, n(%)			
Yes	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
No	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Sample Site of Estrogen Receptor, n(%)			
Breast	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Lymph Node	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Other	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
% of Tumor Cells with Estrogen Receptor (Local)			
n	xxx	xx	Xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
< 10%, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
≥ 10%, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Progesterone Receptor, Performed , n(%)			
Yes	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
No	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Sample Site of Progesterone Receptor, n(%)			
Breast	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Lymph Node	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Other	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

% of Tumor Cells with Progesterone Receptor (Local)			
n	xxx	xx	Xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
< 1%, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
≥ 1%, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

Note: All the data are from local laboratories unless otherwise indicated.
Source: Listing 16.2.4.5.
Date of data extraction: DDMMMYYYY; Date of Creation: DDMMMYYYY.

Programming Note:

Repeat the following table with Table 14.1.7.1 shell

Table 14.1.7.2
Summary of Disease Molecular Biology at Baseline
Analysis Set: Ki-67 Evaluable Set

Table 14.1.8
Summary of Prior Cancer Related Surgery/Biopsy
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Any Prior Surgery/Biopsy Related to Trial Disease[1], n(%)			
Yes	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Procedure[1], n(%)			
Sentinel node biopsy	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Axillary sampling	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Fine needle aspiration,	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Core needle biopsy	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Other	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Procedure Location[1], n(%)			
Breast	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Lymph node	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Other	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Laterality[1], n(%)			
Left	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Right	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Bilateral	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Not applicable	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Time since Most Recent Surgery/Biopsy (months)			
n	xxx	xx	Xxx
Mean	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

Note: Time since most recent surgery/biopsy is defined as time from the most recent date of surgery to the date of first ARV-471/Anastrozole dose.
[1] A subject might receive multiple Surgery/Biopsy.
Date of data extraction: DDMMMYYYY; Date of Creation: DDMMMYYYY.

Table 14.1.9
Summary of Prior Medication Analysis Set: Full Analysis Set

ATC level 2 Preferred Name	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Subjects with Any Prior Medication, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ATC level 2 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Preferred Name 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Preferred Name 2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ATC level 2 2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Preferred Name 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Preferred Name 2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

Note: Prior medications are coded according to the World Health Organization drug dictionary (WHO-Drug B3 Global version September 2024).
Note: Prior medications include non-study drug medications that are ended before Day 1.
Source: Listing 16.2.4.6.
Date of data extraction: DDMMMYYYY; Date of Creation: DDMMMYYYY.

Programming Note:

Table 14.1.10
Summary of Concomitant Medication Analysis Set: Full Analysis Set

ATC level 2 Preferred Name	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Subjects with Any Concomitant Medication, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ATC level 2 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Preferred Name 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Preferred Name 2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ATC level 2 2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Preferred Name 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Preferred Name 2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

Note: Prior medications are coded according to the World Health Organization drug dictionary (WHO-Drug B3 Global version September 2024).
Note: Concomitant medications include non-study drug medications that are used/started on/after Day 1 and within 30 days from the last administration of the study intervention (ie, study drug treatment or surgical resection, whichever occurs last).
Source: Listing 16.2.4.6.
Date of data extraction: DDMMMYYYY; Date of Creation: DDMMMYYYY.

Programming Note:

Table 14.1.11
Summary of ARV-471 and Anastrozole Compliance and Exposure
Analysis Set: Safety Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX
Duration of Treatment (week)		
n	xxx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx
Cumulative Dose (mg)		
n	xxx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx
Absolute Dose Intensity (mg/week)		
n	xxx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx
Total Planned Dose (mg)		
n	xxx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx
Compliance (%)		
n	xxx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx
Number (%) of Compliant Patients, n(%)	XXX(XX.X)	XX(XX.X)
Relative Dose Intensity (%)		
n	xxx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx

Number of Subjects with at Least One Action Taken, n(%)	XXX(XX.X)	XX(XX.X)
Dose Interrupted	XXX(XX.X)	XX(XX.X)
Dose Discontinued	XXX(XX.X)	XX(XX.X)
Dose Reduced	XXX(XX.X)	XX(XX.X)
Dose Increased	XXX(XX.X)	XX(XX.X)
Reason for Dose Interrupted[1], n(%)		
Adverse event	XXX(XX.X)	XX(XX.X)
Participant missed/Skipped dose	XXX(XX.X)	XX(XX.X)
Medication error	XXX(XX.X)	XX(XX.X)
Other	XXX(XX.X)	XX(XX.X)
Reason for Dose Reduced[1], n(%)		
Adverse event	XXX(XX.X)	XX(XX.X)
Participant missed/Skipped dose	XXX(XX.X)	XX(XX.X)
Medication error	XXX(XX.X)	XX(XX.X)
Other	XXX(XX.X)	XX(XX.X)
Reason for Dose Discontinued[1], n(%)		
Adverse event	XXX(XX.X)	XX(XX.X)
Participant missed/Skipped dose	XXX(XX.X)	XX(XX.X)
Medication error	XXX(XX.X)	XX(XX.X)
Other	XXX(XX.X)	XX(XX.X)
Reason for Dose Increased[1], n(%)		
Adverse event	XXX(XX.X)	XX(XX.X)
Participant missed/Skipped dose	XXX(XX.X)	XX(XX.X)
Medication error	XXX(XX.X)	XX(XX.X)
Other	XXX(XX.X)	XX(XX.X)

[1] Multiple reasons might be reported.
Note: Compliance is 100*(Total cumulative dose/Total planned dose), accounting for planned dose modifications and interruptions. Compliant Patients are those with compliance >= 80% - <= 120%. Absolute Dose Intensity (mg/week)is (Cumulative Dose (mg))/(Duration of Treatment (week)). Relative Dose Intesity (%) is 100*(Absolute Dose Intensity (mg/week))/(Initial Planned Weekly Dose (mg/week), 1400 mg/week for ARV-471 and 7 mg/week for Anastrozole)).
Source: Listing 16.2.5.1, and Listing 16.2.5.2.
Date of data extraction: DDMMMYYYY; Date of Creation: DDMMMYYYY.

Programming Note:

Table 14.2.1.1.1
Summary of Ki-67 Percentage Change from Baseline at C1D15 with Central Ki-67 as a Covariate
Analysis Set: Ki-67 Evaluable Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at C1D15)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at C1D15) - log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between Ki-67 at C1D15 and Ki-67 at baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: The endpoint is the ratio between the Ki-67 measurements obtained from C1D15 visit and baseline, which will be derived as = exp(log(Ki-67 at C1D15) - log(Ki-67 at baseline)).
[1] Analysis based on an analysis of covariance (ANCOVA) model with baseline Ki-67 score (assessed **centrally**: <20% vs ≥20%), the tumor size (≤2 cm, >2 to <5 cm, or ≥5 cm) as covariates for treatment. Baseline Ki-67 score and/or the tumor size categories are derived based on data collected instead of data reported in IRT.
[2] Back transformed values of [1].
Source: Listing 16.2.6.1.
Date of data extraction: DDMMMYYYY; Date of Creation: DDMMMYYYY.

Table 14.2.1.1.2
Summary of Ki-67 Percentage Change from Baseline at C1D15 with Local Ki-67 as a Covariate
Analysis Set: Ki-67 Evaluable Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at C1D15)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at C1D15) - log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between Ki-67 at C1D15 and Ki-67 at baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: The endpoint is the ratio between the Ki-67 measurements obtained from C1D15 visit and baseline, which will be derived as = exp(log(Ki-67 at C1D15) - log(Ki-67 at baseline)).
[1] Analysis based on an analysis of covariance (ANCOVA) model with baseline Ki-67 score (assessed **locally**: <20% vs ≥20%), the tumor size (≤2 cm, >2 to <5 cm, or ≥5 cm) as covariates for treatment. Baseline Ki-67 score and/or the tumor size categories are derived based on data collected instead of data reported in IRT.
[2] Back transformed values of [1].
Source: Listing 16.2.6.1.
Date of data extraction: DDMMMYYYY; Date of Creation: DDMMMYYYY.

Table 14.2.1.1.3
Summary of Ki-67 Percentage Change from Baseline at C1D15 without Covariate
Analysis Set: Ki-67 Evaluable Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at C1D15)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at C1D15) - log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between Ki-67 at C1D15 and Ki-67 at baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: The endpoint is the ratio between the Ki-67 measurements obtained from C1D15 visit and baseline, which will be derived as = exp(log(Ki-67 at C1D15) - log(Ki-67 at baseline)).
[1] Analysis based on an analysis of variance (ANOVA) model.
[2] Back transformed values of [1].
Source: Listing 16.2.6.1.

Table 14.2.1.2.1
Summary of Ki-67 Percentage Change from Baseline at C1D15– Subgroup Analysis by Tumor Size
Analysis Set: Ki-67 Evaluable Set

Tumor Size: ≤2 cm

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at C1D15)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at C1D15) - log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between Ki-67 at C1D15 and Ki-67 at baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: The endpoint is the ratio between the Ki-67 measurements obtained from C1D15 visit and baseline, which will be derived as = exp(log(Ki-67 at C1D15) - log(Ki-67 at baseline)).
Note: Baseline tumor size categories are derived based on data collected instead of data reported in IRT.
[1] Analysis based on an analysis of variance (ANOVA) model.
[2] Back transformed values of [1].
Source: Listing 16.2.6.1.

Programming Note:

Repeat the table for ‘Tumor Size: >2 to <5 cm’, and ‘Tumor Size: ≥5 cm’ on new page.

Table 14.2.1.2.2
Summary of Ki-67 Percentage Change from Baseline at C1D15 – Subgroup Analysis by Local Ki-67 Baseline Score
Analysis Set: Ki-67 Evaluable Set

Local Ki-67 Baseline Score: < 20%

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at C1D15)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at C1D15) - log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between Ki-67 at C1D15 and Ki-67 at baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: The endpoint is the ratio between the Ki-67 measurements obtained from C1D15 visit and baseline, which will be derived as = exp(log(Ki-67 at C1D15) - log(Ki-67 at baseline)).
Note: Baseline Ki-67 score are derived based on data collected instead of data reported in IRT.
[1] Analysis based on an analysis of variance (ANOVA) model.
[2] Back transformed values of [1].
Source: Listing 16.2.6.1.

Programming Note:

Repeat the table for 'Local Ki-67 Baseline Score: ≥ 20%" on new page.

Table 14.2.1.2.3
Summary of Ki-67 Percentage Change from Baseline at C1D15– Subgroup Analysis by Central Ki-67 Baseline Score of 20%
Analysis Set: Ki-67 Evaluable Set

Central Ki-67 Baseline Score: < 20%

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at C1D15)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at C1D15) - log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between Ki-67 at C1D15 and Ki-67 at baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: The endpoint is the ratio between the Ki-67 measurements obtained from C1D15 visit and baseline, which will be derived as = exp(log(Ki-67 at C1D15) - log(Ki-67 at baseline)).
Note: Baseline Ki-67 score are derived based on data collected instead of data reported in IRT.[1] Analysis based on an analysis of variance (ANOVA) model.
[2] Back transformed values of [1].
Source: Listing 16.2.6.1.

Programming Note:
Repeat the table for ‘Central Ki-67 Baseline Score: ≥ 20%” on new page.

Table 14.2.1.2.4
Summary of Ki-67 Percentage Change from Baseline at C1D15 – Subgroup Analysis by Central Ki-67 Baseline Score of 5%
Analysis Set: Ki-67 Evaluable Set

Central Ki-67 Baseline Score: < 5%

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at C1D15)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at C1D15) - log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between Ki-67 at C1D15 and Ki-67 at baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: The endpoint is the ratio between the Ki-67 measurements obtained from C1D15 visit and baseline, which will be derived as = exp(log(Ki-67 at C1D15) - log(Ki-67 at baseline)).
Note: Baseline Ki-67 score are derived based on data collected instead of data reported in IRT.
[1] Analysis based on an analysis of variance (ANOVA) model.
[2] Back transformed values of [1].
Source: Listing 16.2.6.1.

Programming Note:

Repeat the table for ‘Central Ki-67 Baseline Score: ≥ 5%” on new page.

Table 14.2.1.3.1
Summary of Ki-67 Percentage Change from Baseline at Surgery with Central Ki-67 as a Covariate
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at Surgery)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at Surgery) - log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between Ki-67 at Surgery and Ki-67 at baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: The endpoint is the ratio between the Ki-67 measurements obtained from Surgery visit and baseline, which will be derived as = exp(log(Ki-67 at Surgery) - log(Ki-67 at baseline)).
[1] Analysis based on an analysis of covariance (ANCOVA) model with baseline Ki-67 score (assessed **centrally**: <20% vs ≥20%), the tumor size (≤2 cm, >2 to <5 cm, or ≥5 cm) as covariates for treatment. Baseline Ki-67 score and/or the tumor size categories are derived based on data collected instead of data reported in IRT.
[2] Back transformed values of [1].
Source: Listing 16.2.6.1.

Programming Note:

Table 14.2.1.3.2
Summary of Ki-67 Percentage Change from Baseline at Surgery with Local Ki-67 as a Covariate
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at Surgery)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at Surgery) - log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between Ki-67 at Surgery and Ki-67 at baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: The endpoint is the ratio between the Ki-67 measurements obtained from Surgery visit and baseline, which will be derived as = exp(log(Ki-67 at Surgery) - log(Ki-67 at baseline)).
[1] Analysis based on an analysis of covariance (ANCOVA) model with baseline Ki-67 score (assessed **locally**: <20% vs ≥20%), the tumor size (≤2 cm, >2 to <5 cm, or ≥5 cm) as covariates for treatment. Baseline Ki-67 score and/or the tumor size categories are derived based on data collected instead of data reported in IRT.
[2] Back transformed values of [1].
Source: Listing 16.2.6.1.

Programming Note:

Table 14.2.1.3.3
Summary of Ki-67 Percentage Change from Baseline at Surgery without Covariate
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at Surgery)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at Surgery) - log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between Ki-67 at Surgery and Ki-67 at baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: The endpoint is the ratio between the Ki-67 measurements obtained from Surgery visit and baseline, which will be derived as = exp(log(Ki-67 at Surgery) - log(Ki-67 at baseline)).
[1] Analysis based on an analysis of variance (ANOVA) model.
[2] Back transformed values of [1].
Source: Listing 16.2.6.1.

Table 14.2.1.4.1
Summary of Ki-67 Percentage Change from Baseline at Surgery – Subgroup Analysis by Tumor Size
Analysis Set: Full Analysis Set

Tumor Size: ≤2 cm

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at Surgery			
n)	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at Surgery) - log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between Ki-67 at Surgery and Ki-67 at baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: The endpoint is the ratio between the Ki-67 measurements obtained from Surgery visit and baseline, which will be derived as = exp(log(Ki-67 at Surgery) - log(Ki-67 at baseline)).
Note: Baseline tumor size categories are derived based on data collected instead of data reported in IRT.
[1] Analysis based on an analysis of variance (ANOVA) model.
[2] Back transformed values of [1].
Source: Listing 16.2.6.1.

Programming Note:

Repeat the table for ‘Tumor Size: >2 to <5 cm’, and ‘Tumor Size: ≥5 cm’ on new page.

Table 14.2.1.4.2
Summary of Ki-67 Percentage Change from Baseline at Surgery – Subgroup Analysis by Local Ki-67 Baseline Score
Analysis Set: Full Analysis Set

Local Ki-67 Baseline Score: < 20%

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at Surgery			
n)	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at Surgery) - log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between Ki-67 at Surgery and Ki-67 at baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: The endpoint is the ratio between the Ki-67 measurements obtained from Surgery visit and baseline, which will be derived as = exp(log(Ki-67 at Surgery) - log(Ki-67 at baseline)).
Note: Baseline Ki-67 score are derived based on data collected instead of data reported in IRT.
[1] Analysis based on an analysis of variance (ANOVA) model.
[2] Back transformed values of [1].
Source: Listing 16.2.6.1.

Programming Note:

Repeat the table for ‘Local Ki-67 Baseline Score: ≥ 20%” on new page.

Table 14.2.1.4.3
Summary of Ki-67 Percentage Change from Baseline at Surgery – Subgroup Analysis by Central Ki-67 Baseline Score
Analysis Set: Full Analysis Set

Central Ki-67 Baseline Score: < 20%

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at Surgery)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(Ki-67 at Surgery) - log(Ki-67 at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between Ki-67 at Surgery and Ki-67 at baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: The endpoint is the ratio between the Ki-67 measurements obtained from Surgery visit and baseline, which will be derived as = exp(log(Ki-67 at Surgery) - log(Ki-67 at baseline)).
Note: Baseline Ki-67 score are derived based on data collected instead of data reported in IRT.
[1] Analysis based on an analysis of variance (ANOVA) model.
[2] Back transformed values of [1].
Source: Listing 16.2.6.1.

Programming Note:

Repeat the table for ‘Central Ki-67 Baseline Score: ≥ 20%” on new page.

Table 14.2.1.5.1
Summary of Concordance Ki-67 Baseline Score between Central and Local Laboratories
Analysis Set: Ki-67 Evaluable Set

	Local Ki-67 Baseline Score <20%	Local Ki-67 Baseline Score ≥20%	Total
ARV-471 200 mg (N=XXX), n(%)			
Central Ki-67 Baseline Score <20%	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)
Central Ki-67 Baseline Score ≥20%	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)
Total	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)
Anastrozole 1 mg (N=XX), n(%)			
Central Ki-67 Baseline Score <20%	XX(XX.X)	XX(XX.X)	XX(XX.X)
Central Ki-67 Baseline Score ≥20%	XX(XX.X)	XX(XX.X)	XX(XX.X)
Total	XX(XX.X)	XX(XX.X)	XX(XX.X)

Note: The percentage is based on N.
Source: Listing 16.2.6.1.

