A Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy, Safety, and Tolerability of Serlopitant for the Treatment of Pruritus in Adults With Prurigo Nodularis

ClinicalTrials.gov Identifier: NCT03546816

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STATISTICAL ANALYSIS PLAN

Protocol Number:	MTI-105
Study Title:	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF THE EFFICACY, SAFETY, AND TOLERABILITY OF SERLOPITANT FOR THE TREATMENT OF PRURITUS IN ADULTS WITH PRURIGO NODULARIS
Development Phase of Study:	Phase 3
Sponsor:	Menlo Therapeutics Inc. 200 Cardinal Way, 2nd Floor Redwood City, CA 94063 USA
Sponsor Contact:	PPD
Statistical Analysis Plan based on Protocol Version:	Version 4.0, 16 December 2019
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Statistical Analysis Plan Version:	Version 5

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DATE: 17 Dec 2019

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DATE: 17 Dec 2019

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DATE: 17-DEC-2019

DATE: 17 Dec 2019

Revisions to the Statistical Analysis Plan described herein must be approved through a formal written amendment with the exception of minor editorial changes to tables, figures, or listing shells, and any necessary textual clarifications for programmers that do not affect the stated analysis variables, study endpoints, or statistical methods.

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Revision History:

Version	Date	Summary of Changes	Author
Version 1	13 November 2018	Original document	Brian Armstrong
Version 2	03 April 2019	Updated title page to reflect current version of protocol. Updated SAP version and date. Sections 2, 3, 4.1, 5.2 updated and Section 6.9.4.7 added to update follow-up period and include assessment of physical dependence. Sections 5.1.2 and 6.1.8 (previously 6.1.7), 6.7.2, 6.8.2 updated to remove Day 7 and Day 3 key secondary endpoints. Section 6.1 updated, Section 6.1.6 added to reflect potential interim analysis. Section 6.1.3, 6.1.5, 6.7 updated to include Week 1 for WI-NRS data. Sections 6.1.6 – 6.1.9 renumbered to allow for additional section added as 6.1.6. Section 7 updated sample size per Phase 2 information.	Brian Armstrong
Version 3	10 April 2019	Updated SAP version and date. Section 6.9.4.7 updated to include AE summaries by weekly periods following study drug discontinuation. Added summaries of AEs by sex.	Brian Armstrong
Version 4	27 August 2019	Updated SAP version and date. Editorial and grammatical updates including abbreviations and references.	Brian Armstrong

		DLQI Question 1 included as Additional Seconary Endpoint; modified changes to planned analysis section. Modified language to indicate no interim analysis will be performed. Clarified visit nomenclature for follow-up period. Added subgroup summaries of primary efficacy endpoint. Added table, figure and listing shells.	
Version 5	16 December 2019	Updated SAP version and date. Modified WI-NRS Weekly average computation to require a minimum of 4 values to compute average. DLQI moved from Key Secondary Endpoint to Additional Secondary Endpoint; removed multiple imputation of DLQI. WI-NRS 4-point responder at Week 2 added as Key Secondary Endpoint. Updated changes to planned analysis section to reflect no changes, as protocol was amended. Updated table, figure and listing shells.	Brian Armstrong

1. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

AE(s)	Adverse event(s)
ANCOVA	Analysis of covariance
CMH	Cochran-Mantel-Haenszel
DLQI	Dermatology Life Quality Index
ECG	Electrocardiogram
eDiary	Electronic diary
ESS	Epworth Sleepiness Scale

HADS	Hospital Anxiety and Depression Scale
IGA PN-A	Investigator's Global Assessment of Prurigo Nodularis Activity
IGA PN-S	Investigator's Global Assessment of Prurigo Nodularis Stage
ITT	Intent-to-treat
LOCF	Last observation carried forward
MedDRA	Medical Dictionary for Regulatory Activities
MCMC	Markov Chain Monte Carlo
PN	Prurigo Nodularis
PP	Per Protocol
SAE(s)	Serious adverse event(s)
SAS®	Statistical Analysis System (SAS® Institute Inc., Cary, NC)
TEAE(s)	Treatment-emergent adverse event(s)
WHO-DDE	World Health Organization Drug Dictionary Enhanced
WI-NRS	Worst-Itch Numeric Rating Scale

2. INTRODUCTION

Prurigo nodularis (PN) is a distinctive and easily diagnosable chronic skin condition characterized by the presence of multiple highly pruritic and often symmetrically distributed nodules and papules on the skin (Jorizzo 1981). The nodules and papules in PN can range in size from approximately 0.5 to 3.0 cm and often appear hyperkeratotic, sometimes crateriform, in appearance. Plaques are occasionally present, and the lesions of PN frequently exhibit other features secondary to prolonged and severe scratching behavior, such as post-inflammatory hyperpigmentation, erosion, ulceration, crusting, and bleeding (Zeidler 2016).

Menlo Therapeutics Inc. is pursuing the development of serlopitant for treatment of itch. The MTI-105 study described herein is a double-blind, randomized, placebo-controlled study to assess the efficacy, safety, tolerability, and physical dependence of serlopitant for the treatment of pruritus in adults with PN.

3. STUDY OBJECTIVES

The efficacy objective of this study is to assess the efficacy of serlopitant for the treatment of pruritus in adults with PN.

The safety objectives of this study are to assess the safety and tolerability of repeated oral doses of serlopitant in adults with PN, and to assess whether serlopitant produces physical dependence.

4. STUDY DESIGN

4.1 Overall Study Design

This is a double-blind, randomized, placebo-controlled study to assess the efficacy, safety, and tolerability of serlopitant for the treatment of pruritus in adults with PN. The study will be conducted at approximately 50 study sites. Subjects who meet the study entry criteria will be randomized in a 1:1 ratio to receive daily oral doses of serlopitant 5 mg or placebo for 10 weeks. After completion of the treatment period or early discontinuation of study drug treatment, all subjects will enter a 5-week follow-up (post-study drug observation) period.

This study will consist of three periods, for a total study period of 19 weeks:

- Screening period: 2-4 weeks
- Treatment period: 10 weeks
- Follow-up period: 5 weeks

4.1.1 Schedule of Visits and Assessments

The schedule of assessments can be found in Section 6.5 and Appendix A of the Protocol.

4.1.2 Method of Assigning Subjects to Treatment Groups

Eligible subjects will be randomized to receive serlopitant 5 mg or placebo in a 1:1 ratio. Stratified permuted block randomization will be used. Randomization will be stratified by the subject's reported Worst-Itch Numeric Rating Scale (WI-NRS) score for the 1-week period prior to the Baseline visit (6.5 to < 9, 9 to 10).

An interactive web response system will be used to perform the randomization.

4.1.3 Blinding

This study will be conducted as a double-blind study with the treatment assignment concealed from the subjects, the investigators and their staff, the Sponsor, and any designees of the Sponsor as required. The placebo will be formulated to be indistinguishable from the active study product(s). Study materials will be packaged and issued in a manner designed to maintain the blind for subjects and all study personnel involved in the direction and execution of study procedures, study assessments, and collection of data. The randomization code for each subject will be available to the sites for use only in an emergency situation. For details of the procedure for unblinding of individual subjects in cases of emergency see Section 7.6 of the Protocol and the Blinding Plan.

5. EFFICACY AND SAFETY ENDPOINTS

5.1 Efficacy Endpoints

5.1.1 Primary Efficacy Endpoint

The primary efficacy endpoint is the WI-NRS 4-point responder rate at Week 10.