Table 14.2.1.5.2
Summary of Concordance Central/Local Ki-67 Baseline Score with Randomization Baseline Ki-67 Score
Analysis Set: Ki-67 Evaluable Set

	Randomization Baseline Ki-67 Score <20%	Randomization Baseline Ki-67 Score ≥20%	Total
ARV-471 200 mg (N=XXX), n(%)			
Central Ki-67 Baseline Score <20%	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)
Central Ki-67 Baseline Score ≥20%	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)
Total	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)
ARV-471 200 mg (N=XXX), n(%)			
Local Ki-67 Baseline Score <20%	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)
Local Ki-67 Baseline Score ≥20%	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)
Total	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)
Anastrozole 1 mg (N=XX), n(%)			
Central Ki-67 Baseline Score <20%	XX(XX.X)	XX(XX.X)	XX(XX.X)
Central Ki-67 Baseline Score ≥20%	XX(XX.X)	XX(XX.X)	XX(XX.X)
Total	XX(XX.X)	XX(XX.X)	XX(XX.X)
Anastrozole 1 mg (N=XX), n(%)			
Local Ki-67 Baseline Score <20%	XX(XX.X)	XX(XX.X)	XX(XX.X)
Local Ki-67 Baseline Score ≥20%	XX(XX.X)	XX(XX.X)	XX(XX.X)
Total	XX(XX.X)	XX(XX.X)	XX(XX.X)

Note: The percentage is based on N.
Source: Listing 16.2.6.1.

Table 14.2.1.5.3
Summary of Concordance Acutal Primary Breast Tumor Size with Randomization Primary Breast Tumor Size
Analysis Set: Ki-67 Evaluable Set

	Randomization Primary Breast Tumor Size <=2 cm	Randomization Primary Breast Tumor Size >2-<5 cm	Randomization Primary Breast Tumor Size >2-<5 cm	Total
ARV-471200 mg (N=XXX), n(%)				
Acutal Primary Breast Tumor Size <=2 cm	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)
Acutal Primary Breast Tumor Size >2-<5 cm	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)
Acutal Primary Breast Tumor Size >2-<5 cm	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)
Total	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)
ARV-471200 mg (N=XXX), n(%)				
Acutal Primary Breast Tumor Size <=2 cm	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)
Acutal Primary Breast Tumor Size >2-<5 cm	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)
Acutal Primary Breast Tumor Size >2-<5 cm	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)
Total	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)	XXX(XX.X)

Note: The percentage is based on N.
Source: Listing 16.2.6.1.

Table 14.2.2.1.1
Summary of Post-Surgery Pathological Response and pCR Rate - Determined by Site Pathologist
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
Participants Not Receiving Surgery, n(%)	XXX(XX.X)	XX(XX.X)	
Participants Receiving Unscheduled Surgery, n(%)	XXX(XX.X)	XX(XX.X)	
Post-Surgery Pathological Response in Participants Receiving Surgery at C6D18, n(%)			
Pathological Complete Response (pCR)	XXX(XX.X)	XX(XX.X)	
Pathological Partial Response (pPR)	XXX(XX.X)	XX(XX.X)	
No Response (NR)	XXX(XX.X)	XX(XX.X)	
pCR Rate in Participants Receiving Surgery at C6D18, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
80% Wilson confidence interval	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
95% Wilson confidence interval	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X

Note: pCR rate is the proportion of participants with pCR.
Source: Listing 16.2.6.2.

Table 14.2.2.1.2
Summary of Post-Surgery Pathological Response and pCR Rate – Calculated
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
Participants Not Receiving Surgery, n(%)	XXX(XX.X)	XX(XX.X)	
Participants Receiving Unscheduled Surgery, n(%)	XXX(XX.X)	XX(XX.X)	
Post-Surgery Pathological Response in Participants Receiving Surgery at C6D18, n(%)			
Calculated Pathological Complete Response (pCR)	XXX(XX.X)	XX(XX.X)	
Non pCR	XXX(XX.X)	XX(XX.X)	
pCR Rate in Participants Receiving Surgery at C6D18, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
80% Wilson confidence interval	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
95% Wilson confidence interval	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X

Note: pCR is programmatically derived according to the definition in the protocol using Disease Staging – Post-Surgery data: pCR is defined as no invasive cancer in the breast and sampled axillary lymph nodes following completion of neoadjuvant systemic therapy (Pathologic Tumor - ypT = ypT0 or ypTis, and Pathologic Lymph Nodes – ypN = ypN0).pCR rate is the proportion of participants with pCR.
Source: Listing 16.2.6.2.

Table 14.2.2.1.3.1
Summary of Post-Surgery Disease Staging
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Participants Not Receiving Surgery, n(%)	XXX(XX.X)	XX(XX.X)	XX(XX.X)
Participants Receiving Unscheduled Surgery, n(%)	XXX(XX.X)	XX(XX.X)	XX(XX.X)
Pathologic Tumor - ypT in Participants Receiving Surgery at C6D18, n(%)			
ypTx	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypT0	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypTis	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypT1mi	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypT1a	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypT1b	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypT1c	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypT2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypT3	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypT4a	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypT4b	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypT4c	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Multiple Foci of Residual Tumor? in Participants Receiving Surgery at C6D18, n(%)			
Yes	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
No	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Pathologic Lymph Nodes – ypN in Participants Receiving Surgery at C6D18, n(%)			
ypNX	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypN0	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypN0(i+)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypN0(mol+)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypN1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypN1mi	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypN1a	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypN1b	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypN1c	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypN2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypN2a	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypN2b	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypN3	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypN3a	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypN3b	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
ypN3c	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

Distant Metastasis (M) in Participants Receiving Surgery at C6D18, n(%)			
M0	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
pM1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Unknown	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Lymphatic Vascular Invasion Classification in Participants Receiving Surgery at C6D18, n(%)			
Present	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Not Present	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Unknown	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

Source: Listing 16.2.6.8.
Date of data extraction: DDMMMYYYY; Date of Creation: DDMMMYYYY.

Repeat the following table with Table 14.2.2.1.3.1 shell

Table 14.2.2.1.3.2
Summary of Post-Surgery Disease Staging
Analysis Set: Ki-67 Evaluable Set

Table 14.2.2.2
Summary of Modified Pre-operative Endocrine Prognostic Index (mPEPI) Score and mPEPI 0 Rate
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
Participants Not Assessed at C6D18, n(%)	XXX(XX.X)	XX(XX.X)	
(mPEPI) Score at at C6D18, n(%)			
0	XXX(XX.X)	XX(XX.X)	
1~2	XXX(XX.X)	XX(XX.X)	
3	XXX(XX.X)	XX(XX.X)	
>3	XXX(XX.X)	XX(XX.X)	
mPEPI 0 Rate, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
80% Wilson confidence interval	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
95% Wilson confidence interval	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
Odds Ratio of mPEPI0 Rate [1]	XX.XX		
80% confidence interval [1]	XX.XX,XX.XX		
95% confidence interval [1]	XX.XX,XX.XX		
Odds Ratio of mPEPI0 Rate [2]	XX.XX		
80% confidence interval [2]	XX.XX,XX.XX		
95% confidence interval [2]	XX.XX,XX.XX		

Note: mPEPI0 rate is the proportion of participants achieving 0 for total mPEPI after treatment (before surgery).
[1] Analysis based on Cochran-Mantel-Haenszel method adjusted for the stratification factors, including baseline Ki-67 score (assessed centrally: <20% vs ≥20%) and tumor size (≤2 cm, >2 to <5 cm, or ≥5 cm). Baseline Ki-67 score and/or the tumor size categories are derived based on data collected instead of data reported in IRT.
[2] Analysis based on Cochran-Mantel-Haenszel method adjusted for the stratification factors, including baseline Ki-67 score (assessed locally: <20% vs ≥20%) and tumor size (≤2 cm, >2 to <5 cm, or ≥5 cm). Baseline Ki-67 score and/or the tumor size categories are derived based on data collected instead of data reported in IRT.
Source: Listing 16.2.6.1.

Table 14.2.2.3
Summary of Breast Conserving Surgery (BCS) and BCS Rate
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
Participants Not Receiving Surgery, n(%)	XXX(XX.X)	XX(XX.X)	
Participants Receiving Unscheduled Surgery, n(%)	XXX(XX.X)	XX(XX.X)	
Participants Receiving Mastectomy at C6D18, n(%)	XXX(XX.X)	XX(XX.X)	
Participants Receiving Breast Conserving Surgery at C6D18, n(%)	XXX(XX.X)	XX(XX.X)	
BCS Rate in Participants Receiving Breast Conserving Surgery at C6D18, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
80% Wilson confidence interval	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
95% Wilson confidence interval	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X

Note: Breast conserving surgery (BCS) Rate is the proportion of participants receiving breast conserving surgery.
Source: Listing 16.2.6.2.

Table 14.2.2.4
Summary of Radiographic Response per mRECIST during Cycle 6
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX
Radiographic Response per mRECIST during Cycle 6, n(%)		
Complete response (CR)	XXX(XX.X)	XX(XX.X)
Partial response (PR)	XXX(XX.X)	XX(XX.X)
Stable disease (SD)	XXX(XX.X)	XX(XX.X)
Progressive disease (PD)	XXX(XX.X)	XX(XX.X)
Not evaluable (NE)	XXX(XX.X)	XX(XX.X)

Note: Participants without disease assessment is categorized as Not evaluable.
Source: Listing 16.4.6.1.

Table 14.2.2.5.1
Summary of Complete Cycle Cell Arrest (CCCA) and CCCA Rate
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
Complete Cycle Cell Arrest at Week 2, n(%)			
No	XXX(XX.X)	XX(XX.X)	
Yes	XXX(XX.X)	XX(XX.X)	
CCCA Rate, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
80% Wilson confidence interval	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
95% Wilson confidence interval	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
Odds Ratio of CCCA Rate [1]	XX.XX		
80% confidence interval [1]	XX.XX,XX.XX		
95% confidence interval [1]	XX.XX,XX.XX		
Odds Ratio of CCCA Rate [2]	XX.XX		
80% confidence interval [2]	XX.XX,XX.XX		
95% confidence interval [2]	XX.XX,XX.XX		
Participants Not Receiving Surgery, n(%)	XXX(XX.X)	XX(XX.X)	
Participants Receiving Unscheduled Surgery, n(%)	XXX(XX.X)	XX(XX.X)	
Complete Cycle Cell Arrest at C6D18 Surgery, n(%)			
No	XXX(XX.X)	XX(XX.X)	
Yes	XXX(XX.X)	XX(XX.X)	
CCCA Rate, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
80% Wilson confidence interval	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
95% Wilson confidence interval	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
Odds Ratio of CCCA Rate [1]	XX.XX		
80% confidence interval [1]	XX.XX,XX.XX		
95% confidence interval [1]	XX.XX,XX.XX		
Odds Ratio of CCCA Rate [2]	XX.XX		
80% confidence interval [2]	XX.XX,XX.XX		
95% confidence interval [2]	XX.XX,XX.XX		

Note: Complete cycle cell arrest (CCCA) at Week 2/surgery is defined as Ki67 score ≤ 2.7%. CCCA rate is the proportion of participants achieving CCCA) at Week 2 (or C1D15)/surgery.
[1] Analysis based on Cochran-Mantel-Haenszel method adjusted for the stratification factors, including baseline Ki-67 score (assessed centrally: <20% vs ≥20%) and tumor size (≤2 cm, >2 to <5 cm, or ≥5 cm). Baseline Ki-67 score and/or the tumor size categories are derived based on data collected instead of data reported in IRT.
[2] Analysis based on Cochran-Mantel-Haenszel method adjusted for the stratification factors, including baseline Ki-67 score (assessed locally: <20% vs ≥20%) and tumor size (≤2 cm, >2 to <5 cm, or ≥5 cm). Baseline Ki-67 score and/or the tumor size categories are derived based on data collected instead of data reported in IRT.

Source: Listing 16.2.6.2.

Table 14.2.2.5.2
Summary of Complete Cycle Cell Arrest (CCCA) and CCCA Rate – Subgroup Analysis by Central Ki-67 Baseline Score
Analysis Set: Full Analysis Set

Central Ki-67 Baseline Score: < 5%

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
Complete Cycle Cell Arrest at Week 2, n(%)	XXX(XX.X)	XX(XX.X)	
No	XXX(XX.X)	XX(XX.X)	
Yes	XXX(XX.X)	XX(XX.X)	
CCCA Rate, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
80% Wilson confidence interval	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
95% Wilson confidence interval	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
Odds Ratio of CCCA Rate [1]	XX.XX		
80% confidence interval [1]	XX.XX,XX.XX		
95% confidence interval [1]	XX.XX,XX.XX		
Odds Ratio of CCCA Rate [2]	XX.XX		
80% confidence interval [2]	XX.XX,XX.XX		
95% confidence interval [2]	XX.XX,XX.XX		
Participants Not Receiving Surgery, n(%)	XXX(XX.X)	XX(XX.X)	
Participants Receiving Unscheduled Surgery, n(%)	XXX(XX.X)	XX(XX.X)	
Complete Cycle Cell Arrest at C6D18 Surgery, n(%)	XXX(XX.X)	XX(XX.X)	
No	XXX(XX.X)	XX(XX.X)	
Yes	XXX(XX.X)	XX(XX.X)	
CCCA Rate, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
80% Wilson confidence interval	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
95% Wilson confidence interval	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
Odds Ratio of CCCA Rate [1]	XX.XX		
80% confidence interval [1]	XX.XX,XX.XX		
95% confidence interval [1]	XX.XX,XX.XX		
Odds Ratio of CCCA Rate [2]	XX.XX		
80% confidence interval [2]	XX.XX,XX.XX		
95% confidence interval [2]	XX.XX,XX.XX		

Note: Complete cycle cell arrest (CCCA) at Week 2/surgery is defined as Ki67 score ≤ 2.7%. CCCA rate is the proportion of participants achieving CCCA at Week 2 (or C1D15)/surgery.
[1] Analysis based on Cochran-Mantel-Haenszel method adjusted for the stratification factors, including baseline Ki-67 score (assessed centrally: <20% vs ≥20%) and tumor size (≤2 cm, >2 to <5 cm, or ≥5 cm). Baseline Ki-67 score and/or the tumor size categories are derived based on data collected instead of data reported in IRT.
[2] Analysis based on Cochran-Mantel-Haenszel method adjusted for the stratification factors, including baseline Ki-67 score (assessed locally: <20% vs ≥20%) and tumor size (≤2 cm, >2 to <5 cm, or ≥5 cm). Baseline Ki-67 score and/or the tumor size categories are derived based on data collected instead of data reported in IRT.

Source: Listing 16.2.6.2.

Programming Note:
Repeat the table for ‘Central Ki-67 Baseline Score: ≥ 5%” on new page.

Table 14.2.3.1.1
Summary of the Primary Breast Tumor Change - Caliper-based
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Baseline (mm)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Best Percentage Change from Baseline (%)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
<Cycle x Day Y>			
Tumor Assessment (mm)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Percentage Change from Baseline (%)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
<insert Visit>			

Note: The best percentage change from baseline is maximum percentage decrease or minimum percentage increase if there is no decrease per participant.
Source: Listing 16.2.6.4

Table 14.2.3.1.2
Summary of the Primary Breast Tumor Change - Caliper-based by Baseline Tumor Size
Analysis Set: Full Analysis Set

Baseline Tumor Size: ≤2 cm

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Baseline (mm)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Best Percentage Change from Baseline (%)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
<Cycle x Day Y>			
Tumor Assessment (mm)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Percentage Change from Baseline (%)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
<insert Visit>			

Note: The best percentage change from baseline is maximum percentage decrease or minimum percentage increase if there is no decrease per participant.
Note: Baseline tumor size categories are derived based on data collected instead of data reported in IRT.
Source: Listing 16.2.6.4.

Programming Note:

Repeated >2 to <5 cm, and ≥5 cm on separated pages

Table 14.2.3.2.1
Summary of Target Lesion Change
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Baseline (mm)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Best Percentage Change from Baseline (%)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
<Cycle x Day Y>			
Tumor Assessment (mm)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Percentage Change from Baseline (%)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
<insert Visit>			

Note: The percentage change is based on the sum of all target lesions per participant.
Note: The best percentage change from baseline is maximum percentage decrease or minimum percentage increase if there is no decrease per participant.
Source: Listing 16.2.6.3.

Table 14.2.3.2.2
Summary of Target Lesion Change by Baseline Tumor Size
Analysis Set: Full Analysis Set

Baseline Tumor Size: ≤2 cm

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Baseline (mm)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Best Percentage Change from Baseline (%)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
<Cycle x Day Y>			
Tumor Assessment (mm)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Percentage Change from Baseline (%)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
<insert Visit>			

Note: The percentage change is based on the sum of all target lesions per participant.
Note: The best percentage change from baseline is maximum percentage decrease or minimum percentage increase if there is no decrease per participant.
Note: Baseline tumor size categories are derived based on data collected instead of data reported in IRT.
Source: Listing 16.2.6.3.

Programming Note:

Repeated >2 to <5 cm, and ≥5 cm on separated pages

Table 14.2.3.3.1
Summary of Target Lesion (Primary Tumor) Change
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Baseline (mm)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Best Percentage Change from Baseline (%)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
<Cycle x Day Y>			
Tumor Assessment (mm)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Percentage Change from Baseline (%)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
<insert Visit>			

Note: The percentage change is based on the target lesions being marked as the primary tumor per participant.
Note: The best percentage change from baseline is maximum percentage decrease or minimum percentage increase if there is no decrease per participant.
Source: Listing 16.2.6.3.

Table 14.2.3.3.2
Summary of Target Lesion (Primary Tumor) Change by Baseline Tumor SizeAnalysis Set: Full Analysis Set

Baseline Tumor Size: ≤2 cm

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Baseline (mm)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Best Percentage Change from Baseline (%)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
<Cycle x Day Y>			
Tumor Assessment (mm)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Percentage Change from Baseline (%)			
n	xxx	xx	xx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
<insert Visit>			

Note: The percentage change is based on the target lesions being marked as the primary tumor per participant.
Note: The best percentage change from baseline is maximum percentage decrease or minimum percentage increase if there is no decrease per participant.
Note: Baseline tumor size categories are derived based on data collected instead of data reported in IRT.
Source: Listing 16.2.6.3.

Programming Note:

Repeated >2 to <5 cm, and ≥5 cm on separated pages

Table 14.2.4.1.1
Summary of ER AQUA Score Percentage Change at C1D15 from Baseline Value
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
ER AQUA score at baseline			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
ER AQUA score at C1D15			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
ER AQUA score percentage change at C1D15			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx

Note: AQUA = absolute quantification score in arbitrary units.
[1] Analysis based on an analysis of covariance (ANCOVA) model with baseline Ki-67 score (assessed **centrally**: <20% vs ≥20%), the tumor size (≤2 cm, >2 to <5 cm, or ≥5 cm) as covariates for treatment. Baseline Ki-67 score and/or the tumor size categories are derived based on data collected instead of data reported in IRT.
Source: Listing 16.2.6.2.

Programming Note:

Table 14.2.4.1.2
Summary of ER AQUA Score Percentage Change at C1D15 from Baseline Value without Covariate
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
ER AQUA score at baseline			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
ER AQUA score at C1D15			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
ER AQUA score percentage change at C1D15			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx

Note: AQUA = absolute quantification score in arbitrary units.
[1] Analysis based on an analysis of variance (ANOVA) model.
Source: Listing 16.2.6.2.

Programming Note:

Table 14.2.4.1.3
Summary of Log-Transformed ER AQUA Score Change at C1D15 from Baseline Value without Covariate
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(ER AQUA score at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(ER AQUA score at C1D15)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(ER AQUA score at C1D15) - log(ER AQUA score at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between ER AQUA score at C1D15 and baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: AQUA = absolute quantification score in arbitrary units.
[1] Analysis based on an analysis of variance (ANOVA) model.
[2] Back transformed values of [1].
Source: Listing 16.2.6.2.

Table 14.2.4.2.1
Summary of ER AQUA Score Percentage Change at Surgery from Baseline Value
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
ER AQUA score at baseline			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
ER AQUA score at surgery			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
ER AQUA score percentage change at surgery			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx

Note: AQUA = absolute quantification score in arbitrary units.
[1] Analysis based on an analysis of covariance (ANCOVA) model with baseline Ki-67 score (assessed **centrally**: <20% vs ≥20%), the tumor size (≤2 cm, >2 to <5 cm, or ≥5 cm) as covariates for treatment. Baseline Ki-67 score and/or the tumor size categories are derived based on data collected instead of data reported in IRT.
Source: Listing 16.2.6.2.

Table 14.2.4.2.2
Summary of ER AQUA Score Percentage Change at Surgery from Baseline Value without Covariate
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
ER AQUA score at baseline			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
ER AQUA score at surgery			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
ER AQUA score percentage change at surgery			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx

Note: AQUA = absolute quantification score in arbitrary units.
[1] Analysis based on an analysis of variance (ANOVA) model.
Source: Listing 16.2.6.2.

Programming Note:

Table 14.2.4.2.3
Summary of Log-Transformed ER AQUA Score Change at Surgery from Baseline Value without Covariate
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(ER AQUA score at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(ER AQUA score at surgery)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(ER AQUA score at surgery) - log(ER AQUA score at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between ER AQUA score at Surgery and baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: AQUA = absolute quantification score in arbitrary units.
[1] Analysis based on an analysis of variance (ANOVA) model.
[2] Back transformed values of [1].
Source: Listing 16.2.6.2.

Table 14.2.5.1.1
Summary of PR H-score Percentage Change at C1D15 from Baseline Value without Covariate
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
PR H-score at baseline			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
PR H-score at C1D15			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
PR H-score percentage change at C1D15			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx

Note: PR (progesterone receptor) H-score = (SCORE_1)*1 + (SCORE_2)*2 + (SCORE_3)*3 from PgR636 assessment.
[1] Analysis based on an analysis of variance (ANOVA) model.
Source: Listing 16.2.6.1.

Programming Note:

Table 14.2.5.1.2
Summary of Log-Transformed PR H-score Change at C1D15 from Baseline Value without Covariate
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(PR H-score at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(PR H-score at C1D15)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(PR H-score at C1D15) - log(PR H-score at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between PR H-score at C1D15 and baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: PR (progesterone receptor) H-score = (SCORE_1)*1 + (SCORE_2)*2 + (SCORE_3)*3 from PgR636 assessment.
[1] Analysis based on an analysis of variance (ANOVA) model.
[2] Back transformed values of [1].
Source: Listing 16.2.6.1.

Table 14.2.5.2.1
Summary of PR H-score Percentage Change at Surgery from Baseline Value without Covariate
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
PR H-score at baseline			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
PR H-score at surgery			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
PR H-score percentage change at surgery			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx

Note: PR (progesterone receptor) H-score = (SCORE_1)*1 + (SCORE_2)*2 + (SCORE_3)*3 from PgR636 assessment.
[1] Analysis based on an analysis of variance (ANOVA) model.
Source: Listing 16.2.6.1.

Programming Note:

Table 14.2.5.2.2
Summary of Log-Transformed PR H-score Change at Surgery from Baseline Value without Covariate
Analysis Set: Full Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Difference
log(PR H-score at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(PR H-score at surgery)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
log(PR H-score at surgery) - log(PR H-score at baseline)			
n	xxx	xx	
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	
Median	xx.x	xx.x	
Min, Max	xx, xx	xx, xx	
LSM (Standard Error)[1]	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
80% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for LSM[1]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
95% Confidence Interval for LSM Difference[1]			xx.xx, xx.xx
Ratio between PR H-score at surgery and baseline			
Geometric Means[2]	xx.x	xx.x	xx.x
80% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
95% Confidence Interval for Geometric Means[2]	xx.xx, xx.xx	xx.xx, xx.xx	
80% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx
95% Confidence Interval for Geometric Means Difference[2]			xx.xx, xx.xx

Note: PR (progesterone receptor) H-score = (SCORE_1)*1 + (SCORE_2)*2 + (SCORE_3)*3 from PgR636 assessment.
[1] Analysis based on an analysis of variance (ANOVA) model.
[2] Back transformed values of [1].
Source: Listing 16.2.6.1.

Table 14.3.1
Summary of Treatment Emergent Adverse Events Overview
Analysis Set: Safety Analysis Set

Number of subjects with any of, n(%)	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
TEAEs	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
TEAEs related to study drug	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
TEAEs with grade 3 or higher	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
TEAEs with grade 3 or higher related to study drug	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Serious TEAEs	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Serious TEAEs related to study drug	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
TEAEs leading to drug withdrawn	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
TEAEs related to study drug leading to drug withdrawn	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
TEAEs leading to drug interruption	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
TEAEs related to study drug leading to drug interruption	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
TEAEs leading to dose reduction	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
TEAEs related to study drug leading to dose reduction	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
TEAEs with outcome of death	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

Note: A TEAE is an AE that emerges or worsens (ie increase in CTCAE grade) on/after the first dose of ARV-471/Anastrozole to 30 days from the last administration of the study intervention (ie, study drug treatment or surgical resection, whichever occurs last).
Source: Listing 16.2.7.1.

Table 14.3.2.1
Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Analysis Set: Safety Analysis Set

System organ class Preferred Term	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Subjects with any TEAE, n(%)	XX(XX.X)	XX(XX.X)	XX(XX.X)
System organ class 1	XX(XX.X)	XX(XX.X)	XX(XX.X)
Preferred Term 1	XX(XX.X)	XX(XX.X)	XX(XX.X)
Preferred Term 2	XX(XX.X)	XX(XX.X)	XX(XX.X)
System organ class 2	XX(XX.X)	XX(XX.X)	XX(XX.X)
Preferred Term 1	XX(XX.X)	XX(XX.X)	XX(XX.X)
Preferred Term 2	XX(XX.X)	XX(XX.X)	XX(XX.X)

Note: Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) version 27.0.
Note: A TEAE is an AE that emerges or worsens (ie increase in CTCAE grade) on/after the first dose of ARV-471/Anastrozole to 30 days from the last administration of the study intervention (ie, study drug treatment or surgical resection, whichever occurs last).
Source: Listings 16.2.7.1.

Programming Note:

Repeat the following tables with Table 14.3.2.1 shell

Table 14.3.2.2
Summary of Treatment Emergent Adverse Events Related to Study Drug by System Organ Class
and Preferred Term
Analysis Set: Safety Analysis Set

Programming Note: update “Subjects with any TEAE” to “Subjects with any TEAE Related to Study Drug”

Table 14.3.2.3
Summary of Treatment Emergent Adverse Events with Grade 3 or Higher by System Organ Class
and Preferred Term
Analysis Set: Safety Analysis Set

Programming Note: update “Subjects with any TEAE” to “Subjects with any Grade 3 or higher TEAE”

Table 14.3.2.4
Summary of Treatment Emergent Adverse Events with Grade 3 or Higher Related to Study Drug by System Organ Class
and Preferred Term
Analysis Set: Safety Analysis Set

Programming Note: update “Subjects with any TEAE” to “Subjects with any Grade 3 or higher TEAE Related to Study Drug”

Table 14.3.2.5.1
Summary of Treatment Emergent Adverse Events Leading to Drug Withdrawn by System Organ Class
and Preferred Term
Analysis Set: Safety Analysis Set

Programming Note:
update “Subjects with any TEAE” to “Subjects with any TEAE Leading to Drug Withdrawn”

Table 14.3.2.5.2
Summary of Treatment Emergent Adverse Events Related to Study Drug Leading to Drug Withdrawn
by System Organ Class and Preferred Term
Analysis Set: Safety Analysis Set

Programming Note:
update “Subjects with any TEAE” to “Subjects with any TEAE Related to Study Drug Leading to Drug Withdrawn”

Table 14.3.2.6.1
Summary of Treatment Emergent Adverse Events Leading to Drug Interrupted by System Organ Class
and Preferred Term
Analysis Set: Safety Analysis Set

Programming Note:
update “Subjects with any TEAE” to “Subjects with any TEAE Leading to Drug Interrupted”

Table 14.3.2.6.2
Summary of Treatment Emergent Adverse Events Related to Study Drug Leading to Drug Interrupted
by System Organ Class and Preferred Term
Analysis Set: Safety Analysis Set

Programming Note:
update “Subjects with any TEAE” to “Subjects with any TEAE Related to Study Drug Leading to Drug Interrupted”

Table 14.3.2.7.1
Summary of Treatment Emergent Adverse Events Leading to Dose Reduced by System Organ Class
and Preferred Term
Analysis Set: Safety Analysis Set

Programming Note:
update “Subjects with any TEAE” to “Subjects with any TEAE Leading to Dose Reduced”

Table 14.3.2.7.2
Summary of Treatment Emergent Adverse Events Related to Study Drug Leading to Dose Reduced
by System Organ Class and Preferred Term
Analysis Set: Safety Analysis Set

Programming Note:
update “Subjects with any TEAE” to “Subjects with any TEAE Related to Study Drug Leading to Dose Reduced”

Table 14.3.2.8
Summary of Treatment Emergent Adverse Events by Preferred Term
Analysis Set: Safety Analysis Set

Preferred Term	ARV-471 200 mg N=XX	Anastrozole 1 mg N=XX	Total N=XXX
Subjects with any TEAE, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Preferred Term 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Preferred Term 2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Preferred Term 3	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Preferred Term 4	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

Note: Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) version 27.0.
Note: A TEAE is an AE that emerges or worsens (ie increase in CTCAE grade) on/after the first dose of ARV-471/Anastrozole to 30 days from the last administration of the study intervention (ie, study drug treatment or surgical resection, whichever occurs last).
Source: Listings 16.2.7.1.

Programming Note:

Repeat the following tables with Table 14.3.2.8 shell

Table 14.3.2.9
Summary of Treatment Emergent Adverse Events Related to Study Drug by Preferred Term
Analysis Set: Safety Analysis Set

Programming Note: update “Subjects with any TEAE” to “Subjects with any TEAE Related to Study Drug”

Table 14.3.2.10
Summary of Treatment Emergent Adverse Events by System Organ Class,
Preferred Term and Maximum CTCAE Grade
Analysis Set: Safety Analysis Set

System organ class Preferred Term CTCAE Grade	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Subjects with any TEAE, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 3	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 4	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 5	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
System organ class 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 3	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 4	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 5	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Preferred Term 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 3	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 4	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 5	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

Note: Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) version 27.0, and graded according to the NCI-CTCAE version 5.0.
Note: A TEAE is an AE that emerges or worsens (ie increase in CTCAE grade) on/after the first dose of ARV-471/Anastrozole to 30 days from the last administration of the study intervention (ie, study drug treatment or surgical resection, whichever occurs last).
Source: Listings 16.2.7.1.

Repeat the following tables with Table 14.3.2.10 shell

Table 14.3.2.11
Summary of Treatment Emergent Adverse Events Related to Study Drug by System Organ Class,
Preferred Term and Maximum CTCAE Grade
Analysis Set: Safety Analysis Set

Programming Note: update “Subjects with any TEAE” to “Subjects with any TEAE Related to Study Drug”

Table 14.3.2.12
Summary of MedDRA SMQ for Torsade de Pointes by Preferred Term and Maximum CTCAE Grade
Analysis Set: Safety Analysis Set

Preferred Term CTCAE Grade	ARV-471 200 mg N=XX	Anastrozole 1 mg N=XX	Total N=XXX
Subjects with any SMQ for Torsade de Pointes, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 3	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 4	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 5	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Preferred Term 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 3	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 4	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 5	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Preferred Term 2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 1	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 2	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 3	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 4	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Grade 5	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

Note: Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) version 27.0, and graded according to the NCI-CTCAE version 5.0.
Source: Listings 16.2.7.1.

Programming Note:
PTs include Electrocardiogram QT interval abnormal, Electrocardiogram QT prolonged, Long QT syndrome, Long QT syndrome congenital, Torsade de pointes, Ventricular tachycardia, Arrhythmic storm, Cardiac arrest, Cardiac death, Cardiac fibrillation, Cardio-respiratory arrest, Electrocardiogram repolarisation abnormality, Electrocardiogram U wave inversion, Electrocardiogram U wave present, Electrocardiogram U-wave abnormality, Loss of consciousness, Seizure, Sudden cardiac death, Sudden death, Syncope, Ventricular arrhythmia, Ventricular fibrillation, Ventricular flutter, Ventricular tachyarrhythmia.

Repeat the following tables with Table 14.3.2.1 shell

Table 14.3.3.1
Summary of Serious Treatment Emergent Adverse Events by System Organ Class
and Preferred Term
Analysis Set: Safety Analysis Set

Programming Note:
update “Subjects with any TEAE” to “Subjects with any Serious TEAE”
update “Source: Listings 16.2.7.1. ” to “Source: Listings 16.2.7.2.”

Table 14.3.3.2
Summary of Serious Treatment Emergent Adverse Events Related to Study Drug by System Organ Class
and Preferred Term
Analysis Set: Safety Analysis Set

Programming Note:
update “Subjects with any TEAE” to “Subjects with any Serious TEAE Related to Study Drug”
update “Source: Listings 16.2.7.1. ” to “Source: Listings 16.2.7.2.”

Repeat the following tables with Table 14.3.2.8 shell

Table 14.3.3.3
Summary of Serious Treatment Emergent Adverse Events by Preferred Term
Analysis Set: Safety Analysis Set

Programming Note:
update “Subjects with any TEAE” to “Subjects with any Serious TEAE”
update “Source: Listings 16.2.7.1. ” to “Source: Listings 16.2.7.2.”

Table 14.3.3.4
Summary of Serious Treatment Emergent Adverse Events Related to Study Drug by Preferred Term
Analysis Set: Safety Analysis Set

Programming Note:
update “Subjects with any TEAE” to “Subjects with any Serious TEAE Related to Study Drug”
update “Source: Listings 16.2.7.1. ” to “Source: Listings 16.2.7.2.”

Repeat the following tables with Table 14.3.2.10 shell

Table 14.3.3.5
Summary of Serious Treatment Emergent Adverse Events by System Organ Class,
Preferred Term and Maximum CTCAE Grade
Analysis Set: Safety Analysis Set

Programming Note:
update “Subjects with any TEAE” to “Subjects with any Serious TEAE”
update “Source: Listings 16.2.7.1. ” to “Source: Listings 16.2.7.2.”

Table 14.3.3.6
Summary of Serious Treatment Emergent Adverse Events Related to Study Drug by System Organ Class,
Preferred Term and Maximum CTCAE Grade
Analysis Set: Safety Analysis Set

Programming Note:
update “Subjects with any TEAE” to “Subjects with any Serious TEAE Related to Study Drug”
update “Source: Listings 16.2.7.1. ” to “Source: Listings 16.2.7.2.”

Repeat the following tables with Table 14.3.2.1 shell

Table 14.3.3.7
Summary of Treatment Emergent Adverse Events Leading to Death by System Organ Class

and Preferred Term
Analysis Set: Safety Analysis Set

Programming Note:
update “Subjects with any TEAE” to “Subjects with any TEAE Leading to Death”

Table 14.3.3.8
Summary of Subject Death
Analysis Set: Safety Analysis Set

	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Number of Subject Death, n(%)	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Reason of Subject Death, n(%)			
Disease progression	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Adverse Event	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Unknown	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Other	XXX(XX.X)	XX(XX.X)	XXX(XX.X)

Source: Listing 16.2.1.1.

Programming Note:

Table 14.3.7.1
Summary of Hematology Laboratory by Visit
Analysis Set: Safety Analysis Set

Test (SI unit): Hemoglobin (g/L)

Time point	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Baseline			
n	xxx	xx	xxx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Cycle 1 Day x			
Absolute Value			
n	xxx	xx	xxx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Change from Baseline			
n	xxx	xx	xxx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
<insert Visit>			

Note: The baseline value is defined to be the last non-missing assessment on/before the date of the first ARV-471/anastrozole dose.
Source: Listing 16.2.8.3.

Programming Note:
Each Test starts from a new page.