5.1.2 Key Secondary Efficacy Endpoints

The key secondary efficacy endpoints are as follows:

- The WI-NRS 4-point responder rate at Week 4
- The WI-NRS 4-point responder rate at Week 2

5.1.3 Additional Secondary Efficacy Endpoints

Additional secondary efficacy endpoints include the following:

- Change from baseline in WI-NRS to Weeks 2, 4, 6 and 8
- WI-NRS 3-point responder rate at Weeks 2, 4 and 10
- Change from baseline in Investigator's Global Assessment of PN Activity (IGA PN-A) to Weeks 2, 4, 10
- Change from baseline in Investigator's Global Assessment of PN Stage (IGA PN-S) to Weeks 2, 4, 10
- Change from baseline in Dermatology Life Quality Index (DLQI) to Week 10
- Change from baseline in DLQI Question 1 to Week 10

5.2 Safety Endpoints

Safety endpoints include the following:

- Incidence of treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs)
- Changes from baseline in clinical laboratory parameters following study drug exposure
- Changes from baseline in vital sign and electrocardiogram (ECG) parameters following study drug exposure
- Change from baseline in the Hospital Anxiety and Depression Scale (HADS)
- Change from baseline in the Epworth Sleepiness Scale (ESS)

- Assessment of physical dependence following study drug exposure in the 5-week post-drug observation period

6. STATISTICAL AND ANALYTICAL PLANS

6.1 General Methodology

All statistical processing will be performed using SAS® Version 9.3 or later, unless otherwise stated. Endpoints will be summarized with descriptive statistics by treatment group and visit. For continuous variables, the following information will be presented: n (number of subjects), mean, standard deviation (SD), median, minimum and maximum. For categorical variables, counts and percentages will be used.

Reported adverse events (AEs), medical history, and prior and concomitant procedures and therapies will be classified on the basis of Medical Dictionary for Regulatory Activities (MedDRA) terminology. Concomitant medications will be classified on the basis of World Health Organization Drug Dictionary Enhanced (WHO-DDE) terminology.

6.1.1 Statistical Analysis

All summary tables and data listings will be prepared by QST Consultations, Ltd., utilizing SAS® Version 9.3 or later software. All relevant data collected within the CRF will be included in data listings.

The standard operating procedures of QST Consultations, Ltd. will be followed in the creation and quality control of all data displays.

6.1.2 Baseline Definition

Baseline, for measures other than those collected daily, will be the last recorded value prior to the start of treatment. For daily WI-NRS data captured via electronic diary (eDiary), baseline will be the average result measured over the 7 days prior to treatment.

6.1.3 Visit Windowing

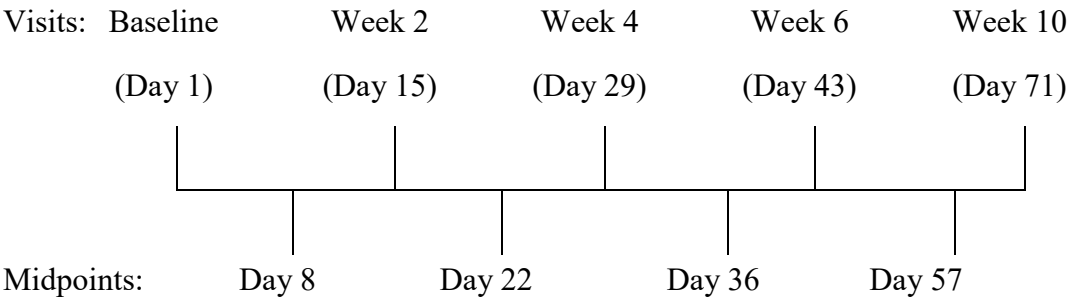
Data will be summarized based on nominal visit indications. Due to protocol revisions, differing follow-up visit schedules were used. Data collected during post-treatment follow-up will be summarized as

Protocol Version(s)	Nominal Visit	Analysis Visit
V2.0; V2.1	3-Week Follow-up	3-Week Follow-up
V2.0; V2.1	5-Week Follow-up	5-Week Follow-up

V3.0	Post-Drug Observation Day 3	3-Day Follow-up
V3.0	Post-Drug Observation Day 7	1-Week Follow-up
V3.0	Post-Drug Observation Day 14	2-Week Follow-up
V3.0	Post-Drug Observation Day 21	3-Week Follow-up
V3.0	Post-Drug Observation Day 28	4-Week Follow-up
V3.0	Post-Drug Observation Day 35	5-Week Follow-up

In addition, a "Latest Follow-up" visit will be summarized, which will include the latest available follow-up information for each subject from the 3-, 4-, 5- Week Follow-up visits.

Information collected at early treatment discontinuation visits will be mapped to the most appropriate visit based on the midpoints between scheduled visits.



For example, if a subject terminates use of study drug on or after Day 22 but before Day 36, data collected at the early end of treatment visit will be mapped to the Week 4 evaluation for summaries. If the subject has Week 4 values present, the data collected at the early end of treatment visit will not replace the data collected at Week 4. For the sensitivity efficacy analyses, last observation carried forward (LOCF) will be applied subsequent to mapping the information to the appropriate visit.

Additionally, WI-NRS will be summarized at Weeks 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and 3- and 5-Week Follow-up by averaging the daily results for the 7 days prior to each week. The weekly average values will be calculated if a subject has at least four responses during the 7 day range, as defined below:

Week/Visit	**Study Day Range**
Week 1	2-7 (as Day 1 may be pre or post first dose)
Week 2	8-14
Week 3	15-21
Week 4	22-28
Week 5	29-35
Week 6	36-42

Week 7	43-49
Week 8	50-56
Week 9	57-63
Week 10	64-70
3-Week Follow-up	Post-treatment days 15-21
5-Week Follow-up	Post-treatment days 29-35

6.1.4 Adjustments for Covariates

Analysis of covariance will include baseline value as a covariate.

6.1.5 Handling of Dropouts or Missing Data

Should a determination of treatment period (on treatment, pre-treatment, post-treatment) be required for AEs or concomitant medication but the corresponding date is missing, or is a partial date, the event/medication will be considered on treatment unless the portions of the date that are available indicate this is not possible.

The primary method of handling missing efficacy data will be Markov Chain Monte Carlo (MCMC) multiple imputation. Imputation will be conducted within each treatment group independently, so the pattern of missing observations in one treatment group cannot influence missing value estimations in another. For each imputation process, 25 imputations will be performed.

Subjects that withdrew from the study due to lack of efficacy will have missing values imputed, however, the WI-NRS responder status will be defined as non-responder. Subjects that used an excluded therapy to treat worsening of pruritus or PN will have data values collected after the use of the excluded therapy set to missing and subsequently imputed. These subjects will also have the WI-NRS responder status defined as non-responder.

Missing WI-NRS data will be derived for the analysis using the method of MCMC multiple imputation. The 4-point responder status will be derived from imputed WI-NRS values. Since both primary and key secondary endpoints require WI-NRS, the following steps will be followed:

1. Using the daily eDiary data, calculate Baseline and Week 1 through Week 10 values by averaging available values. In order to compute a week's average, a minimum of 4 values must be available for that week. The weekly average will be imputed when there are fewer than 4 values available.
2. From step 1, create a dataset for each treatment group, of subjects with observed values and those needing estimation by MCMC. The missing WI-NRS values in each dataset

will be filled in using the MCMC method to generate 25 datasets. The resulting datasets for each treatment group will be combined into one complete dataset.