Repeat the following tables with Table 14.3.7.1 shell

Table 14.3.7.3
Summary of Coagulation Laboratory by Visit
Analysis Set: Safety Analysis Set

Replace ‘Source: Listing 16.2.8.3’ with ‘Source: Listing 16.2.8.5’

Table 14.3.7.5
Summary of Serum Chemistry Laboratory by Visit
Analysis Set: Safety Analysis Set

Replace ‘Source: Listing 16.2.8.3’ with ‘Source: Listing 16.2.8.4’

Table 14.3.7.2.1
Shift of Hematology CTCAE Grade from Baseline to Worst Post-baseline
Analysis Set: Safety Analysis Set

Test: Anemia

		Worst Post-baseline CTCAE Grade, n(%)						
	Baseline CTCAE Grade	Missing	0	1	2	3	4	Total
ARV-471200 mg (N=XXX)	Missing	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	0	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	1	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	2	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	3	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	4	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	Total	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(100)
Anastrozole 1 mg (N=XX)	Missing	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	0	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	1	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	2	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	3	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	4	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	Total	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(100)
Total (N=XXX)	Missing	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	0	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	1	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	2	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	3	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	4	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
	Total	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XXX(100)

Note: The baseline value is defined to be the last non-missing assessment on/before the date of the first ARV-471/anastrozole dose.
Note: Grade is derived using CTCAE 5.0.
Source: Listing 16.2.8.3.

Programming Note:
Each Test starts from a new page

Table 14.3.7.2.2
Summary of Hematology CTCAE On-Treatment Worsening
Analysis Set: Safety Analysis Set

	ARV-471 200 mg N=XXX		Anastrozole 1 mg N=XX	
	N'	Worsened from Baseline, n(%)	N'	Worsten from Baseline, n(%)
Neutrophil count decreased	XXX	XX(XX.X)	XXX	XX(XX.X)
White blood cell count decrease	XXX	XX(XX.X)	XXX	XX(XX.X)
Anemia	XXX	XX(XX.X)	XXX	XX(XX.X)
Platelat count decreased	XXX	XX(XX.X)	XXX	XX(XX.X)

Note: The baseline value is defined to be the last non-missing assessment on/before the date of the first ARV-471/anastrozole dose.
Note: Include lab data up to 28 days after the last dose of study intervention, which is grade using CTCAE 5.0.
Note: N' is the number of participants with baseline and at least on on-treatment assessment for the parameter of interest. It is the denominator of the percentage. n is the number of participants with CTCAE grade of on-treatment lab results worsten than baseline CTCAE grade.
Note: Treatment-worsening shift includes grade 0 baseline to grade 1/2/3/4 postbaseline, grade 1 at baseline to grade 2/3/4 postbaseline, grade 2 at baseline to grade 3/4 postbaseline, or grade 3 at baseline to grade 4 postbaseline.
Source: Listing 16.2.8.3

Programming Note:

Repeat the following tables with Table 14.3.7.2.1 shell

Table 14.3.7.4
Shift of Coagulation CTCAE Grade from Baseline to Worst Post-baseline
Analysis Set: Safety Analysis Set

Replace ‘Source: Listing 16.2.8.3’ with ‘Source: Listing 16.2.8.5’

Table 14.3.7.6
Shift of Serum Chemistry CTCAE Grade from Baseline to Worst Post-baseline
Analysis Set: Safety Analysis Set

Replace ‘Source: Listing 16.2.8.3’ with ‘Source: Listing 16.2.8.4’

Table 14.3.8.1
Summary of 12-lead ECGs by Visit
Analysis Set: Safety Analysis Set

Test (SI unit): Heart rate (beats/min)

Time point	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
Baseline			
n	xxx	xx	xxx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Cycle 1 Day x			
Absolute Value			
n	xxx	xx	xxx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Change from Baseline			
n	xxx	xx	xxx
Mean (Standard Deviation)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
<insert Visit>			

Note: The baseline value is defined to be the last non-missing assessment on/before the date of the first ARV-471/anastrozole dose.
Source: Listing 16.2.10.

Programming Note:
Each test starts on a new page.

Table 14.3.8.2
Summary of QTcF/QTcB Interval Clinically Significant
Analysis Set: Safety Analysis Set

Test: QTcF

Time point	ARV-471 200 mg N=XXX	Anastrozole 1 mg N=XX	Total N=XXX
QTcF at Baseline, n(%)			
QTcF >450 msec	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
QTcF >480 msec	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
QTcF >500 msec	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
QTcF Worst Post-Baseline, n(%)			
QTcF >450 msec	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
QTcF >480 msec	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
QTcF >500 msec	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
QTcF Worst Change from Baseline, n(%)			
>30 msec	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
>60 msec	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Cycle X Day Y, n(%)			
Value QTcF >450 msec	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Value QTcF >480 msec	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Value QTcF >500 msec	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Change from baseline >30 msec	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
Change from baseline >60 msec	XXX(XX.X)	XX(XX.X)	XXX(XX.X)
<insert Visit>			

Note: The baseline value is defined to be the last non-missing assessment on/before the date of the first ARV-471/anastrozole dose.
Source: Listing 16.2.10.

Programming Note:

Repeat Table for QTcB and Change QTcF to QTcB in the Table

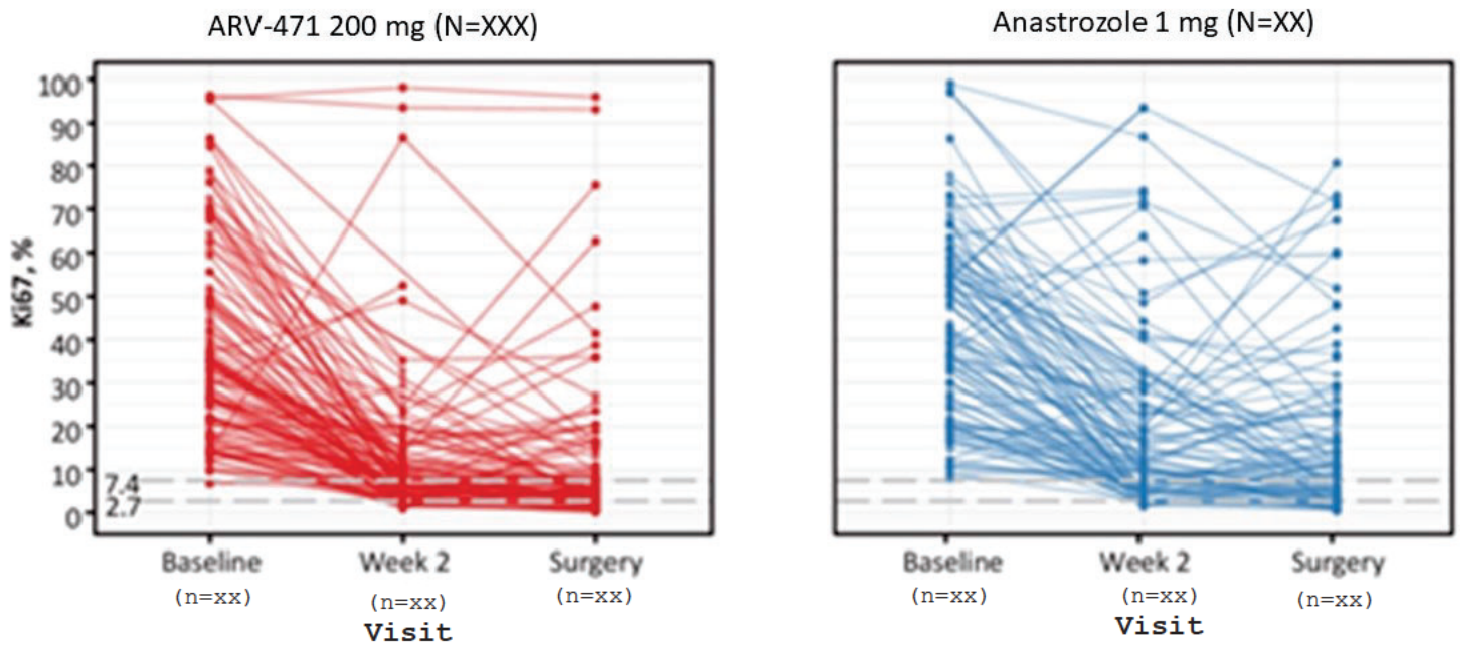
Table 14.3.10
Summary of ARV-471 and ARV-473 Plasma Concentration (unit) by Visit
Analysis Set: Pharmacokinetic Analysis Set

	n	Mean (SD)	Median	Min, Max	Geometric Mean	Geometric CV%
ARV-471 Plasm Concentration (unit)						
Pre-biopsy	xxx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
CxDy Pre-dose	xxx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
CxDy 1 hour (± 15 min) post-dose	xxx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
CxDy 2 hours (± 15 min) post-dose	xxx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
CxDy 4 hours (± 30 min) post-dose	xxx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
Pre-surgery	xxx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
ARV-473 Plasm Concentration (unit)						
Pre-biopsy	xxx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
CxDy Pre-dose	xxx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
CxDy 1 hour (± 15 min) post-dose	xxx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
CxDy 2 hours (± 15 min) post-dose	xxx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
CxDy 4 hours (± 30 min) post-dose	xxx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
Pre-surgery	xxx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx

Note: SD = Standard deviation; CV = Coefficient of variation.
Source: Listing 16.2.5.4.

Programming Note:

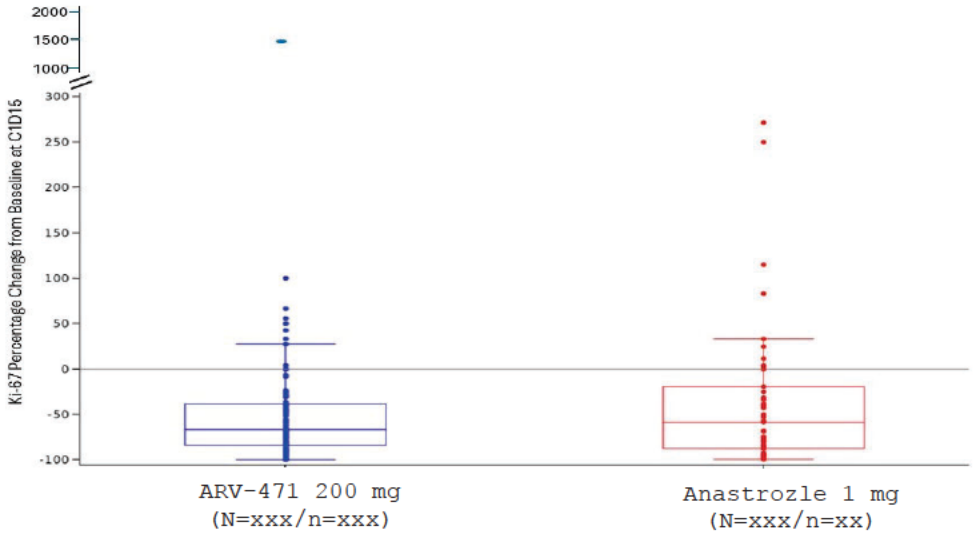
Figure 14.2.1.1
Spider Plot for Individual Ki-67 Value
Analysis Set: Full Analysis Set



Note: N is the number of participants in the Full Analysis Set. n is the number of participants with Ki-67 assessment at each visit.
Note: Week 2 Visit occurs on Cycle 1 Day 15 (C1D15).Note: Missing data is not included in the ARV-471 and anastrozole plots. Subjects treated with ARV-471 with missing data at baseline include XXX, XXXX, XXX; with missing at week 2 include XXXX, XXXXX, XXXX; with missing at C6D18 include 015-002, 015-005, xxxx. Subjects treated with Anastrozle with missing data at baseline include XXX, XXXX, XXX; with missing at week 2 include XXXX, XXXXX, XXXX; with missing at C6D18 include xxx, xxxx, xxxx.
Source: Listing 16.2.6.1.

Programming Note:

Figure 14.2.1.2.1
Box Plot for Ki-67 Percentage Change from Baseline at Cycle 1 Day 15
Analysis Set: Ki-67 Evaluable Set

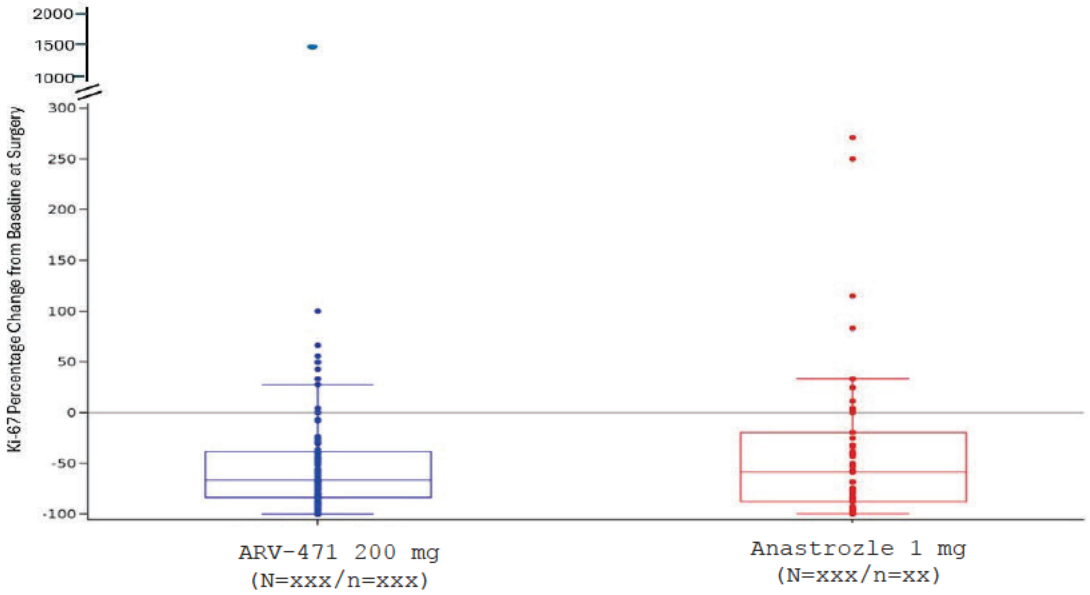


Note: Ki-67 Percentage Change from Baseline at C1D15 = 100 ×(Ki-67 at C1D15 - Ki-67 at baseline)/Ki-67 at baseline.
Note: N is the number of participants in the Ki-67 Evaluable Set. n is the number of participants with Ki-67 assessment at baseline and C1D15.
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the ARV-471 plot.
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the Anastrozle plot.
Source: Table 14.2.1.1.3 and Listing 16.2.6.1.

Programming Note:

Add panel on separated page for Surgery

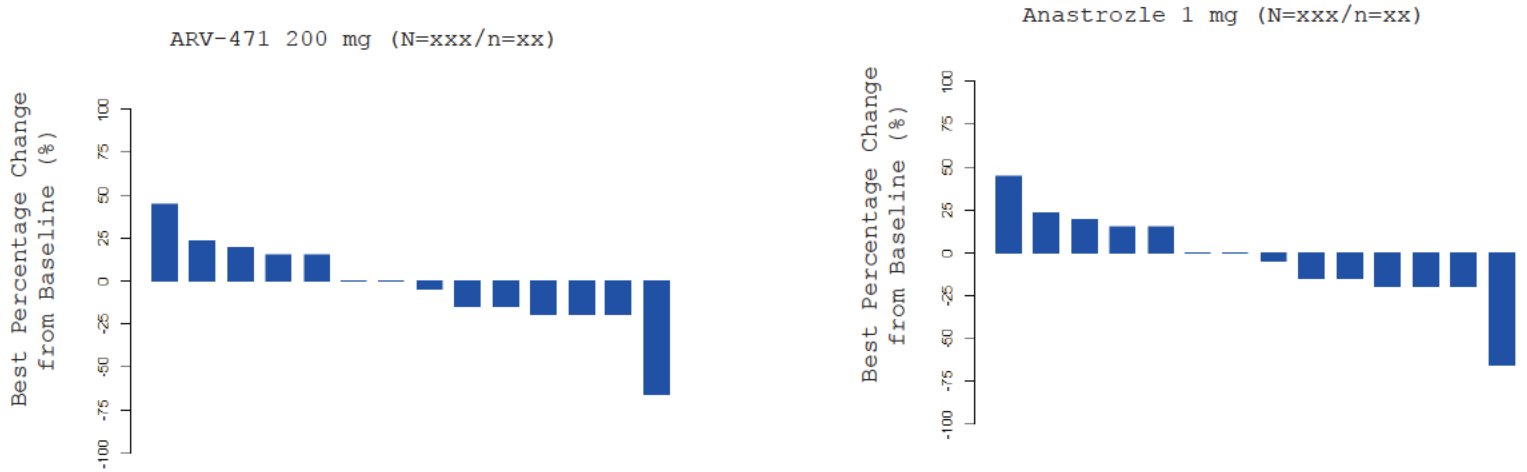
Figure 14.2.1.2.2
Box Plot for Ki-67 Percentage Change from Baseline at Surgery
Analysis Set: Full Analysis Set



Note: Ki-67 Percentage Change from Baseline at surgery = 100 ×(Ki-67 at surgery - Ki-67 at baseline)/Ki-67 at baseline.
Note: N is the number of participants in the Full Analysis Set. n is the number of participants with Ki-67 assessment at baseline and Surgery (C6D18).
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the ARV-471 plot.
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the Anastrozle plot.
Source: Table 14.2.1.3.3 and Listing 16.2.6.1.