Syntax:

```
proc mi data=datain out=dataout seed=&seed. Nimpute=25 <options>;
  where trtpn=(TRT); /* Note TRT = [1, 2]; depending on treatment group */;
  mcmc chain=single;
  var baseline week1 week2 week3 week4 week5 week6 week7 week8 week9
      week10;
run;
```

3. From each complete dataset, the dichotomous responder rate will be determined. Each complete dataset will be analyzed as specified for the particular analysis.

The results from the analyses will be combined into a single inference using SAS® PROC MIANALYZE. In the case of the primary analysis and the secondary responder analyses, the Cochran Mantel Haenszel (CMH) statistics computed in the analyses of WI-NRS responder rates will be normalized using the Wilson-Hilferty transformation prior to combining them using SAS® PROC MIANALYZE.

A total of 2 random seeds will be needed to impute missing data. Those random seeds have been pre-specified by using a random number generator:

- WI-NRS Serlopitant: Seed= 1537248074
- WI-NRS Placebo: Seed= 474752918

6.1.6 Interim Analyses and Data Monitoring

No interim analyses will be performed.

6.1.7 Multicenter Studies

The clinical study will be conducted under a common protocol for each investigational site with the intention of pooling all data for analysis. Every effort will be made to promote consistency in study execution at each study site.

6.1.8 Multiple Comparisons/Multiplicity

The primary and key secondary endpoints will be analyzed. However, the statistical significance of the key secondary endpoints will only be considered should statistical significance be reached for the primary endpoint. Similarly, statistical significance within the key secondary endpoints will be considered based on a hierarchical approach, starting with the WI-NRS Week 4 responder rate followed by the WI-NRS Week 2 responder rate. If the first key secondary

endpoint fails to reach statistical significance at a level of 0.05, then subsequent endpoints will not be considered statistically significant.

6.1.9 Examination of Subgroups

Descriptive summaries of the primary efficacy endpoint will be created for subgroups of the Intent-to-Treat (ITT) population. Subgroups include age (< median age; >= median age), sex, ethnicity, race and Baseline WI-NRS randomization strata.

6.2 Disposition of Subjects

An accounting of all randomized subjects by disposition will be presented. Subjects who discontinue study drug prematurely or withdraw from the study will be summarized and listed, with a description of the reason for early termination/withdrawal.

The number of subjects included in each population will be summarized. Subjects who are excluded from a population will be summarized by the reasons for exclusion.

6.3 Protocol Deviations

Protocol deviations leading to exclusion from an analysis population will be tabulated. Other protocol deviations will be presented in a data listing.

6.4 Data Sets Analyzed

The following analysis populations will be reviewed and approved by the Sponsor prior to unblinding the study.

6.4.1 Intent-to-Treat (ITT) Population

The primary efficacy population will be the ITT population, which will include all randomized subjects who were dispensed study drug. Subjects will be analyzed within the treatment group to which they are randomized.

6.4.2 Safety Population

The primary safety population will be all treated subjects with at least one post-baseline assessment or a reported TEAE. For safety analyses, subjects will be classified based upon treatment received. In the case that a subject received both treatments, subjects will be summarized within the serlopitant 5 mg group.

6.4.3 Per Protocol Population

Additional analyses performed on the Per Protocol (PP) population will be considered supportive. The PP population will include all subjects in the safety population who complete the

Week 10 evaluations without any significant protocol deviations/violations (i.e., any subject or investigator activity that could have possibly interfered with the therapeutic administration of the treatment or the precise evaluation of treatment efficacy). The PP population will include subjects in the safety population who do not meet any of the following criteria:

- Violated the inclusion/exclusion criteria;
- Received a strong CYP3A4 inhibitor (See Appendix B in the Protocol);
- Received an excluded medication which may plausibly impact the primary endpoint at Week 10 (e.g. was provided to treat pruritus or PN);
- Have not been compliant with the dosing regimen (i.e. subjects must comply with 80-120% of the expected dosage of study medication during participation in the study);
- Have not completed Week 10 visit within ±7 days window
- Have not completed the eDiary to provide the Week 10 WI-NRS Primary Endpoint

Subjects who discontinue from the study drug due to an adverse event related to study treatment or documented lack of treatment effect, or who met protocol-defined non-responder criteria, will be included in the PP population. Prior to breaking the blind other additional criteria may be added to the lists above to accommodate for unforeseen events that occurred during the conduct of the trial that result in noteworthy study protocol deviations.

Subjects will be analyzed within the treatment group to which they are randomized.

6.5 Demographic and Other Baseline Characteristics

Demographic and baseline characteristics summaries will be done for the ITT, Safety, and PP populations.

Sex, race, and ethnicity will be summarized by counts and percentages. Age, height (cm), and weight (kg) will be summarized with descriptive statistics.

IGA PN-A, and IGA PN-S will be summarized by counts and percentages. WI-NRS (average result measured over the week prior to treatment) and DLQI will be summarized with descriptive statistics.

Medical histories will be coded using MedDRA, tabulated by System Organ Class and Preferred Term for the Safety population, and presented in a by-subject listing.

PN history and prior PN therapies will be presented in by-subject listings.

6.6 Prior and Concomitant Medications

Prior and concomitant medications will be coded by the WHO-DDE to Anatomical Therapeutic Classification (ATC) and preferred drug name. Concomitant medications will be summarized by ATC level 2 term and preferred drug name.

A by-subject listing of all prior and concomitant medications will be presented. The associated by-subject listing will have a prior/concomitant determination that is based on the date of first dose.

6.7 Analysis of Efficacy

The efficacy endpoints will be summarized within the ITT and PP populations using descriptive statistics by time point and treatment. Available results including averaged imputed values, as well as change from baseline, will be summarized for each applicable time point. The WI-NRS and change from baseline will also be presented for each study day in a by-subject listing.

For the 4- and 3-point responder rate endpoints, subjects will be considered responders if they have at least a 4- / 3-point reduction between baseline and the corresponding week. Subjects that discontinued study drug due to lack of efficacy or used an excluded medication to treat worsening of pruritus or PN will be considered non-responders.

6.7.1 Primary Efficacy Analysis

The difference in the primary efficacy outcome measure (WI-NRS 4-point responder rate at Week 10) will be tested using a CMH test controlling for the 'as randomized' stratification factors. Conceptually the hypotheses being tested are:

H_0: $P_{Placebo} \geq P_{Serlopitant}$ H_a: $P_{Placebo} < P_{Serlopitant}$

where $P_{Placebo}$ is the percent of placebo responders and $P_{Serlopitant}$ is the similar percent for serlopitant.

6.7.2 Key Secondary Efficacy Analysis

The WI-NRS 4-point responder rates at Week 4 and Week 2 will be analyzed using methods consistent with testing the primary endpoint.

The preceding analyses are to be conducted for the ITT and PP populations.

6.7.3 Additional Secondary Efficacy Analysis

Additional secondary efficacy endpoints which may be drawn from the primary and key secondary imputations (including all WI-NRS endpoints) will be analyzed using the imputed

data. Additional secondary efficacy endpoints otherwise will be analyzed using available data. P-values will be included for descriptive purposes only.

Additional secondary efficacy endpoints which are dichotomous (responder) will include analyses analogous to the primary and key secondary efficacy analyses.

Additional secondary efficacy endpoints based on change from baseline will be analyzed using an analysis of covariance (ANCOVA) model with treatment group and stratification factor as fixed effects and the baseline value as a covariate. Both least squares means and observed means will be presented.

To confirm the assumptions for the ANCOVA model (i.e., that the errors are normally distributed with equal variances), residuals will be examined using the Shapiro-Wilk test. If there is overwhelmingly strong evidence that the assumptions are not satisfied, the data will be rank-transformed prior to submitting to the ANCOVA. Results of the rank-transformed analysis then will be considered the primary analysis; however, results of the non-rank transformed analysis will also be presented.