Programming Note:

Figure 14.2.3.1
Waterfall Plot for Best Percentage Change of Primary Tumor from Baseline (Caliper-based)
Analysis Set: Full Analysis Set

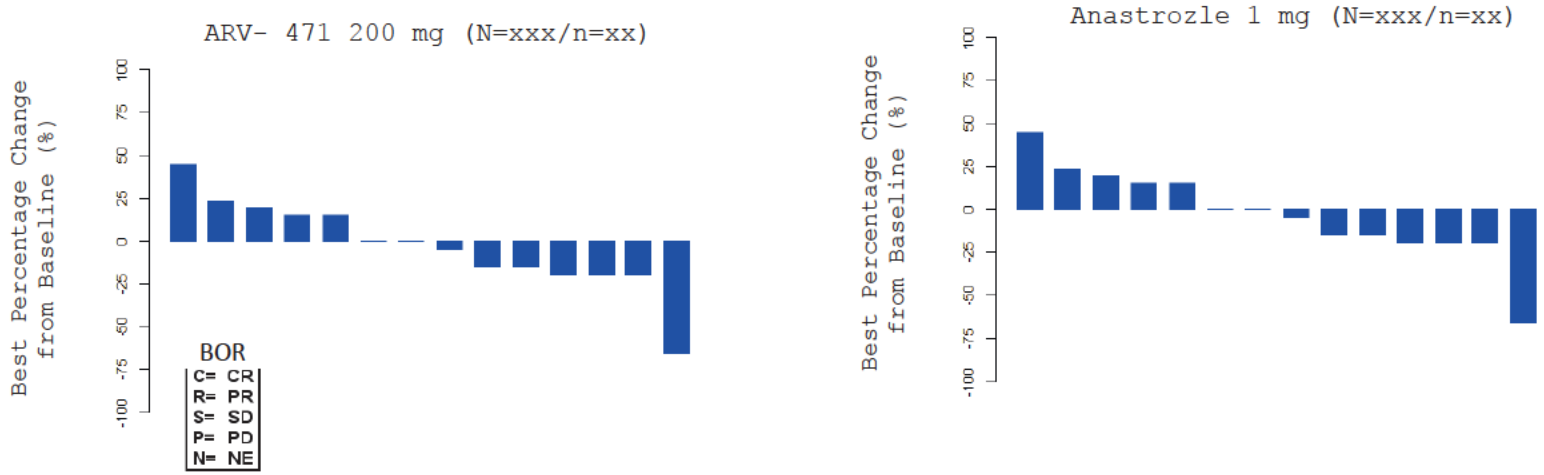


Note: Best percentage change of primary tumor from baseline is maximum decrease or minimum increase if no decrease being observed.
Note: N is the number of participants in the Full Analysis Set. n is the number of participants with Primary Tumor assessment at baseline and post-baseline.
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the ARV-471 plot.
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the Anastrozle plot.Source: Listing 16.2.6.2.

Programming Note:

- ARV- 471 uses blue color and Anastrozle uses red color as Figure 14.2.1.1.Add subject ID at the bottom.

Figure 14.2.3.2.1
Waterfall Plot for Best Percentage Change of Target Lesion from Baseline
Analysis Set: Full Analysis Set

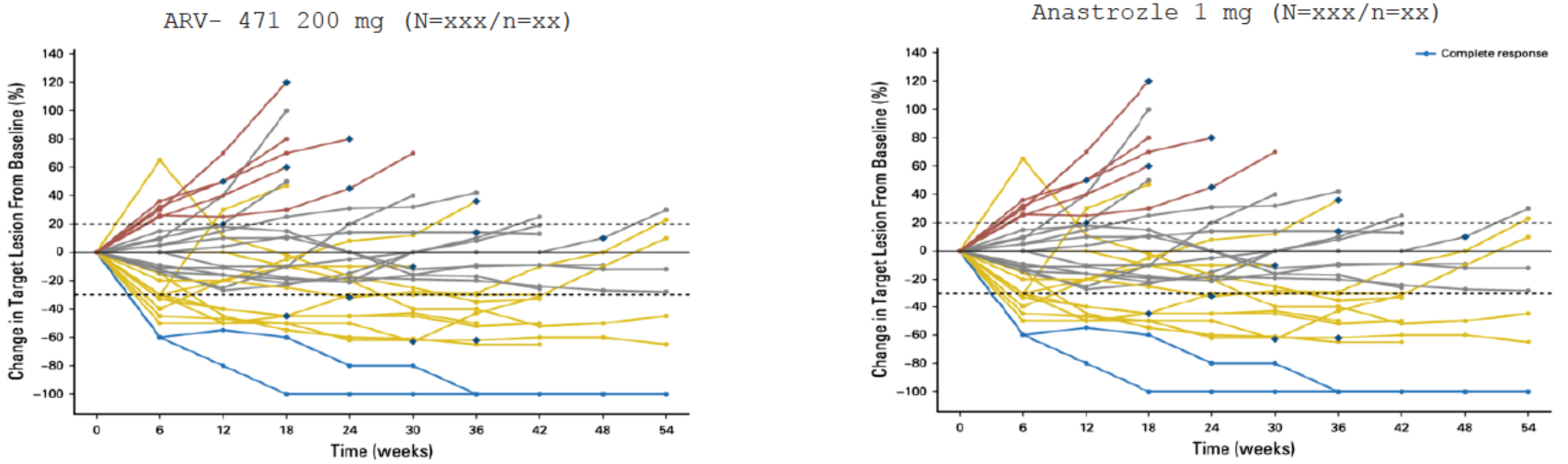


Note: Best percentage change of all targte lesions from baseline is maximum decrease or minimum increase if no decrease being observed.
Note: N is the number of participants in the Full Analysis Set. n is the number of participants with Target Lesion assessment at baseline and post-baseline.
Note: Select Best Overall Response(BOR) based on the order:CR,PR,SD,PD,NE.
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the ARV-471 plot.
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the Anastrozle plot.Source: Table 14.2.3.2 and 16.2.6.3.

Programming Note:

- ARV- 471 uses blue color and Anastrozle uses red color as Figure 14.2.1.1.
- Add subject ID at the bottom. add BOR on the top or bottom of each bar.Please use imgsu. IMGSRES and imgun. IMGRESP for Figure 14.2.3.2.1 (select the best response based on the sequency of CR>PR>SD>PD>NE)

Figure 14.2.3.2.2
Spider Plot for the Percent Target Lesion Size Change from Baseline by Subject and Timepoint
Analysis Set: Full Analysis Set

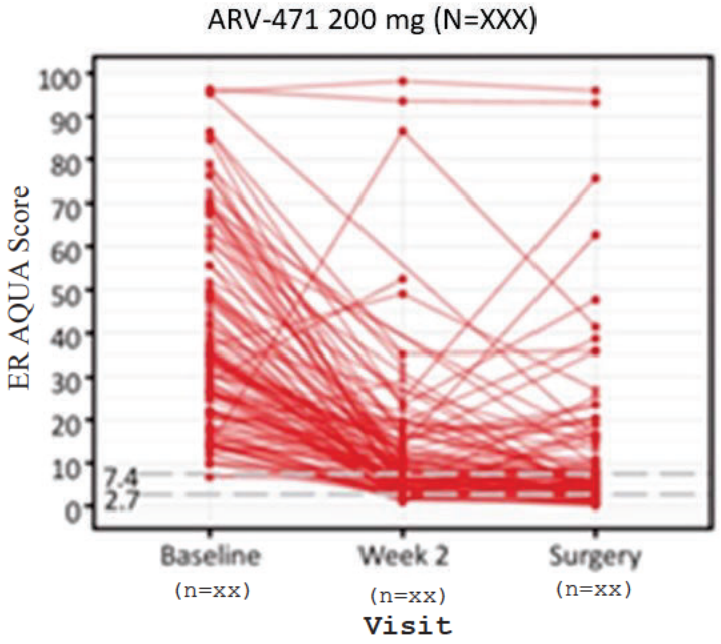


Note: The percentage change is based on the sum of all target lesions per participant.
Note: N is the number of participants in the Full Analysis Set. n is the number of participants with Target Lesion assessment at baseline and post-baseline.
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the ARV-471 plot.
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the Anastrozle plot.Source: Table 14.2.3.2 and 16.2.6.3.

Programming Note:

- ARV- 471 uses blue color and Anastrozle uses red color as Figure 14.2.1.1.
- Timepoint use Screen, Cycle 1, Cycle 2, Cycle 3 ….. instead of Time (week)

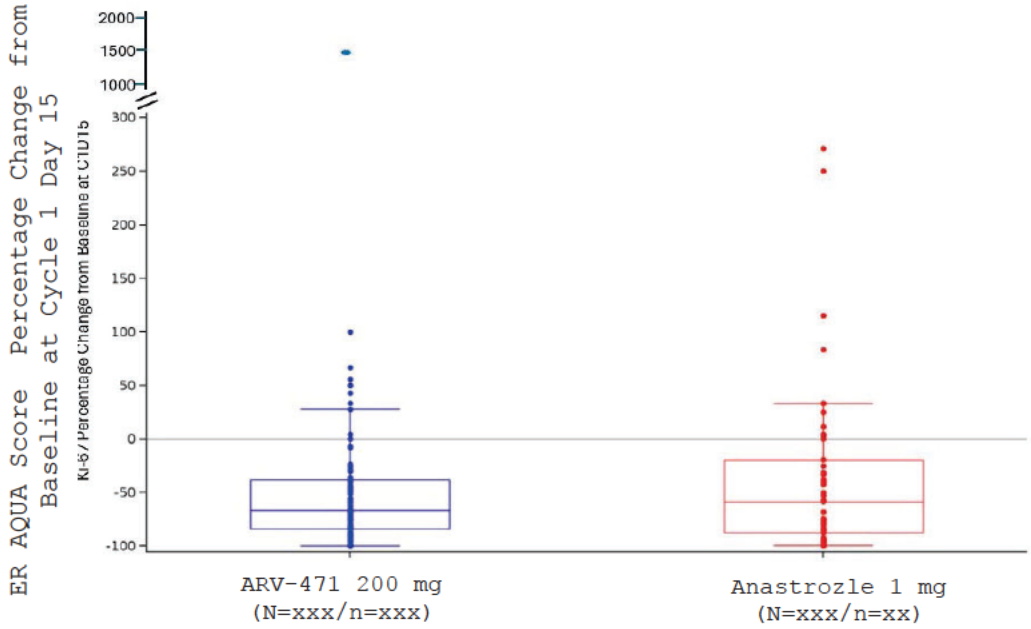
Figure 14.2.4.1
Spider Plot for Individual ER AQUA Score
Analysis Set: Full Analysis Set



Note: N is the number of participants in the Full Analysis Set. n is the number of participants with ER AQUA Score at each visit.
Note: Missing data is not included in the ARV-471 and anastrozole plots. Subjects treated with ARV-471 with missing data at baseline include XXX, XXXX, XXX; with missing at week 2 include XXXX, XXXXX, XXXX; with missing at C6D18 include 015-002, 015-005, xxxx. Subjects treated with Anastrozle do not have ER AQUA score assessment.Source: Table 14.2.1.1.3 and Listing 16.2.6.2.
Note: Week 2 Visit occurs on Cycle 1 Day 15 (C1D15).

Programming Note:

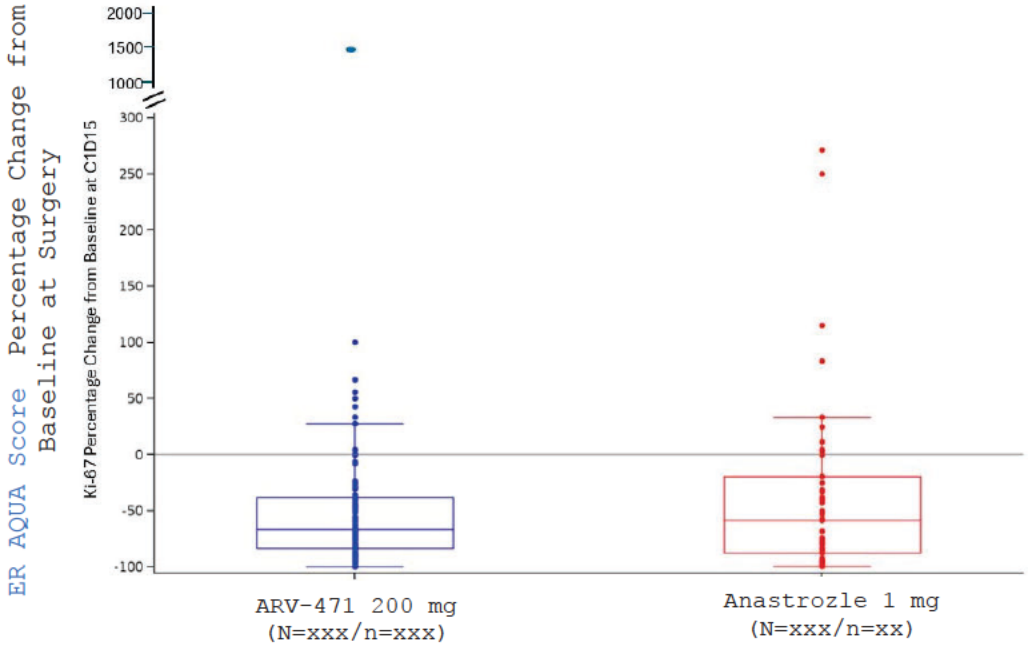
Figure 14.2.4.2.1
Box Plot for ER AQUA Score Percentage Change from Baseline at Cycle 1 Day 15
Analysis Set: Full Analysis Set



Note: ER AQUA Score Percentage Change from Baseline at C1D15 = 100 ×(ER AQUA Score at C1D15 - ER AQUA Score at baseline)/ER AQUA Score at baseline.
Note: N is the number of participants in the Full Analysis Set. n is the number of participants with ER AQUA Score at baseline and C1D15.
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the ARV-471 plot.
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the Anastrozle plot.
Source: Table 14.2.4.1.2 and Listing 16.2.6.2.

Programming Note:
See Figure 14.2.1.2.1 for reference as well.

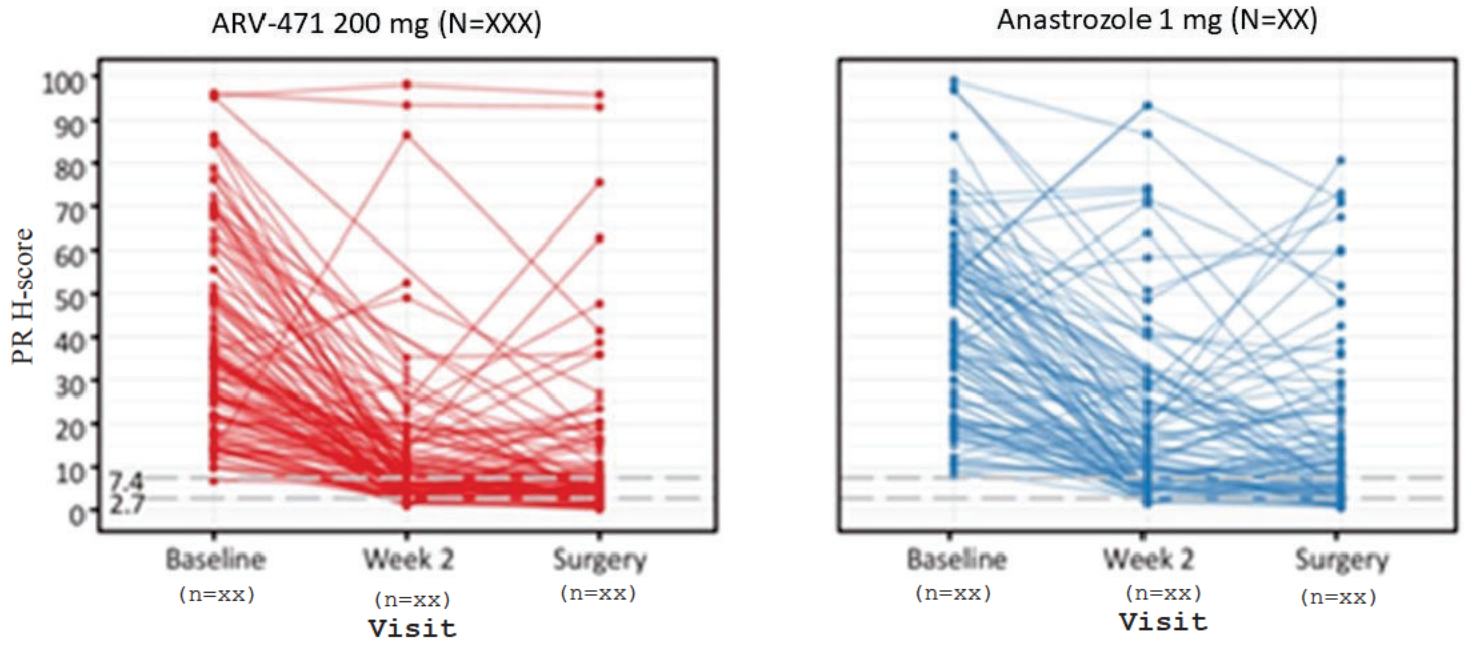
Figure 14.2.4.2.2
Box Plot for ER AQUA Score Percentage Change from Baseline at Surgery
Analysis Set: Full Analysis Set



Note: ER AQUA Score Percentage Change from Baseline at surgery = 100 ×(ER AQUA Score at surgery - ER AQUA Score at baseline)/ ER AQUA Score at baseline.
Note: N is the number of participants in the Full Analysis Set. n is the number of participants with ER AQUA Score at baseline and Surgery (C6D18).
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the ARV-471 plot.
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the Anastrozle plot.
Source: Table 14.2.4.2.2 and Listing 16.2.6.2.

Programming Note:
See Figure 14.2.1.2.1 for reference as well.

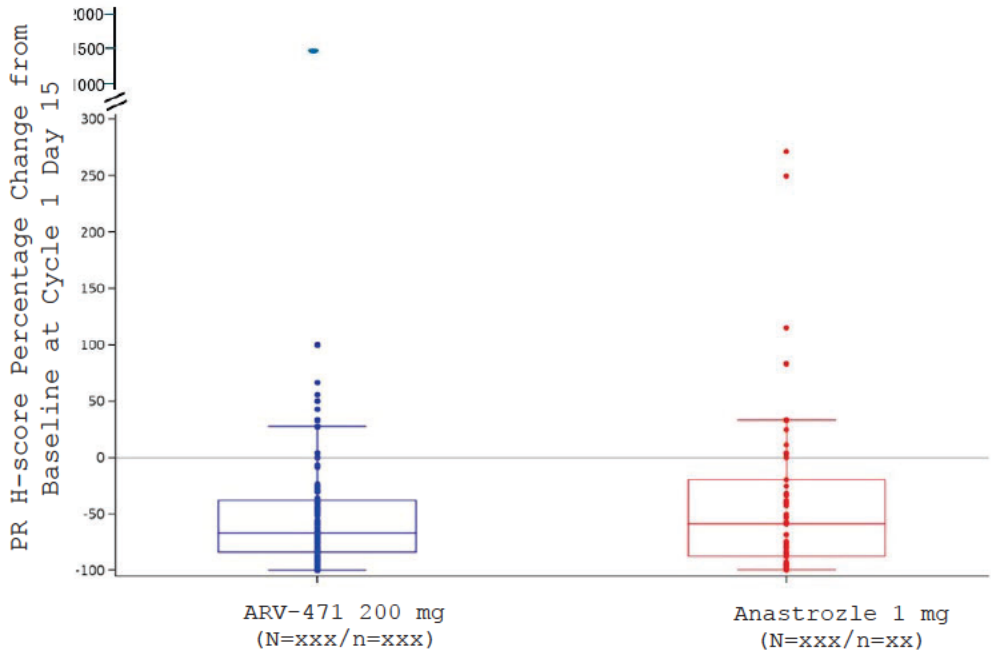
Figure 14.2.5.1
Spider Plot for Individual PR H-score
Analysis Set: Full Analysis Set



Note: N is the number of participants in the Full Analysis Set. n is the number of participants with PR H-score at each visit.
Note: Missing data is not included in the ARV-471 and anastrozole plots. Subjects treated with ARV-471 with missing data at baseline include XXX, XXXX, XXX; with missing at week 2 include XXXX, XXXXX, XXXX; with missing at C6D18 include 015-002, 015-005, xxxx. Subjects treated with Anastrozle with missing data at baseline include XXX, XXXX, XXX; with missing at week 2 include XXXX, XXXXX, XXXX; with missing at C6D18 include xxx, xxxx, xxxx.Source: Listing 16.2.6.1.
Note: Week 2 Visit occurs on Cycle 1 Day 15 (C1D15).

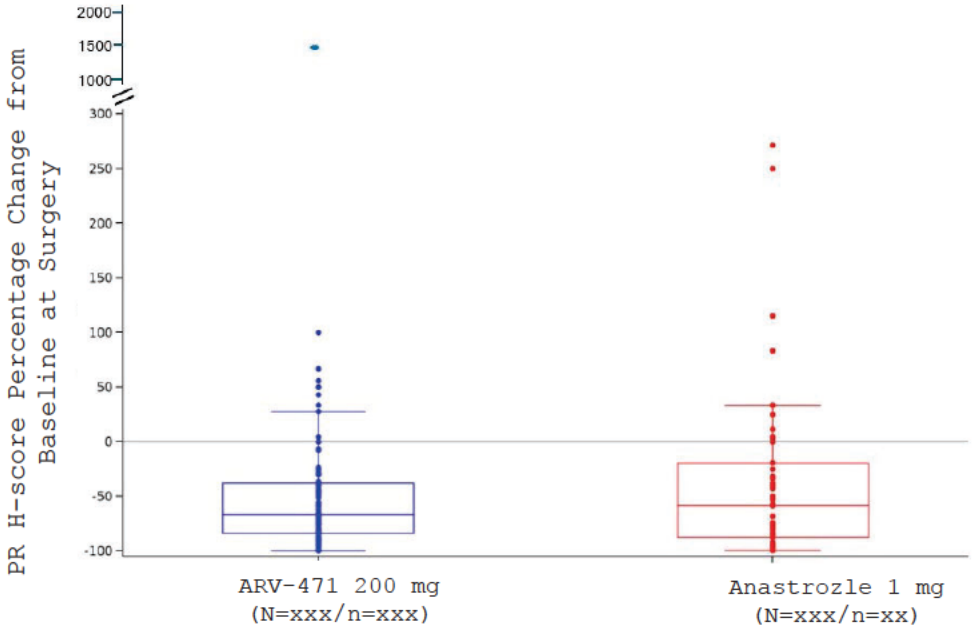
Programming Note:

Figure 14.2.5.2.1
Box Plot for PR H-score Percentage Change from Baseline at Cycle 1 Day 15
Analysis Set: Full Analysis Set



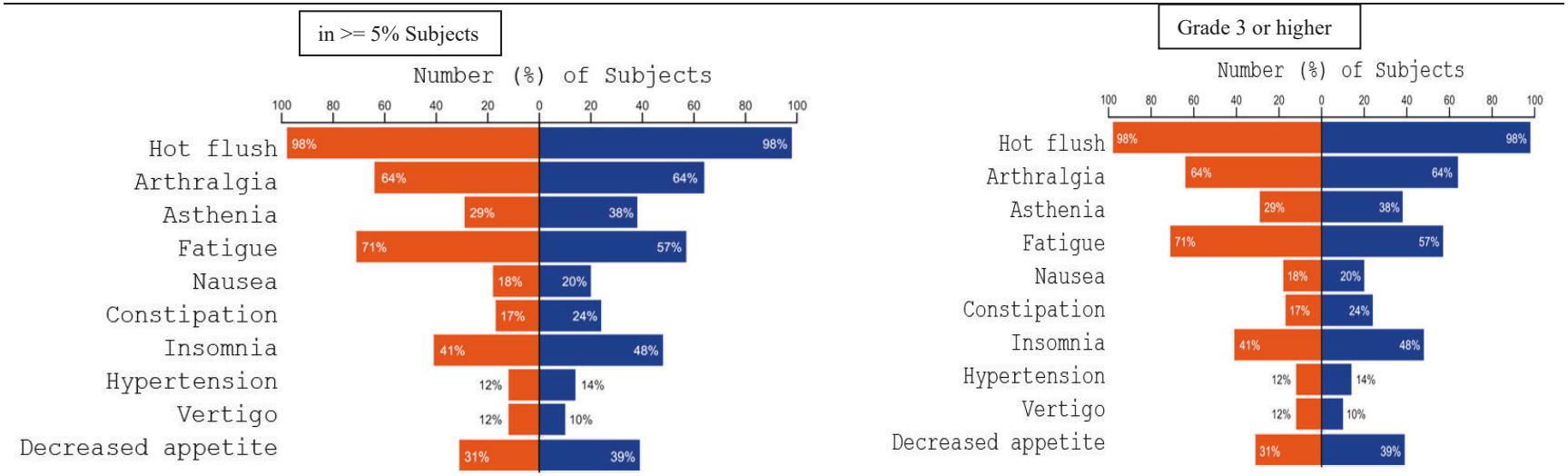
Note: PR H-score Percentage Change from Baseline at C1D15 = 100 ×(PR H-score at C1D15 - PR H-score at baseline)/PR H-score at baseline.
Note: N is the number of participants in the Full Analysis Set. n is the number of participants with PR H-score at baseline and C1D15.
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the ARV-471 plot.
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the Anastrozle plot.
Source: Listing 16.2.6.1.

Figure 14.2.5.2.2
Box Plot for PR H-score Percentage Change from Baseline at Surgery
Analysis Set: Full Analysis Set



Note: PR H-score Percentage Change from Baseline at surgery = 100 ×(PR H-score at surgery - PR H-score at baseline)/PR H-score at baseline.
Note: N is the number of participants in the Full Analysis Set. n is the number of participants with PR H-score at baseline and Surgery (C6D18).
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the ARV-471 plot.
Note: Subjects without baseline and/or postbaseline assessment (XXXX, XXX, and XXX), or with different number of tumor at baseline/postbaseline (XXX, XXX, and XXXX) are not included in the Anastrozle plot.
Source: Listing 16.2.6.1.

Figure 14.3.2.8
Tornado Plot for Treatment Emergent Adverse Events by Preferred Term
Analysis Set: Safety Analysis Set



Note: Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) version 27.0.
Note: A TEAE is an AE that emerges or worsens (ie increase in CTCAE grade) on/after the first dose of ARV-471/Anastrozole to 30 days from the last administration of the study intervention (ie, study drug treatment or surgical resection, whichever occurs last).
Source: Table 14.3.2.8, Table 14.3.2.3 and Listings 16.2.7.1.

Programming Note:

- Add figure legend to indicate Arm A and Arm B color.

Listing 16.2.1.1
Subject Enrollment
Analysis Set: Full Analysis Set

Randomized Treatment: ARV-471 200 mg

Subject ID	Informed Consent Date	Date of First ARV-471/ Anastrozole Dose	Date of Last ARV-471/Anastrozole Dose (Study Day)	Safety Analysis Set/ Ki-67 Evaluable Set/ Pharmacodynamic Analysis Set/ Pharmacokinetic Analysis set	Date of Death (Study Day)	Primary Cause of Death
XXXX-XXX	DDMMMYYY	DDMMMYYY	DDMMMYYY (xx)	Yes/Yes/Yes/Yes		
XXXX-XXX	DDMMMYYY	DDMMMYYY	DDMMMYYY (xx)	Yes/Yes/Yes/Yes	DDMMMYYY (xx)	Disease Progression
XXXX-XXX	DDMMMYYY	DDMMMYYY	DDMMMYYY (xx)	No/No/No/No		
XXXX-XXX	DDMMMYYY	DDMMMYYY	DDMMMYYY (xx)	Yes/No/Yes/Yes	DDMMMYYY (xx)	Other: XXXXX
XXXX-XXX	DDMMMYYY	DDMMMYYY	DDMMMYYY (xx)	Yes/Yes/No/Yes		
XXXX-XXX	DDMMMYYY	DDMMMYYY	DDMMMYYY (xx)	Yes/Yes/Yes/No	DDMMMYYY (xx)	Adverse Event

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.
Note: Full Analysis Set is defined as all enrolled participants who were randomized. Safety Analysis Set is defined as all enrolled participants who receive at least 1 dose of study intervention. Ki-67 Evaluable Set is defined as all enrolled participants who were randomized and received at least one dose of study treatment and had evaluable Ki-67 measurements other than '0' or '< 1' from baseline and evaluable Ki-67 measurements from C1D15 visits.
Pharmacodynamic/Biomarker Analysis Set is defined as all enrolled participants with at least 1 of the Pharmacodynamic/Biomarkers evaluated at pre and/or post dose. PK Concentration Analysis Set includes all participants in the Safety Analysis Set who have at least one plasma concentration (including those below the limit of quantification) for ARV-471, or ARV-473.

Programming Note:

- Sorting order is by Subject ID.

Listing 16.2.1.2
Subject Disposition
Analysis Set: Enrolled Participants

Randomized Treatment: ARV-471 200 mg

Subject ID	Date of Last ARV-471/Anastrozole Dose (Study Day)	Reason for Treatment Discontinuation	Date of Study Discontinuation (Study Day)	Reason for Study Discontinuation
XXXX-XXX	DDMMMYYY (XX)	Never Dosed	DDMMMYYY (XX)	Withdrawal of Consent: DDMMMYYY
XXXX-XXX	DDMMMYYY (XX)	Disease Progression per Response Criteria	DDMMMYYY (XX)	Study Terminated by Sponsor
XXXX-XXX	DDMMMYYY (XX)	Clinical Progression: XXXXXXXXXXXXX	DDMMMYYY (XX)	Completed study per protocol
XXXX-XXX	DDMMMYYY (XX)	Withdrawal of Consent: Other - XXXXXXXXXX	DDMMMYYY (XX)	Lost to Follow-up
XXXX-XXX	DDMMMYYY (XX)	Completed Treatment per protocol		Death
XXXX-XXX	DDMMMYYY (XX)	Significant non-compliance	DDMMMYYY (XX)	Other: XXXXXXXXXXXXXXXXX
XXXX-XXX	DDMMMYYY (XX)	Pregnancy	DDMMMYYY (XX)	Withdrawal of Consent: DDMMMYYY
XXXX-XXX	DDMMMYYY (XX)	Death	DDMMMYYY (XX)	Study Terminated by Sponsor
XXXX-XXX	DDMMMYYY (XX)	Adverse Event: XX, XX, XX	DDMMMYYY (XX)	Completed study per protocol
XXXX-XXX	DDMMMYYY (XX)	Study Terminated by Sponsor	DDMMMYYY (XX)	Lost to Follow-up: DDMMMYYY
XXXX-XXX	DDMMMYYY (XX)	Lost to Follow-up		Death
XXXX-XXX	DDMMMYYY (XX)	Other: XXXXXXXXXXXXX	DDMMMYYY (XX)	Other: XXXXXXXXXXXXXXXXX
XXXX-XXX	DDMMMYYY (XX)	Withdrawal of Consent: Participant refused further study treatment/intervention, but will continue to be followed	DDMMMYYY (XX)	Withdrawal of Consent: DDMMMYYY
XXXX-XXX	DDMMMYYY (XX)	Withdrawal of Consent: Participant withdrawal from study	DDMMMYYY (XX)	Study Terminated by Sponsor

Note: Enrolled Participants included all subjects who signed the Informed Consent.
Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.

Programming Note:

- Sorting order is by Subject ID.
- Include Screen Failure in a separated page.
- Date after Lost to Follow-up is for the date of last Know to be Alive.

Listing 16.2.2
Deviations from the Clinical Protocol
Analysis Set: Full Analysis Set

Randomized Treatment: ARV-471 200 mg

Subject ID	Date of Protocol Deviation (Study Day)	Protocol Deviation Description	Protocol Deviation Category	Protocol Deviation Severity
XXXX-XXX	DDMMMYYYY (xx)	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXX	Minor
	DDMMMYYYY (xx)	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX	Minor
	DDMMMYYYY (xx)	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXX	Minor
XXXX-XXX	DDMMMYYYY (xx)	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX	Minor
XXXX-XXX	DDMMMYYYY (xx)	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXX	Minor

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.

Programming Note:

- Sorting order is by Subject ID, Date of Protocol Deviation.

Listing 16.2.4.1
Demographic Characteristics
Analysis Set: Full Analysis Set

Randomized Treatment: ARV-471 200 mg

Subject ID	Year of Birth/Age (years)	Sex/	Ethnicity	Race	Weight (kg) at Baseline	Height (cm) at Baseline	ECOG Performance Status at Baseline
XXXX-XXX	YYYY/XX	Female	Hispanic or Latino	American Indian or Alaskan Native	xxx.x	xxx.x	0
XXXX-XXX	YYYY/XX	Female	Not Hispanic or Latino	Asian	xxx.x	xxx.x	0
XXXX-XXX	YYYY/XX	Female	Not Reported	Black or African American	xxx.x	xxx.x	1
XXXX-XXX	YYYY/XX	Female	Not Reported	Native Hawaiian or Other Pacific Islander	xxx.x	xxx.x	1
XXXX-XXX	YYYY/XX	Female	Not Hispanic or Latino	White	xxx.x	xxx.x	1
XXXX-XXX	YYYY/XX	Female	Not Hispanic or Latino	Not Reported	xxx.x	xxx.x	1
XXXX-XXX	YYYY/XX	Female	Not Hispanic or Latino	White	xxx.x	xxx.x	0
XXXX-XXX	YYYY/XX	Female	Not Reported	Other: XXXXXX	xxx.x	xxx.x	1

Programming Note:

- Sorting order is by Subject ID.

Listing 16.2.4.2
Medical History
Analysis Set: Full Analysis Set

Randomized Treatment: ARV-471 200 mg

Subject ID	Category	System Organ Class/ Preferred Term/ Medical Condition or Past Surgery Term	Start Date (Study Day)/ Stop Date (Study Day)	CTCAE Grade	Taking Medication for Condition?
XXXX-XXX	Medical Condition	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing	Grade 1	No
	Medical Condition	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)	Grade 2	Yes
	Surgery	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)	Grade 3	Yes
XXXX-XXX	Medical Condition	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)	Grade 4	Yes
	Medical Condition	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)	Grade 1	No
	Medical Condition	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing	Grade 2	Yes
	Medical Condition	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing	Grade 1	Yes

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date − Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date − Date of Day 1 for assessment prior to Day 1.
Note: Medical Condition/Past Surgery was coded with MedDRA version 24.1.

Programming Note:
Sorting order is by Subject ID, System Organ Class, Preferred Term.

Listing 16.2.4.3
Disease Staging - Initial Diagnosis
Analysis Set: Full Analysis Set

Randomized Treatment: ARV-471 200 mg

Subject ID	Date of Initial Diagnosis (Study Day)	Primary Diagnosis	Disease Stage at Initial Diagnosis	Primary Tumor/ Regional Lymph Node/ Distant Metastasis	Histopathological Classification	Histopathological Grade
XXXX-XXX	DDMMMYYY(xx)	ER+ HER2- BC	Stage 0	TX/cNX/Unknown	In-Situ Carcinoma	Grade 1
XXXX-XXX	DDMMMYYY(xx)	ER+ HER2- BC	Stage IA	T0/cN0/M0	Invasive Ductal Carcinoma	Grade 3
XXXX-XXX	DDMMMYYY(xx)	ER+ HER2- BC	Stage IB	Tis/cN1/M1	Invasive Lobular Carcinoma	Grade 1
XXXX-XXX	DDMMMYYY(xx)	ER+ HER2- BC	Stage IIA	T1mi/cN2a/M0	Invasive Carcinoma NOS	Grade x
XXXX-XXX	DDMMMYYY(xx)	ER+ HER2- BC	Stage IIB	T1a/cN2b/M0	Invasive Mucinous	Grade 1
XXXX-XXX	DDMMMYYY(xx)	ER+ HER2- BC	Stage IIIA	T1b/cN2c/M0	Adenocarcinoma	Grade 2
XXXX-XXX	DDMMMYYY(xx)	ER+ HER2- BC	Unknown	T1c/cN3c/M1	Other: XXXXXXX	Grade 1

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.
Note: BC = Breast Cancer.