6.8 Sensitivity Analysis

6.8.1 Last Observation Carried Forward

In the first set of sensitivity analyses, missing values will be imputed using LOCF. Data will be imputed using LOCF unless the subject withdrew from the study due to lack of efficacy, or the subject used an excluded therapy to treat worsening of pruritus or PN, in which case their responder status will be defined as non-responder. Each primary and key secondary endpoint will be analyzed as it was using the multiply imputed data.

6.8.2 Repeated Measures Analysis

The second set of sensitivity analyses will be performed on observed data.

The dichotomized primary and key secondary WI-NRS endpoints will each be analyzed with a repeated measures logistic regression model (generalized estimating equations), with the dichotomized endpoint as the dependent variable and treatment, stratification factor and visit (Weeks 1-10) as independent factors.

6.8.3 Tipping Point Analysis

A sensitivity analysis for the handling of missing data for the primary efficacy endpoint will be carried out using a tipping point analysis. Specifically, a range of response rates for both groups will be explored to determine the tipping point(s) at which the combinations result in no longer reaching statistical significance.

6.9 Safety Evaluation

6.9.1 Extent of Exposure

The extent of exposure to study drug in each treatment group will be summarized by days with exposure and total number of tablets used.

A subject will be considered compliant with the dosing regimen if the subject takes 80% to 120% of the expected number of doses while enrolled in the study. Total number of days of exposure will be computed as follows:

Total Exposure = Date of Last Dose – Date of First Dose + 1

Total Doses = (Date of Last Dose – Date of First Dose + 1 + 2)

– Missed Doses + Extra Doses

Treatment compliance will be based on the expected number of doses given the treatment period duration. The number of expected doses will be computed from the Baseline/Day 1 visit date and the Week 10 visit date. If a subject does not have a Week 10 visit, the number of expected doses will be calculated based on end of treatment period date given available information (e.g., date of last dose, last completed visit date).

Expected Doses = End of Treatment Period Date – Day 1 Date + 2

If the subject is documented as dosing on the End of Treatment Period Date, a dose will be added to the Expected Doses. To allow for the +7 day window around Week 10 that is used for defining PP population, if the number of expected doses exceeds 80, the number of expected doses will be considered 80 doses.

Percent compliance will be calculated from total number of doses and total number of expected doses as follows:

Percent Compliance = 100*(Total Doses/Expected Doses).

Percent compliance will not be calculated for subjects who are lost to follow-up during the treatment period.

6.9.2 Adverse Events

The incidence of all AEs and TEAEs will be tabulated by treatment received. These AEs will be classified by system organ class and preferred term using MedDRA. For incidence reporting, if a subject reported more than one AE that was coded to the same system organ class or preferred term, the subject will be counted only once for the specific system organ class or preferred term. An overview of AEs, which includes subject incidence of AEs, treatment-related AEs, AEs by severity, SAEs, deaths, and AEs leading to discontinuation, will be presented.

SAEs will be listed and summarized in a similar manner to AEs.

6.9.3 Clinical Laboratory Evaluation

Clinical safety laboratory values will be measured by a central laboratory. Summary statistics for actual values and for changes from baseline will be tabulated for laboratory results by scheduled visit.

Subjects with clinical laboratory values outside of the normal reference range at any post-baseline assessment will be summarized. Shifts from baseline laboratory values will be tabulated, with the exception of most reproductive endocrinology laboratory values.

Serum follicle-stimulating hormone, luteinizing hormone, estradiol, progesterone and anti-mullerian hormone will be summarized separately for women using hormonal contraception/therapies and those not using hormonal contraception/therapies.

By-subject listings of all laboratory data, as well as abnormal laboratory results, will be presented.

6.9.4 Other Observations Related to Safety

6.9.4.1 ECG Measurements

Summary statistics for actual values and for changes from baseline will be tabulated for ECG parameter results by scheduled visit. The overall ECG assessment (abnormal or normal) will be summarized along with a summary of how many subjects developed a post treatment abnormal result. The study relevance of the finding (i.e. clinical significance as determined by the investigator) will be provided in a by-subject listing.

6.9.4.2 Vital Signs

The observed data and change from baseline for each measurement day will be summarized with descriptive statistics, as well as provided in a by-subject listing.

6.9.4.3 Physical Exams

Clinically significant physical exam findings will be recorded by the sites within medical history or adverse events and otherwise not summarized.

6.9.4.4 Menstrual Diaries

Menstrual diary dates will be used to summarize number and duration of menses.

6.9.4.5 Hospital Anxiety and Depression Scale (HADS)

The observed data and change from baseline for the HADS will be summarized with descriptive statistics by scheduled visit. Both the Depression and Anxiety subscales will be reported.

6.9.4.6 Epworth Sleepiness Scale (ESS)

The observed data and change from baseline for the ESS will be summarized with descriptive statistics by scheduled visit.

6.9.4.7 Potential for Physical Dependence

In order to assess physical dependence and withdrawal, data collected during a 5-week post-drug observation period will be summarized. For each assessment, an on-drug baseline value is defined as Week 10 (for subjects completing treatment) or the last observation prior to last dose of study drug (for subjects that discontinued treatment early).

The observed data and change from on-drug baseline for the HADS will be summarized with descriptive statistics by time point (3-Day Follow-up, and 1-, 2-, 3-, 4- and 5-Week Follow-up). Both the Depression and the Anxiety subscales will be reported.

The observed data and change from on-drug baseline for the ESS will be summarized with descriptive statistics by time point (3-Day Follow-up, and 1-, 2-, 3-, 4- and 5-Week Follow-up).

Vital signs including change from on-drug baseline will be summarized with descriptive statistics for each post-study drug observation visit.

Overall ECG assessments (abnormal or normal), as well as observed and change from on-drug baseline for ECG parameters, will be summarized for the 5-week post-study drug visit. In addition, a summary of how many subjects developed a post–drug abnormal result will be presented.

Assessment of AEs reported after study drug discontinuation, i.e. during the post-study drug observation period, will be summarized separately by treatment group. AEs during the post-study drug observation period will be summarized by weekly periods and sex.

6.10 Pharmacokinetic Analysis

The plasma concentrations of serlopitant and metabolites will be summarized using descriptive statistics.

By-subject listings of the plasma concentrations of serlopitant and metabolites will be presented.

7. DETERMINATION OF SAMPLE SIZE

This study will use a 5% two-sided alpha level. While the alpha level is two-sided, clinically relevant results require a serlopitant benefit.

The target sample size of 280 randomized and dosed subjects (140 per group) has been determined based upon a 1:1 allocation of subjects to treatment groups and a 5% alpha level. Completed Phase 2 studies indicate that placebo responder rates vary between 20% and 25% and serlopitant rates between 33% and 47%. A sample size of 280 subjects provides >90% power assuming a placebo responder rate of CCI and serlopitant rate of CCI.

The sample size calculations have been performed in PASS 13 ("PASS 13 Power Analysis and Sample Size Software" 2014) and use a Chi-Squared test. The primary analysis will control for the stratification factors. It is expected that this unstratified power estimate will under-estimate the true power as it does not take the variance reduction resulting from stratification into account (Matts 1988).

8. CHANGES IN THE PLANNED ANALYSES

No changes to planned analyses.

9. REFERENCES

Jorizzo JL, Gatti S, Smith EB. Prurigo: a clinical review. J Am Acad Dermatol. 1981;4(6): 723-728.

Matts JP LJ. Properties of permuted-block randomization in clinical trials. *Control ClinTrials*. 1988;9(4):327-344.

PASS 13 Power Analysis and Sample Size Software [computer program]. Kaysville, Utah, USA, ncss.com/software/pass.: NCSS, LLC; 2014.

Zeidler C, Ständer S. The pathogenesis of prurigo nodularis--'Super-Itch' in exploration. Eu J Pain. 2016;20(1):37-40.

10. INDEX OF PLANNED END-OF-TEXT TABLES AND FIGURES

Table 14.0.1: Summary of Subject Completion/Discontinuation
(Randomized Subjects)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Completed Treatment		
Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)
Reason for Discontinuation from Treatment		
Adverse Event	xx (xx.x%)	xx (xx.x%)
Lack of Efficacy	xx (xx.x%)	xx (xx.x%)
Pregnancy	xx (xx.x%)	xx (xx.x%)
Investigator Decision	xx (xx.x%)	xx (xx.x%)
Withdrawal by Subject from Treatment	xx (xx.x%)	xx (xx.x%)
Protocol Deviation	xx (xx.x%)	xx (xx.x%)
Sponsor Decision	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)
Completed Follow-up		
Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)
Reason for Discontinuation from Follow-up		
Withdrawal by Subject from Study	xx (xx.x%)	xx (xx.x%)
Lost to Follow-up	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.0.2: Summary of Subjects Excluded from Analyses
(Randomized Subjects)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Intent-to-Treat Population		
Number of Subjects Included	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion		
Not Dispensed Study Drug	xx (xx.x%)	xx (xx.x%)
Safety Population		
Number of Subjects Included	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion		
No Evidence of Subject Dosing	xx (xx.x%)	xx (xx.x%)
No Post-Baseline Assessment/TEAE	xx (xx.x%)	xx (xx.x%)
Per-Protocol Population		
Number of Subjects Included	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion		
No Evidence of Subject Dosing	xx (xx.x%)	xx (xx.x%)
No Post-Baseline Assessment/TEAE	xx (xx.x%)	xx (xx.x%)
Violated the Inclusion/Exclusion Criteria	xx (xx.x%)	xx (xx.x%)
Received a Strong CYP3A4 Inhibitor	xx (xx.x%)	xx (xx.x%)
Received an Excluded Medication	xx (xx.x%)	xx (xx.x%)
Was not Compliant with the Dosing Regimen	xx (xx.x%)	xx (xx.x%)
Week 10 WI-NRS Data Not Available	xx (xx.x%)	xx (xx.x%)
Did not Attend the Week 10 Visit	xx (xx.x%)	xx (xx.x%)
Week 10 Visit not within +/- 7 days Window	xx (xx.x%)	xx (xx.x%)

Note: TEAE = Treatment Emergent Adverse Event; WI-NRS=Worst-Itch Numeric Rating Scale
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.0.3: Summary of Subject Visit Attendance
(Randomized Subjects)

Subjects Attending	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Screening	xx (xx.x%)	xx (xx.x%)
Baseline	xx (xx.x%)	xx (xx.x%)
Week 2	xx (xx.x%)	xx (xx.x%)
Week 4	xx (xx.x%)	xx (xx.x%)
Week 6	xx (xx.x%)	xx (xx.x%)
Week 10	xx (xx.x%)	xx (xx.x%)
3-Day Follow-up	xx (xx.x%)	xx (xx.x%)
1-Week Follow-up	xx (xx.x%)	xx (xx.x%)
2-Week Follow-up	xx (xx.x%)	xx (xx.x%)
3-Week Follow-up	xx (xx.x%)	xx (xx.x%)
4-Week Follow-up	xx (xx.x%)	xx (xx.x%)
5-Week Follow-up	xx (xx.x%)	xx (xx.x%)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.1.1: Summary of Subject Demographics
(Intent-to-Treat Population)
(Page 1 of 2)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Total (N=xxx)
Age (years)			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Sex			
n	xxx	xxx	xxx
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity			
n	xxx	xxx	xxx
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race			
n	xxx	xxx	xxx
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or African American	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Multiple/Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.1.1: Summary of Subject Demographics
(Intent-to-Treat Population)
(Page 2 of 2)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Total (N=xxx)
Height (cm)			
n	xxx	xxx	xxx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Weight (kg)			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xxx	xx to xxx	xx to xxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.1.1.1 for the following:

Table 14.1.1.2: Summary of Subject Demographics (Per-Protocol Population)
Table 14.1.1.3: Summary of Subject Demographics (Safety Population)

Table 14.1.2.1: Subject Baseline Characteristics
(Intent-to-Treat Population)
(Page 1 of 2)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Total (N=xxx)
Baseline WI-NRS (1-Week Average Prior to Baseline)			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Investigator's Global Assessment of Prurigo Nodularis Activity			
n	xxx	xxx	xxx
Grade 0	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Investigator's Global Assessment of Prurigo Nodularis Stage			
n	xxx	xxx	xxx
Grade 0	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.1: Subject Baseline Characteristics
(Intent-to-Treat Population)
(Page 2 of 2)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Total (N=xxx)
Dermatology Life Quality Index			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.1.2.1 for the following:

Table 14.1.2.2: Subject Baseline Characteristics (Per-Protocol Population)
Table 14.1.2.3: Subject Baseline Characteristics (Safety Population)

Table 14.1.3: Summary of Medical History by MedDRA System Organ Class and Preferred Term
(Intent-to-Treat Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Total (N=xxx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more medical histories that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.
Note: MedDRA Version 21.1.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.4: Summary of Concomitant Medications by ATC Level 2 Term and Preferred Drug Name
(Intent-to-Treat Population)
(Page 1 of xx)

ATC Level 2 Term[a] Preferred Drug Name	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Total (N=xxx)
ATC Level 2 Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATC Level 2 Term			
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more concomitant medications that map to the WHO-DDE. At each level of summarization (ATC Level 2 Term or Standard Medication Name) subjects are counted once.
Note: WHO Drug Dictionary, Version September 1, 2018.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1: Analysis of the Primary Efficacy Endpoint: Worst-Itch Numeric Rating Scale (WI-NRS) 4-Point Responder at Week 10 (Intent-to-Treat Population)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	P-value[a]
At Least 4-Point Reduction from Baseline in Weekly Average WI-NRS at Week 10			
Success	xx.xx%	xx.xx%	x.xxx
Failure	xx.xx%	xx.xx%	

[a] P-value from a Cochran Mantel Haenszel (CMH) test stratified by Baseline WI-NRS used for randomization stratification. Value has been adjusted for multiple imputation.