Programming Note:

- Sorting order is by Subject ID

Listing 16.2.4.4
Disease Staging - Current Diagnosis
Analysis Set: Full Analysis Set

Randomized Treatment: ARV-471 200 mg

Subject ID	Date of Current Staging (Study Day)	Primary Diagnosis	Disease Stage at Initial Diagnosis	Primary Tumor/ Regional Lymph Node/ Distant Metastasis	Histopathological Classification/ Histopathological Grade	Imaging Modality/ Planned Type of Surgery
XXXX-XXX	DDMMMYYY(xx)	ER+ HER2- BC	Stage 0	TX/cNX/Unknown	In-Situ Carcinoma/1	CT/Mastectomy
XXXX-XXX	DDMMMYYY(xx)	ER+ HER2- BC	Stage IA	T0/cN0/M0	Invasive Ductal Carcinoma/3	MRI/Mastectomy
XXXX-XXX	DDMMMYYY(xx)	ER+ HER2- BC	Stage IB	Tis/cN1/M1	Invasive Lobular Carcinoma/2	Ultrasound/BCS
XXXX-XXX	DDMMMYYY(xx)	ER+ HER2- BC	Stage IIA	T1mi/cN2a/M0	Invasive Carcinoma NOS/2	Mammogram/BCS
XXXX-XXX	DDMMMYYY(xx)	ER+ HER2- BC	Stage IIB	T1a/cN2b/M0	Invasive Mucinous/1	PET-CT/BCS
XXXX-XXX	DDMMMYYY(xx)	ER+ HER2- BC	Stage IIIA	T1b/cN2c/M0	Adenocarcinoma/1	PET-MRI/BCS
XXXX-XXX	DDMMMYYY(xx)	ER+ HER2- BC	Unknown	T1c/cN3c/M1	Other: XXXXXXX/X	CT/BCS

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.
Note: BC = Breast Cancer; BCS = Breast conserving surgery.

Programming Note:

- Sorting order is by Subject ID

Listing 16.2.4.5
Molecular Biology of Disease
Analysis Set: Full Analysis Set

Randomized Treatment: ARV-471 200 mg

Subject ID	Analyte/ Biomarker	Date of Collection (Study Day)	Specimen Type	Sample Site	Analytical Method/Result	Quantitative Parameter	Quantitative Result (%)
XXXX-XXX	HER2	DDMMMYYY(xx)	Tumor tissue	Breast	IHC/1+		
	KI67	DDMMMYYY(xx)	Tumor tissue	Lymph Node		Tumor cells	xx.x
	Estrogen receptor	DDMMMYYY(xx)	Tumor tissue	Other: XXXXX		Tumor cells	xx.x
	Progesterone receptor	DDMMMYYY(xx)	Tumor tissue	Breast		Tumor cells	xx.x
XXXX-XXX	HER2	DDMMMYYY(xx)	Tumor tissue	Breast	ISH/Negative		
	KI67	DDMMMYYY(xx)	Tumor tissue	Breast		Tumor cells	xx.x
	Estrogen receptor	DDMMMYYY(xx)	Tumor tissue	Other: XXXXX		Tumor cells	xx.x
	Progesterone receptor	DDMMMYYY(xx)	Tumor tissue	Other: XXXXX		Tumor cells	xx.x

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.
* indicates the baseline value.

Programming Note:
Sorting order is by Subject ID, Analyte/Biomarker, Date of Collection.
Include data in ‘Molecular Biology of Disease - HER2 Status’ and ‘Molecular Biology of Disease - Hormone Receptor/KI67 Status’

Listing 16.2.4.6
Prior and Concomitant Medications
Analysis Set: Full Analysis Set

Randomized Treatment: ARV-471 200 mg

Subject ID	Prior or Concomitant	ATC Category II/ Preferred Name/ Medication Name	Start Date (Study Day)/ Stop Date (Study Day)	Dose/ Unit	Frequency/ Route	Use
XXXX-XXX	Prior	XXXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXXXX	DDMMMYYYY (XX)/ Ongoing	XX/ Capsule	TID/ Oral	AE:#1, #5
	Concomitant	XXXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXXXX	DDMMMYYY (XX)/ DDMMMYYY (XX)	XX/ Gram	QIS/ Intramuscular	MH
	Concomitant	XXXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXXXX	DDMMMYYY (XX)/ DDMMMYYY (XX)	XX/ Microgram	BID/ Subcutaneous	MH
XXXX-XXX	Concomitant	XXXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXXXX	DDMMMYYY (XX)/ DDMMMYYY (XX)	XX/ Spray	UNKNOWN / Topical	AE:#1
	Concomitant	XXXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXXXX	DDMMMYYY (XX)/ DDMMMYYY (XX)	XX/ Other: XXXX	Other: XXX/ Unknown	Prophylaxis
XXXX-XXX	Prior	XXXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXXXX	DDMMMYYY (XX)/ DDMMMYYY (XX)	XX/ Tablet	QAM/ Other: XXXX	Other: XXXXX

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.
Note: Prior and Concomitant Medications are coded with WHODRUG Global B3 Sep 2022.
Note: Prior medications include non-study drug medications that are ended before Day 1. Concomitant medications include non-study drug medications that are used/started on/after Day 1 and within 30 days from the last administration of the study intervention (ie, study drug treatment or surgical resection, whichever occurs last).

Programming Note:

- Sorting order is by Subject ID, Prior or Concomitant, ATC Category II, Preferred Name

Listing 16.2.5.1
Study Drug Exposure and Compliance
Analysis Set: Safety Analysis Set

Treatment: ARV-471 200 mg

Subject ID	Duration of Treatment (week)	Cumulative Dose (mg)	Absolute Dose Intensity (mg/week)	Relative Dose Intensity (%)	Total Planned Dose (mg)	Compliance (%)	Number of Doses Interrupted	Number of Doses Reduced
XXXX-XXX	XX.X	XX	XX.X	XX.X	XX	XX.X	XXX	XXX
XXXX-XXX	XX.X	XX	XX.X	XX.X	XX	XX.X	XXX	XXX
XXXX-XXX	XX.X	XX	XX.X	XX.X	XX	XX.X	XXX	XXX
XXXX-XXX	XX.X	XX	XX.X	XX.X	XX	XX.X	XXX	XXX
XXXX-XXX	XX.X	XX	XX.X	XX.X	XX	XX.X	XXX	XXX
XXXX-XXX	XX.X	XX	XX.X	XX.X	XX	XX.X	XXX	XXX

Note: Duration of treatment (week) is defined as the time from the date of first dose to the date of last dose. Cumulative dose (mg) is the sum of 'Actual total daily dose' × (End date- Start date+1) per record. Total planned dose (mg) is the sum of 'Planned total daily dose' × (End date- Start date+1) per record. Compliance is 100*(Cumulative dose/Total planned dose), accounting for planned dose modifications and interruptions. Absolute dose intensity (mg/week)is (Cumulative Dose (mg))/(Duration of Treatment (week)). Relative dose intesity (%) is (Absolute Dose Intensity (mg/week))/(Initial Planned Weekly Dose (mg/week), 1400 for ARV-471 and 7 for Anastrozole)).

Programming Note:

- Sorting order is by Subject ID.

Listing 16.2.5.2
Study Drug Administration
Analysis Set: Safety Analysis Set

Actual Treatment: ARV-471 200 mg

Subject ID	Planned Total Daily Dose/Unit	Route/ Frequency	Start Date (Study Day)	End Date (Study Day)	Actual Total Daily Dose/Unit	Action Taken Regarding Dose Administration?	Reason for Dose Adjustment
XXXX-XXX	xx/XXXX	Oral/QD	DDMMMYYY (XX)	DDMMMYYY (XX)	xx/XXXX	No action taken	
	xx/XXXX	Oral/QD	DDMMMYYY (XX)	DDMMMYYY (XX)	xx/XXXX	Interrupted	Other: XXXX
	xx/XXXX	Oral/QD	DDMMMYYY (XX)	DDMMMYYY (XX)	xx/XXXX	Discontinued	AE: #x
	xx/XXXX	Oral/QD	DDMMMYYY (XX)	DDMMMYYY (XX)	xx/XXXX	Reduced	Missed dose
	xx/XXXX	Oral/QD	DDMMMYYY (XX)	DDMMMYYY (XX)	xx/XXXX	No action taken	
XXXX-XXX	xx/XXXX	Oral/QD	DDMMMYYY (XX)	DDMMMYYY (XX)	xx/XXXX	Interrupted	Medication error
	xx/XXXX	Oral/QD	DDMMMYYY (XX)	DDMMMYYY (XX)	xx/XXXX	No action taken	
	xx/XXXX	Oral/QD	DDMMMYYY (XX)	DDMMMYYY (XX)	xx/XXXX	No action taken	
	xx/XXXX	Oral/QD	DDMMMYYY (XX)	DDMMMYYY (XX)	xx/XXXX	Increased	

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.
Note: AE = Adverse Event; Missed dose = Participant missed/Skipped dose.

Programming Note:

- Sorting order is by Subject ID, Start date.

Listing 16.2.5.3
PK Dosing - ARV-471
Analysis Set: Safety Analysis Set

Actual Treatment: ARV-471 200 mg

Subject ID	Visit	Reference Time Point	Route/ Frequency	Start Date Time (Study Day)	Actual Dose (mg)	Dose Taken with Food?	Vomit within 6 Hours After Dosing?	Post Dose Vomiting Start Date Time
XXXX-XXX	C1D15	Prior dose	Oral/QD	DDMMMYYY HH:MM(XX)	XXX	No	No	
	C2D1	Prior dose	Oral/QD	DDMMMYYY HH:MM(XX)	XXX	No	Yes/AE#XXX	DDMMMYYY HH:MM
	C6D18	Prior dose	Oral/QD	DDMMMYYY HH:MM(XX)	XXX	No	No	
XXXX-XXX	C1D15	In clinic dose	Oral/QD	DDMMMYYY HH:MM(XX)	XXX	Yes	No	
	C2D1	In clinic dose	Oral/QD	DDMMMYYY HH:MM(XX)	XXX	No	Yes/AE#XXXX	DDMMMYYY HH:MM
	C6D18	In clinic dose	Oral/QD	DDMMMYYY HH:MM(XX)	XXX	Yes	No	

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.

Programming Note:

- Sorting order is by Subject ID, Start Date.

Listing 16.2.5.4
ARV-471 and ARV-473 Plasma Concentration
Analysis Set: PK Analysis Set

Actual Treatment: ARV-471 200 mg

Subject ID	Test (unit)	Visit	Collection Date Time (Study Day)	Time Point	Result	Comments	Flag[1]
XXXX-XXX	ARV-471 (unit)	C1D15	DDMMMYYYY HH:MM (XX)	Pre-biopsy	xxx.x		
		C2D1	DDMMMYYYY HH:MM (XX)	Pre-dose	xxx.x		a
			DDMMMYYYY HH:MM (XX)	1 hour (± 15 min) post-dose	xxx.x		
			DDMMMYYYY HH:MM (XX)	2 hours (± 15 min) post-dose	xxx.x	XXXXXX	
			DDMMMYYYY HH:MM (XX)	4 hours (± 30 min) post-dose	xxx.x		
		C6D18	DDMMMYYYY HH:MM (XX)	pre-surgery	xxx.x		c
	ARV-473 (unit)						
XXXX-XXX							

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.
[1] a: Pre-dose samples are collected after dosing time. b: Post-dose samples are collected out of time window on Cycle 2 Day 1. c: When ARV-471 dose is different from planned dose.

Programming Note:

- Sorting order is by Subject ID, Test , Visit.

Listing 16.2.6.1
Efficacy Parameters – Part 1 of 2
Analysis Set: Full Analysis Set

RandomizedTreatment: ARV-471 200 mg

Subject ID	Ki-67 Evaluable Analysis Set	Actual/Randomiztion Size of Primary Breast Tumor (cm)	% of Tumor cells with Ki67 Local/Central/Randomization	Ki-67 Expression (%) at Baseline/ C1D15/Surgery	Ratio of Ki-67 between C1D15/Surgery and Baseline	Percentage Change (%) of Ki-67 at C1D15/Surgery from Baseline	mPEPI Score at Baseline/ after Treatment	Percentage Change (%) of PR H-score at C1D15/Surgery from Baseline
XXXX-XXX	Yes	≤2/≤2	<20%/≥20%/<20%	XX.X/XX.X/XX.X	XX.X/XX.X	XX.X/XX.X	>3/0	XX.X/XX.X
XXXX-XXX	Yes	>2to<5/>2to<5	≥20%/<20%/<20%	XX.X/XX.X/XX.X	XX.X/XX.X	XX.X/XX.X	1~2/0	XX.X/XX.X
XXXX-XXX	Yes	≥5/≥5	<20%/<20%/<20%	XX.X/XX.X/XX.X	XX.X/XX.X	XX.X/XX.X	3/1~2	XX.X/XX.X
XXXX-XXX	Yes	≤2/≤2	≥20%/≥20%/≥20%	XX.X/XX.X/XX.X	XX.X/XX.X	XX.X/XX.X	>3/1~2	XX.X/XX.X
XXXX-XXX	Yes	>2to<5	≥20%/≥20%/≥20%	XX.X/XX.X/XX.X	XX.X/XX.X	XX.X/XX.X	0/0	XX.X/XX.X
XXXX-XXX	Yes	≥5/>2to<5	≥20%/≥20%/≥20%	XX.X/XX.X/XX.X	XX.X/XX.X	XX.X/XX.X	1~2/0	XX.X/XX.X
XXXX-XXX	Yes	≤2/≤2	<20%/<20%/<20%	XX.X/XX.X/XX.X	XX.X/XX.X	XX.X/XX.X	3/0	XX.X/XX.X
XXXX-XXX	No	>2to<5/≥5	≥20%/≥20%/≥20%	XX.X/XX.X/XX.X	XX.X/XX.X	XX.X/XX.X	>3/1~2	XX.X/XX.X

Note: mPEPI = Modified Pre-operative Endocrine Prognostic Index.
Note: Ratio of Ki-67 between C1D15/Surgery and baseline = log(Ki-67 at C1D15/Surgery)-log(Ki-67 at baseline), the variable for the primary endpoint.
Note: Ki-67 Percentage Change from Baseline at C1D15/Surgery = 100 ×(Ki-67 at C1D15/Surgery - Ki-67 at baseline)/Ki-67 at baseline.

Programming Note:

- Sorting order is by Subject ID.

Listing 16.2.6.2
Efficacy Parameters – Part 2 of 2
Analysis Set: Full Analysis Set

RandomizedTreatment: ARV-471 200 mg

Subject ID	Ki-67 Evaluable Analysis Set	Actual/Random iztion Size of Primary Breast Tumor	% of Tumor cells with Ki67 Local/Central/Ra ndomization	Post-Surgery Pathological Response/Derived Response	Breast Conserving Surger	Caliper Based Best Percentage Change from Baseline (%)	Complete Cycle Cell Arrest at Week 2/Surgery	Percentage Change (%) of ER AQUA score at C1D15/Surgery from Baseline
XXXX-XXX	Yes	≤2/≤2	<20%/≥20%/<20%	pCR/pCR	Yes	xx.x	Yes/Yes	XX.X/XX.X
XXXX-XXX	Yes	>2to<5/>2to<5	≥20%/<20%/<20%	pPR/non-pCR	No	xx.x	Yes/Yes	XX.X/XX.X
XXXX-XXX	Yes	≥5/≥5	<20%/<20%/<20%	pPR/pCR	Yes	xx.x	No/Yes	XX.X/XX.X
XXXX-XXX	Yes	≤2/≤2	≥20%/≥20%/≥20%	pCR/pCR	Yes	xx.x	Yes/No	XX.X/XX.X
XXXX-XXX	Yes	>2to<5	≥20%/≥20%/≥20%	pPR/non-pCR	Yes	xx.x	Yes/Yes	XX.X/XX.X
XXXX-XXX	Yes	≥5/>2to<5	≥20%/≥20%/≥20%	pPR/non-pCR	Yes	xx.x	No/Yes	XX.X/XX.X
XXXX-XXX	Yes	≤2/≤2	<20%/<20%/<20%	pCR/non-pCR	No	xx.x	Yes/Yes	XX.X/XX.X
XXXX-XXX	No	>2to<5/≥5	≥20%/≥20%/≥20%	NR/non-pCR	Yes	xx.x	Yes/Yes	XX.X/XX.X

Note: pCR = Pathological Complete Response.
Note: Complete cycle cell arrest at Week 2/Surgery is defined as Ki67 score ≤ 2.7%.
Note: Percentage Change (%) of ER at C1D15/Surgery from Baseline 100 × (ER AQUA at C1D15/surgery – ER AQUA at baseline)/ER AQUA at baseline.

Programming Note:

- Sorting order is by Subject ID.

Listing 16.2.6.3 Target Lesion (TL)
Analysis Set: Full Analysis Set

Randomized Treatment: ARV-471 200 mg

Subject ID	Baseline Tumor Size	Assessment Timepoint	Date of Assessment (Study Day)	Sum of TL (mm)	% Change from Baseline of TL	Sum of Primary Tumor TL (mm)	% Change from Baseline of Primary Tunor TL
XXXX-XXX	≤2 cm	Screen	DDMMMYYY (XX)	XXX		XXX	
		Cycle 1	DDMMMYYY (XX)	XXX	XX.X	XXX	XX.X
		Cycle 2	DDMMMYYY (XX)	XXX	XX.X	XXX	XX.X*
		Cycle 3	DDMMMYYY (XX)	XXX	XX.X	XXX	XX.X
		Cycle 4	DDMMMYYY (XX)	XXX	XX.X*	XXX	XX.X
		Cycle 5	DDMMMYYY (XX)	XXX	XX.X	XXX	XX.X
		Cycle 6	DDMMMYYY (XX)	XXX	XX.X	XXX	XX.X
XXXX-XXX	≤2 cm	Screen	DDMMMYYY (XX)	XXX		XXX	
		Cycle 1	DDMMMYYY (XX)	XXX	XX.X	XXX	XX.X
		Cycle 2	DDMMMYYY (XX)	XXX	XX.X	XXX	XX.X
		Cycle 3	DDMMMYYY (XX)	XXX	XX.X	XXX	XX.X*
		Cycle 4	DDMMMYYY (XX)	XXX	XX.X*	XXX	XX.X

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.
Note: Best percentage change of TL from baseline (indicated with *) is maximum decrease or minimum increase if no decrease being observed.