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.1.1 for the following:

Table 14.2.1.2: Analysis of the Primary Efficacy Endpoint: Worst-Itch Numeric Rating Scale (WI-NRS) 4-Point Responder at Week 10 (Per-Protocol Population)

Table 14.2.1.3: Sensitivity Analyses of the Primary Efficacy Endpoint: Worst-Itch Numeric Rating Scale (WI-NRS) 4-Point Responder at Week 10 (Intent-to-Treat Population)

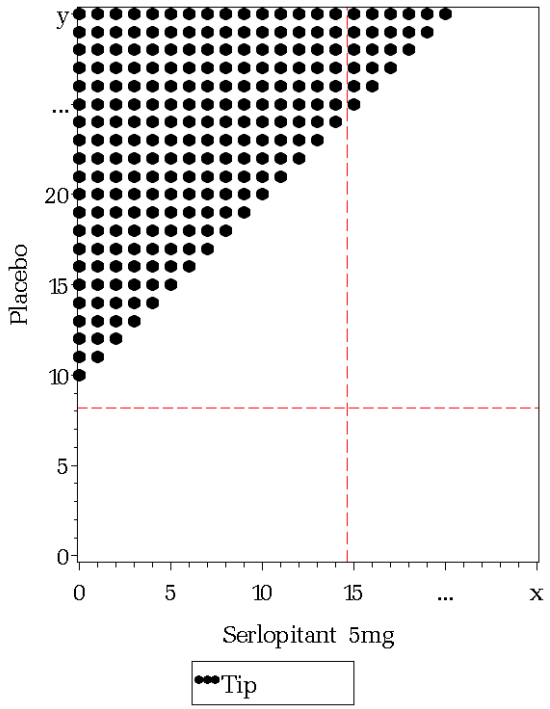
	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	P-value
Missing Values Imputed using Last Observation Carried Forward (LOCF)			
At Least 4-Point Reduction from Baseline in Weekly Average WI-NRS at Week 10			
Success	xx (xx.x%)	xx (xx.x%)	x.xxx[a]
Failure	xx (xx.x%)	xx (xx.x%)	
Repeated Measures Analysis on Observed Data			
At Least 4-Point Reduction from Baseline in Weekly Average WI-NRS at Week 10			
Success	xx.xx%	xx.xx%	x.xxx[b]
Failure	xx.xx%	xx.xx%	

[a] P-value from a Cochran Mantel Haenszel (CMH) test stratified by Baseline WI-NRS randomization stratification.

[b] P-value from a repeated measures logistic regression with factors of treatment group, randomization stratification, visit and treatment group by visit interaction.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Figure 14.2.1.4: Sensitivity Tipping-Point Analyses of the Primary Efficacy Endpoint: Worst-Itch Numeric Rating Scale (WI-NRS)
4-Point Responder at Week 10
(Intent-to-Treat Population)



Note: The horizontal and vertical axes indicate the potential number of successes among subjects with missing data in each treatment group.
Each plotted point indicates the number of imputed successes in each treatment group that results in p-value greater than 0.05.
The red lines represent average number of imputed successes from the primary analysis using multiple imputation (MCMC) to impute missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.4: Subgroup Summaries of Primary Efficacy Endpoint: Worst-Itch Numeric Rating Scale (WI-NRS) 4-Point Responder at Week 10
(Intent-to-Treat Population)
(Page 1 of 3)

Sex	Male		Female	
	Placebo (N=xxx)	Serlopitant 5mg (N=xxx)	Placebo (N=xxx)	Serlopitant 5mg (N=xxx)
At Least 4-Point Reduction from Baseline in Weekly Average WI-NRS at Week 10				
Success	xx.xx%	xx.xx%	xx.xx%	xx.xx%
Failure	xx.xx%	xx.xx%	xx.xx%	xx.xx%
Age	Age < Median Age (xx)		Age >= Median Age (xx)	
	Placebo (N=xxx)	Serlopitant 5mg (N=xxx)	Placebo (N=xxx)	Serlopitant 5mg (N=xxx)
At Least 4-Point Reduction from Baseline in Weekly Average WI-NRS at Week 10				
Success	xx.xx%	xx.xx%	xx.xx%	xx.xx%
Failure	xx.xx%	xx.xx%	xx.xx%	xx.xx%
WI-NRS Randomization Strata	WI-NRS of 6.5 to <9		WI-NRS of 9 to 10	
	Placebo (N=xxx)	Serlopitant 5mg (N=xxx)	Placebo (N=xxx)	Serlopitant 5mg (N=xxx)
At Least 4-Point Reduction from Baseline in Weekly Average WI-NRS at Week 10				
Success	xx.xx%	xx.xx%	xx.xx%	xx.xx%
Failure	xx.xx%	xx.xx%	xx.xx%	xx.xx%

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.4: Subgroup Summary of Primary Efficacy Endpoint: Worst-Itch Numeric Rating Scale (WI-NRS) 4-Point Responder at Week 10
(Intent-to-Treat Population)
(Page 2 of 3)

Ethnicity	Hispanic or Latino		Not Hispanic or Latino	
	Placebo (N=xxx)	Serlopitant 5mg (N=xxx)	Placebo (N=xxx)	Serlopitant 5mg (N=xxx)
At Least 4-Point Reduction from Baseline in Weekly Average WI-NRS at Week 10				
Success	xx.xx%	xx.xx%	xx.xx%	xx.xx%
Failure	xx.xx%	xx.xx%	xx.xx%	xx.xx%

Race	Black or African American		White	
	Placebo (N=xxx)	Serlopitant 5mg (N=xxx)	Placebo (N=xxx)	Serlopitant 5mg (N=xxx)
At Least 4-Point Reduction from Baseline in Weekly Average WI-NRS at Week 10				
Success	xx.xx%	xx.xx%	xx.xx%	xx.xx%
Failure	xx.xx%	xx.xx%	xx.xx%	xx.xx%

Race (continued)	American Indian or Alaska Native		Asian	
	Placebo (N=xxx)	Serlopitant 5mg (N=xxx)	Placebo (N=xxx)	Serlopitant 5mg (N=xxx)
At Least 4-Point Reduction from Baseline in Weekly Average WI-NRS at Week 10				
Success	xx.xx%	xx.xx%	xx.xx%	xx.xx%
Failure	xx.xx%	xx.xx%	xx.xx%	xx.xx%

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.4: Subgroup Summary of Primary Efficacy Endpoint: Worst-Itch Numeric Rating Scale (WI-NRS) 4-Point Responder at Week 10
(Intent-to-Treat Population)
(Page 3 of 3)

Race (continued)	Native Hawaiian or Other Pacific Islander		Multiple/Other	
	Placebo (N=xxx)	Serlopitant 5mg (N=xxx)	Placebo (N=xxx)	Serlopitant 5mg (N=xxx)
At Least 4-Point Reduction from Baseline in Weekly Average WI-NRS at Week 10				
Success	xx.xx%	xx.xx%	xx.xx%	xx.xx%
Failure	xx.xx%	xx.xx%	xx.xx%	xx.xx%

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1: Analysis of Key Secondary Efficacy Endpoints
(Intent-to-Treat Population)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	P-value[a]
At Least 4-Point Reduction from Baseline in Weekly Average Worst Itch Numeric Rating Scale (WI-NRS) at Week 4			
Success	xx.xx%	xx.xx%	x.xxx
Failure	xx.xx%	xx.xx%	
At Least 4-Point Reduction from Baseline in Weekly Average Worst Itch Numeric Rating Scale (WI-NRS) at Week 2			
Success	xx.xx%	xx.xx%	x.xxx
Failure	xx.xx%	xx.xx%	

[a] P-value from a Cochran Mantel Haenszel (CMH) test stratified by Baseline WI-NRS used for randomization stratification. Value has been adjusted for multiple imputation.
Note: Multiple imputation (MCMC) used to impute missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.2.1 for the following:

Table 14.2.2.2: Analysis of Key Secondary Efficacy Endpoints (Per-Protocol Population)

Table 14.2.2.3: Sensitivity Analyses of Key Secondary Efficacy Endpoints
(Intent-to-Treat Population)
(Page 1 of 2)

Missing Values Imputed using Last Observation Carried Forward (LOCF)	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	P-value
At Least 4-Point Reduction from Baseline in Weekly Average Worst Itch Numeric Rating Scale (WI-NRS) at Week 4			
Success	xx (xx.x%)	xx (xx.x%)	x.xxx[a]
Failure	xx (xx.x%)	xx (xx.x%)	
At Least 4-Point Reduction from Baseline in Weekly Average Worst Itch Numeric Rating Scale (WI-NRS) at Week 2			
Success	xx (xx.x%)	xx (xx.x%)	x.xxx[a]
Failure	xx (xx.x%)	xx (xx.x%)	

[a] P-value from a Cochran Mantel Haenszel (CMH) test stratified by Baseline WI-NRS used for randomization stratification.
[b] P-value from a repeated measures logistic regression with factors of treatment group, randomization stratification, visit and treatment group by visit interaction.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3: Sensitivity Analyses of Key Secondary Efficacy Endpoints
(Intent-to-Treat Population)
(Page 2 of 2)

Repeated Measures Analysis on Observed Data	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	P-value
At Least 4-Point Reduction from Baseline in Weekly Average Worst Itch Numeric Rating Scale (WI-NRS) at Week 4			
Success	xx.xx%	xx.xx%	x.xxx[b]
Failure	xx.xx%	xx.xx%	
At Least 4-Point Reduction from Baseline in Weekly Average Worst Itch Numeric Rating Scale (WI-NRS) at Week 2			
Success	xx.xx%	xx.xx%	x.xxx[b]
Failure	xx.xx%	xx.xx%	

[a] P-value from a Cochran Mantel Haenszel (CMH) test stratified by Baseline WI-NRS used for randomization stratification.
[b] P-value from a repeated measures logistic regression with factors of treatment group, randomization stratification, visit and treatment group by visit interaction.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Analysis of Additional Secondary Efficacy Endpoints
(Intent-to-Treat Population)
(Page 1 of 6)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Normality P-Value	Treatment P-Value
Weekly Average Worst Itch Numeric Rating Scale (WI-NRS) – Absolute Change from Baseline to Week 2				
LS Mean[a]	x.xx	x.xx	x.xxx[b]	x.xxx[a]
LS SD[a]	x.xxx	x.xxx		x.xxx[c]
Median[d]	x.xx	x.xx		
Min. to Max.[d]	x.x to x.x	x.x to x.x		
Weekly Average Worst Itch Numeric Rating Scale (WI-NRS) – Absolute Change from Baseline to Week 4				
LS Mean[a]	x.xx	x.xx	x.xxx[b]	x.xxx[a]
LS SD[a]	x.xxx	x.xxx		x.xxx[c]
Median[d]	x.xx	x.xx		
Min. to Max.[d]	x.x to x.x	x.x to x.x		

[a] P-values, least squares means (LS Mean) and standard deviations (LS SD) from an analysis of covariance (ANCOVA) with treatment group and stratification factor as fixed effects, and baseline value as a covariate. Values have been adjusted for multiple imputation.
[b] P-value from a Shapiro-Wilk test for normality. Average p-value across imputations is presented.
[c] P-value from a ranked analysis of covariance (ANCOVA) with treatment group and stratification factor as fixed effects, and baseline value as a covariate. Value has been adjusted for multiple imputation.
[d] Median, minimum and maximum represent average values, obtained from averaging the summary statistics generated from each imputed dataset.
Note: Multiple imputation (MCMC) used to impute missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Analysis of Additional Secondary Efficacy Endpoints
(Intent-to-Treat Population)
(Page 2 of 6)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Normality P-Value	Treatment P-Value
Weekly Average Worst Itch Numeric Rating Scale (WI-NRS) – Absolute Change from Baseline to Week 6				
LS Mean[a]	x.xx	x.xx	x.xxx[b]	x.xxx[a]
LS SD[a]	x.xxx	x.xxx		x.xxx[c]
Median[d]	x.xx	x.xx		
Min. to Max.[d]	x.x to x.x	x.x to x.x		
Weekly Average Worst Itch Numeric Rating Scale (WI-NRS) – Absolute Change from Baseline to Week 10				
LS Mean[a]	x.xx	x.xx	x.xxx[b]	x.xxx[a]
LS SD[a]	x.xxx	x.xxx		x.xxx[c]
Median[d]	x.xx	x.xx		
Min. to Max.[d]	x.x to x.x	x.x to x.x		

[a] P-values, least squares means (LS Mean) and standard deviations (LS SD) from an analysis of covariance (ANCOVA) with treatment group and stratification factor as fixed effects, and baseline value as a covariate. Values have been adjusted for multiple imputation.
[b] P-value from a Shapiro-Wilk test for normality. Average p-value across imputations is presented.
[c] P-value from a ranked analysis of covariance (ANCOVA) with treatment group and stratification factor as fixed effects, and baseline value as a covariate. Value has been adjusted for multiple imputation.
[d] Median, minimum and maximum represent average values, obtained from averaging the summary statistics generated from each imputed dataset.
[e] P-value from a Cochran Mantel Haenszel (CMH) test stratified by Baseline WI-NRS used for randomization stratification. Value has been adjusted for multiple imputation.
Note: Multiple imputation (MCMC) used to impute missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Analysis of Additional Secondary Efficacy Endpoints
(Intent-to-Treat Population)
(Page 3 of 6)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Normality P-Value	Treatment P-Value
At Least 3-Point Reduction from Baseline in Weekly Average Worst Itch Numeric Rating Scale (WI-NRS) at Week 2				
Success	xx.xx%	xx.xx%	N/A	x.xxx[a]
Failure	xx.xx%	xx.xx%		
At Least 3-Point Reduction from Baseline in Weekly Average Worst Itch Numeric Rating Scale (WI-NRS) at Week 4				
Success	xx.xx%	xx.xx%	N/A	x.xxx[a]
Failure	xx.xx%	xx.xx%		
At Least 3-Point Reduction from Baseline in Weekly Average Worst Itch Numeric Rating Scale (WI-NRS) at Week 10				
Success	xx.xx%	xx.xx%	N/A	x.xxx[a]
Failure	xx.xx%	xx.xx%		

[a] P-value from a Cochran Mantel Haenszel (CMH) test stratified by Baseline WI-NRS used for randomization stratification. Value has been adjusted for multiple imputation.

Note: Multiple imputation (MCMC) used to impute missing values.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Analysis of Additional Secondary Efficacy Endpoints
(Intent-to-Treat Population)
(Page 4 of 6)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Normality P-Value	Treatment P-Value
Investigator's Global Assessment of Prurigo Nodularis Activity (IGA PN-A) – Absolute Change from Baseline to Week 2				
LS Mean[a]	x.xx	x.xx	x.xxx[b]	x.xxx[a]
LS SD[a]	x.xxx	x.xxx		x.xxx[c]
Median[d]	x.xx	x.xx		
Min. to Max.[d]	x.x to x.x	x.x to x.x		
Investigator's Global Assessment of Prurigo Nodularis Activity (IGA PN-A) – Absolute Change from Baseline to Week 4				
LS Mean[a]	x.xx	x.xx	x.xxx[b]	x.xxx[a]
LS SD[a]	x.xxx	x.xxx		x.xxx[c]
Median[d]	x.xx	x.xx		
Min. to Max.[d]	x.x to x.x	x.x to x.x		
Investigator's Global Assessment of Prurigo Nodularis Activity (IGA PN-A) – Absolute Change from Baseline to Week 10				
LS Mean[a]	x.xx	x.xx	x.xxx[b]	x.xxx[a]
LS SD[a]	x.xxx	x.xxx		x.xxx[c]
Median[d]	x.xx	x.xx		
Min. to Max.[d]	x.x to x.x	x.x to x.x		