Programming Note:

- Sorting order is by Subject ID, Date of Assessment

Listing 16.2.6.4 Primary Breast Tumor Change - Caliper-based
Analysis Set: Full Analysis Set

Randomized Treatment: ARV-471 200 mg

Subject ID	Baseline Tumor Size	Assessment Timepoint	Date of Assessment (Study Day)	Primary Breast Tumor (mm)	% Change from Baseline	Best % Change from Baseline ?
XXXX-XXX	≤2 cm	Screen	DDMMMYYY (XX)	XXX		
		Cycle 1	DDMMMYYY (XX)	XXX	XX.X	
		Cycle 2	DDMMMYYY (XX)	XXX	XX.X	
		Cycle 3	DDMMMYYY (XX)	XXX	XX.X	
		Cycle 4	DDMMMYYY (XX)	XXX	XX.X	Yes
		Cycle 5	DDMMMYYY (XX)	XXX	XX.X	
		Cycle 6	DDMMMYYY (XX)	XXX	XX.X	
XXXX-XXX	≤2 cm	Screen	DDMMMYYY (XX)	XXX		
		Cycle 1	DDMMMYYY (XX)	XXX	XX.X	
		Cycle 2	DDMMMYYY (XX)	XXX	XX.X	
		Cycle 3	DDMMMYYY (XX)	XXX	XX.X	
		Cycle 4	DDMMMYYY (XX)	XXX	XX.X	Yes

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.
Note: Best percentage change from baseline is maximum decrease or minimum increase if no decrease being observed.

Programming Note:

- Sorting order is by Subject ID, Date of Assessment

Listing 16.2.6.5 Tumor Biopsy
Analysis Set: Full Analysis Set

Randomized Treatment: ARV-471 200 mg

Subject ID	Test (SI unit)	Visit	Collection Date (Study Day)	Result/ % Change from Baseline	Interpretation	Location/ Method
XXXX-XXX	Ki-67 (%)	Screening	DDMMMYYYY (XX)	XX.X*	Positive	Breast/IHC
		C1D15	DDMMMYYYY (XX)	XX.X/XX.X	Intermediate Proliferation Rate	Breast/IHC
		C6D18	DDMMMYYYY (XX)	XX.X/XX.X	High Proliferation Rate	Unknown/IHC
	<Insert (XXX)>	Screening	DDMMMYYYY (XX)	XX.X*	High Proliferation Rate	Breast/IHC
		C1D15	DDMMMYYYY (XX)	XX.X/XX.X	Intermediate Proliferation Rate	Breast/IHC
		C6D18	DDMMMYYYY (XX)	XX.X/XX.X	Positive	Breast/IHC
		Unscheduled	DDMMMYYYY (XX)	XX.X/XX.X	Positive	Breast/IHC
XXXX-XXX	Ki-67 (%)	Screening	DDMMMYYYY (XX)	XX.X*	High Proliferation Rate	Other:XX/IHC
		C1D15	DDMMMYYYY (XX)	Uninterpretable	Uninterpretable	Breast/IHC
		C6D18	DDMMMYYYY (XX)	XX.X/XX.X	Positive	Breast/IHC
		Unscheduled	DDMMMYYYY (XX)	XX.X/XX.X	Positive	Breast/IHC

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date − Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date − Date of Day 1 for assessment prior to Day 1.
Note: IHC = Immunohistochemistry.
Note: * indicates baseline value.

Programming Note:

- Sorting order is by Subject ID, Test, Collection date

Listing 16.2.6.6 Imaging Response Assessment - mRECIST
Analysis Set: Full Analysis Set

Randomized Treatment: ARV-471 200 mg

Subject ID	Assessment Timepoint	Date of Assessment (Study Day)	Target Lesion Response	Non-Target Lesion Response	Any New Lesions?	Response at this Timepoint
XXXX-XXX	Cycle 1	DDMMMYYY (XX)	Partial Response	Non-CR/Non-PD	No	Partial Response
	Cycle 2	DDMMMYYY (XX)	Partial Response	Non-CR/Non-PD	No	Partial Response
	Cycle 3	DDMMMYYY (XX)	Partial Response	Non-CR/Non-PD	No	Partial Response
	Cycle 4	DDMMMYYY (XX)	Partial Response	Non-CR/Non-PD	Yes	Progressive Disease
	Cycle 5	DDMMMYYY (XX)	Progressive Disease	Not Evaluable	Yes	Progressive Disease
	Pre-Surgery	DDMMMYYY (XX)				
XXXX-XXX	Cycle 1	DDMMMYYY (XX)	Stable Disease	Not Evaluable	No	Stable Disease
	Cycle 2	DDMMMYYY (XX)	Stable Disease	Not Evaluable	No	Stable Disease
	Cycle 3	DDMMMYYY (XX)	Not Evaluable	Complete Response	No	Not Evaluable
	Cycle 4	DDMMMYYY (XX)	Complete Response	Complete Response	No	Complete Response

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.

Programming Note:

- Sorting order is by Subject ID, Date of Procedure

Listing 16.2.6.7 Cytology Results
Analysis Set: Full Analysis Set

Randomized Treatment: ARV-471 200 mg

Subject ID	Date Sample Collected (Study Day)	Specimen Type	Findings
XXXX-XXX	DDMMMYYY (XX)	Pleural Effusion	Benign
	DDMMMYYY (XX)	Abdominal/Pelvic Ascites	Atypical
XXXX-XXX	DDMMMYYY (XX)	Other: XXXXXXXXX	Suspicious
	DDMMMYYY (XX)	DDMMMYYY (XX)	Malignant
XXXX-XXX	DDMMMYYY (XX)	DDMMMYYY (XX)	Other: XXXXXXX
	DDMMMYYY (XX)	DDMMMYYY (XX)	Benign
	DDMMMYYY (XX)	DDMMMYYY (XX)	Atypical

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.

Programming Note:

- Sorting order is by Subject ID, Date Sample Collected

Listing 16.2.6.8 Disease Staging - Post-Surgery
Analysis Set: Full Analysis Set

Randomized Treatment: ARV-471 200 mg

Subject ID	Ki-67 Evaluable Analysis Set	Date of Tumor Tissue Collected (Study Day)	Pathologic Tumor - ypT	Multiple Foci of Residual Tumor?	Pathologic Lymph Nodes - ypN	Distant Metastasis ypT	Lymphatic Vascular Invasion Classification
XXXX-XXX	Yes	DDMMMYYY (XX)	ypTx	No	ypNX	M0	Present
XXXX-XXX	Yes	DDMMMYYY (XX)	ypT0	No	ypN0	pM1	Not Present
XXXX-XXX	Yes	DDMMMYYY (XX)	ypTis	No	ypN0(i+)	Unknown	Unknown
XXXX-XXX	Yes	DDMMMYYY (XX)	ypT1mi	Yes	ypN0(mol+)	M0	Not Present
XXXX-XXX	Yes	DDMMMYYY (XX)	ypT1a	Yes	ypN1	M0	Not Present
XXXX-XXX	Yes	DDMMMYYY (XX)	ypT1b	Yes	ypN1mi	M0	Not Present
XXXX-XXX	Yes	DDMMMYYY (XX)	ypT1c	No	ypN1a	M0	Not Present
XXXX-XXX	No	DDMMMYYY (XX)	ypT2	No	ypN1b	Unknown	Not Present

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.

Programming Note:

- Sorting order is by Subject ID, Date of Procedure

Listing 16.2.7.1
Adverse Events by Subject
Analysis Set: Safety Analysis Set

Actual Treatment: ARV-471 200 mg

Subject ID	System Organ Class/ Preferred Term/ Verbatim	Start Date (StudyDay)/ Stop Date (StudyDay)/ TEAE?	Serious?/ Toxicity Grade/ Lead to Study Discontinued	Relation to Study Drug/ Action Taken with Study Drug	Related to Concomitant Medication? / Specify	Outcome/ Concomitant Medication Given/ Non-drug Treatment Given?
XXXX-XXX	XXXXXXXXXXXXXXXXXXXX/	DDMMMYYY (xx)/	No/	Not Related/	No	RED/
	XXXXXXXXXXXXXXXXXX/	Ongoing/	2/	Dose Not Changed		No/
	XXXXXXXXXXXXXXXXXXXX	No	No			Yes
	XXXXXXXXXXXXXXXXXXXX/	DDMMMYYY (xx)/	Yes/	Related/		NRED/
	XXXXXXXXXXXXXXXXXX/	Ongoing/	4/	Dose Reduced		Yes/
	XXXXXXXXXXXXXXXXXXXX	Yes	No			No
XXXX-XXX	XXXXXXXXXXXXXXXXXXXX/	DDMMMYYY (xx)/	Yes/	Not Related /	Yes/	REDWSEQ/
	XXXXXXXXXXXXXXXXXX/	DDMMMYYY(xx)/	1/	Drug Withdrawn	XXXX,XXXXX	No/
	XXXXXXXXXXXXXXXXXXXX	Yes	No			No
	XXXXXXXXXXXXXXXXXXXX/	DDMMMYYY (xx)/	No/	Not Related /	No	Fatal/
	XXXXXXXXXXXXXXXXXX/	DDMMMYYY (xx)/	5/	Not Applicable		Yes/
	XXXXXXXXXXXXXXXXXXXX	Yes	Yes			Yes

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.
Note: Adverse events (AE) were evaluated based on NCI-CTCAE (version 5.0),and coded with MedDRA Version 24.1.
Note: A TEAE is an AE that emerges or worsens (ie increase in CTCAE grade) on/after the first dose of ARV-471/Anastrozole to 30 days from the last administration of the study intervention (ie, study drug treatment or surgical resection, whichever occurs last).
Note: RED=Recovered/Resolved; NRED=Not Recovered/Not Resolved; REDWSEQ=Recovered/Resolved with Sequelae; REING= Recovering/Resolving.

Programming Note:

- Sorting order is by Subject ID, Start Date, System Organ Class and Preferred Term.

Listing 16.2.7.2
Serious Adverse Events by Subject
Analysis Set: Safety Analysis Set

Actual Treatment: ARV-471 200 mg

Subject ID Age/Race/ Sex	System Organ Class/ Preferred Term/ Verbatim	Start Date (StudyDay)/ Stop Date (StudyDay)/ TEAE?	Serious?/ Toxicity Grade/ Lead to Study Discontinued	Relation to Study Drug/ Action Taken with Study Drug	Related to Concomitant Medication?/ Specify	Outcome/ Concomitant Medication Given/ Non-drug Treatment Given?
XXXX-XXX/ XX/W/F	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing/ No	Yes/ 2/ No	Not Related/ Dose Not Changed	No	RED/ No/ Yes
	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing/ Yes	Yes/ 4/ No	Related/ Dose Reduced		NRED/ Yes/ No
XXXX-XXX/ XX/B/M	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY(xx)/ Yes	Yes/ 1/ No	Not Related / Drug Withdrawn	Yes/ XXXX,XXXXX	REDWSEQ/ No/ No
	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)/ Yes	Yes/ 5/ Yes	Not Related / Not Applicable	No	Fatal/ Yes/ Yes

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.
Note: Adverse events (AE) were evaluated based on NCI-CTCAE (version 5.0),and coded with MedDRA Version 24.1.
Note: A TEAE is an AE that emerges or worsens (ie increase in CTCAE grade) on/after the first dose of ARV-471/Anastrozole to 30 days from the last administration of the study intervention (ie, study drug treatment or surgical resection, whichever occurs last).
Note: RED=Recovered/Resolved; NRED=Not Recovered/Not Resolved; REDWSEQ=Recovered/Resolved with Sequelae; REING= Recovering/Resolving.
Note: N = American Indian or Alaskan Native; A = Asian; B = Black or African American; H = Native Hawaiian or Other Pacific Islander; W= White; NR = Not Reported; O= Other; M = Male; F = Female.

Programming Note:

- Sorting order is by Subject ID, Start Date, System Organ Class and Preferred Term.

Subject ID/Age/Race/Sex, Preferred Term, Treatment Arm, Onset Day, Grade, Investigator-Assessed Relatedness

Display order by treatment arm ARV-471 200mg first, then follow by Anastrozole 1mg

Listing 16.2.8.1
Hematology Tests with CTCAE Grade ≥ 3
Analysis Set: Safety Analysis Set

Actual Treatment: ARV-471 200 mg

Subject ID	Test (SI unit)	Visit	Collection Date Time (Study Day)	Result/ Change from Baseline/ % Change from Baseline	Reference Range	Reference Range Indicator	CTCAE Grade
XXXX-XXX	Hemoglobin (g/L)	Screening	DDMMMYYYY HH:MM (XX)	XX.X	XXX,XXX	Low	1
		C1D1	DDMMMYYYY HH:MM (XX)	XX.X*	XXX,XXX	Normal	0
		C1D8	DDMMMYYYY HH:MM (XX)	XX.X/XX.X/XX.X	XXX,XXX	High	2
		<insert>					
	<insert>						
XXXX-XXX							

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.
Note: Lab data is graded with CTCAE version 5.0.
Note: * indicates baseline value.

Programming Note:

- Sorting order is by Subject ID, Test, Collection date
- if a subject has a test with CTCAE grade>=3, all visits of the test will be listed.

Programming note: Repeat Listing 16.2.8.1 for the following listings

Listing 16.2.8.2 Clinical Chemistry Tests with CTCAE Grade ≥ 3
Analysis Set: Safety Analysis Set

Listing 16.2.8.3
Hematology Tests
Analysis Set: Safety Analysis Set

Actual Treatment: ARV-471 200 mg

Subject ID	Test (SI unit)	Visit	Collection Date(Study Day)	Result/ Change from Baselin/	Reference Range	Reference Range Indicator	CTCAE Grade
XXXX-XXX	Hemoglobin (g/L)	Screening	DDMMMYYYY (XX)	XX.X	XXX,XXX	Low	1
		C1D1	DDMMMYYYY (XX)	XX.X*	XXX,XXX	Normal	0
		C1D8	DDMMMYYYY (XX)	XX.X/XX.X	XXX,XXX	High	2
		<insert>					
	<insert>						

XXXX-XXX

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.
Note: Lab data is graded with CTCAE version 5.0.
Note: * indicates baseline value.

Programming Note:

- Sorting order is by Subject ID, Test, Collection date

Programming note: Repeat Listing 16.2.8.3 for the following listings

Listing 16.2.8.4
Clinical Chemistry Tests
Analysis Set: Safety Analysis Set

Listing 16.2.8.5
Coagulation Tests
Analysis Set: Safety Analysis Set

Listing 16.2.8.6
Urinalysis
Analysis Set: Safety Analysis Set

Actual Treatment: ARV-471 200 mg

Subject ID	Test	Visit	Collection Date (Study Day)	Result (unit, if applicable)
XXXX-XXX	Clarity	Screening	DDMMMYYYY (XX)	Trace
		C1D1	DDMMMYYYY (XX)	1+*
		C1D8	DDMMMYYYY (XX)	2+
		<insert>		
	<insert>			
XXXX-XXX				

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.
Note: * indicates baseline value.

Programming Note:

- Sorting order is by Subject ID, Test, Visit.

Listing 16.2.9
Vital Signs
Analysis Set: Safety Analysis Set

Actual Treatment: ARV-471 200 mg

Subject ID	Test (SI unit)	Visit	Vital Signs Date (Study Day)	Result/ Change from Baseline
XXXX-XXX	Diastolic Blood Pressure (mmHg)	Screening	DDMMMYYYY (XX)	XX.X
		C1D1	DDMMMYYYY (XX)	XX.X*
		C1D8	DDMMMYYYY (XX)	XX.X/XX.X
		<insert>		
	<insert>			
XXXX-XXX				

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.
Note: * indicates baseline value.

Programming Note:

- Sorting order is by Subject ID, Test, Visit.
- If Clinical provides a list of any parameter deemed significant, list the parameter of all visits of the patient

Listing 16.2.10
12-Lead ECG
Analysis Set: Safety Analysis Set

Actual Treatment: ARV-471 200 mg

Subject ID	Test (unit)	Visit	ECG Date Time (Study Day)	Time Point	Test Number	Result
XXXX-XXX	Heart Rate (beats per minute)	Screening	DDMMMYYYY HH:MM (XX)	Screening		xxx.x
		C1D1	DDMMMYYYY HH:MM (XX)	Predose	1	xxx.x
			DDMMMYYYY HH:MM (XX)	Predose	2	xxx.x
			DDMMMYYYY HH:MM (XX)	Predose	3	xxx.x
			DDMMMYYYY HH:MM (XX)	4hr post dose	1	xxx.x
			DDMMMYYYY HH:MM (XX)	4hr post dose	2	xxx.x
			DDMMMYYYY HH:MM (XX)	4hr post dose	3	xxx.x
		C1D8	DDMMMYYYY HH:MM (XX)	Predose	1	xxx.x
			DDMMMYYYY HH:MM (XX)	Predose	2	xxx.x
		<insert>				

XXXX-XXX

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.

Programming Note:

- Sorting order is by Subject ID, Test , Visit.

Listing 16.2.11
ECOG Performance Status
Analysis Set: Safety Analysis Set

Actual Treatment: ARV-471 200 mg

Subject ID	ECOG Performance Status performed?	Visit	ECOG Assessment Date (Study Day)	ECOG Performance Status
XXXX-XXX	Yes	Screening	DDMMMYYYY (XX)	0
	Yes	C1D1*	DDMMMYYYY (XX)	0
	Yes	C1D8		
	Yes	<insert>		
XXXX-XXX	No			

Note: Day 1 is the date of first ARV-471/anastrozole dose. Study Day = Assessment Date – Date of Day 1 + 1 for assessment dates on or after date of Day 1. Study Day = Assessment Date – Date of Day 1 for assessment prior to Day 1.
Note: * indicates baseline value.

Programming Note:

- Sorting order is by Subject ID, Visit.

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Certificate Of Completion

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Status: Completed
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Source Envelope:
Document Pages: 175
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Notary Events	**Signature**	**Timestamp**
Envelope Summary Events	**Status**	**Timestamps**
Envelope Sent	Hashed/Encrypted	15-Nov-2024 | 15:11
Certified Delivered	Security Checked	15-Nov-2024 | 15:12
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ii. send us an email to [redacted] and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: https://support.docusign.com/guides/signer-guide-signing-system-requirements.

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

By selecting the check-box next to 'I agree to use electronic records and signatures', you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify Caidya as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by Caidya during the course of your relationship with Caidya.