[a] P-values, least squares means (LS Mean) and standard deviations (LS SD) from an analysis of covariance (ANCOVA) with treatment group and stratification factor as fixed effects, and baseline value as a covariate.
[b] P-value from a Shapiro-Wilk test for normality.
[c] P-value from a ranked analysis of covariance (ANCOVA) with treatment group and stratification factor as fixed effects, and baseline value as a covariate.
Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Analysis of Additional Secondary Efficacy Endpoints
(Intent-to-Treat Population)
(Page 5 of 6)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Normality P-Value	Treatment P-Value
Investigator's Global Assessment of Prurigo Nodularis Stage (IGA PN-S) – Absolute Change from Baseline to Week 2				
LS Mean[a]	x.xx	x.xx	x.xxx[b]	x.xxx[a]
LS SD[a]	x.xxx	x.xxx		x.xxx[c]
Median[d]	x.xx	x.xx		
Min. to Max.[d]	x.x to x.x	x.x to x.x		
Investigator's Global Assessment of Prurigo Nodularis Stage (IGA PN-S) – Absolute Change from Baseline to Week 4				
LS Mean[a]	x.xx	x.xx	x.xxx[b]	x.xxx[a]
LS SD[a]	x.xxx	x.xxx		x.xxx[c]
Median[d]	x.xx	x.xx		
Min. to Max.[d]	x.x to x.x	x.x to x.x		
Investigator's Global Assessment of Prurigo Nodularis Stage (IGA PN-S) – Absolute Change from Baseline to Week 10				
LS Mean[a]	x.xx	x.xx	x.xxx[b]	x.xxx[a]
LS SD[a]	x.xxx	x.xxx		x.xxx[c]
Median[d]	x.xx	x.xx		
Min. to Max.[d]	x.x to x.x	x.x to x.x		

[a] P-values, least squares means (LS Mean) and standard deviations (LS SD) from an analysis of covariance (ANCOVA) with treatment group and stratification factor as fixed effects, and baseline value as a covariate.
[b] P-value from a Shapiro-Wilk test for normality.
[c] P-value from a ranked analysis of covariance (ANCOVA) with treatment group and stratification factor as fixed effects, and baseline value as a covariate.
Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Analysis of Additional Secondary Efficacy Endpoints
(Intent-to-Treat Population)
(Page 6 of 6)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Normality P-Value	Treatment P-Value
Dermatology Life Quality Index (DLQI) – Absolute Change from Baseline to Week 10				
LS Mean[a]	x.xx	x.xx	x.xxx[b]	x.xxx[a]
LS SD[a]	x.xxx	x.xxx		x.xxx[c]
Median[d]	x.xx	x.xx		
Min. to Max.[d]	x.x to x.x	x.x to x.x		
Dermatology Life Quality Index (DLQI) Question 1 – Absolute Change from Baseline to Week 10				
LS Mean[a]	x.xx	x.xx	x.xxx[b]	x.xxx[a]
LS SD[a]	x.xxx	x.xxx		x.xxx[c]
Median[d]	x.xx	x.xx		
Min. to Max.[d]	x.x to x.x	x.x to x.x		

[a] P-values, least squares means (LS Mean) and standard deviations (LS SD) from an analysis of covariance (ANCOVA) with treatment group and stratification factor as fixed effects, and baseline value as a covariate.
[b] P-value from a Shapiro-Wilk test for normality.
[c] P-value from a ranked analysis of covariance (ANCOVA) with treatment group and stratification factor as fixed effects, and baseline value as a covariate.
Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.3.1 for the following:

Table 14.2.3.2: Analysis of Additional Secondary Efficacy Endpoints (Per-Protocol Population)

Table 14.2.4.1: Summary of Worst Itch Numeric Rating Scale (WI-NRS)
(Intent-to-Treat Population)
(Page 1 of 6)

WI-NRS	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.1: Summary of Worst Itch Numeric Rating Scale (WI-NRS)
(Intent-to-Treat Population)
(Page 2 of 6)

WI-NRS	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 1		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%
Week 2		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.1: Summary of Worst Itch Numeric Rating Scale (WI-NRS)
(Intent-to-Treat Population)
(Page 3 of 6)

WI-NRS	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 3		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%
Week 4		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.1: Summary of Worst Itch Numeric Rating Scale (WI-NRS)
(Intent-to-Treat Population)
(Page 4 of 6)

WI-NRS	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 5		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%
Week 6		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.1: Summary of Worst Itch Numeric Rating Scale (WI-NRS)
(Intent-to-Treat Population)
(Page 5 of 6)

WI-NRS	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 7		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%
Week 8		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.1: Summary of Worst Itch Numeric Rating Scale (WI-NRS)
(Intent-to-Treat Population)
(Page 6 of 6)

WI-NRS	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 9		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
N	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%
Week 10		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.4.1 for the following:

Table 14.2.4.2: Summary of Worst Itch Numeric Rating Scale (WI-NRS) (Per-Protocol Population)

Table 14.2.4.3: Summary of Worst Itch Numeric Rating Scale (WI-NRS) – Observed Data with Follow-up
(Intent-to-Treat Population with Observed Week 10 Data)
(Page 1 of 2)

WI-NRS	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 10		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.3: Summary of Worst Itch Numeric Rating Scale (WI-NRS) – Observed Data with Follow-up
(Intent-to-Treat Population with Observed Week 10 Data)
(Page 2 of 2)

WI-NRS	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
3-Week Follow-up (Observed Data)		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%
5-Week Follow-up (Observed Data)		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1.1: Summary of Dermatology Life Quality Index (DLQI)
(Intent-to-Treat Population)
(Page 1 of 2)

DLQI	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 4		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1.1: Summary of Dermatology Life Quality Index (DLQI)
(Intent-to-Treat Population)
(Page 2 of 2)

DLQI	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 10		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.5.1.1 for the following:

Table 14.2.5.1.2: Summary of Dermatology Life Quality Index (DLQI) (Per-Protocol Population)

Table 14.2.5.2.1: Summary of Dermatology Life Quality Index (DLQI) Individual Questions
(Intent-to-Treat Population)
(Page 1 of 2)

DLQI Question 1: Over the last week, how itchy, sore, painful or stinging has your skin been?	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xx	xx
Very much	xx (xx.x%)	xx (xx.x%)
A lot	xx (xx.x%)	xx (xx.x%)
A little	xx (xx.x%)	xx (xx.x%)
Not at all	xx (xx.x%)	xx (xx.x%)
Week 4		
n	xx	xx
Very much	xx (xx.x%)	xx (xx.x%)
A lot	xx (xx.x%)	xx (xx.x%)
A little	xx (xx.x%)	xx (xx.x%)
Not at all	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.2.1: Summary of Dermatology Life Quality Index (DLQI) – Individual Questions
(Intent-to-Treat Population)
(Page 2 of 2)

DLQI Question 1: Over the last week, how itchy, sore, painful or stinging has your skin been?	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 10		
n	xx	xx
Very much	xx (xx.x%)	xx (xx.x%)
A lot	xx (xx.x%)	xx (xx.x%)
A little	xx (xx.x%)	xx (xx.x%)
Not at all	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Include all questions:
Question 2: Over the last week, how embarrassed or self-conscious have you been because of your skin?
Question 3: Over the last week, how much has your skin interfered with you going shopping or looking after your home or yard?
Question 4: Over the last week, how much has your skin influenced the clothes you wear?
Question 5: Over the last week, how much has your skin affected any social or leisure activities?
Question 6: Over the last week, how much has your skin made it difficult for you to do any sport?
Question 7: Over the last week, has your skin prevented you from working or studying?
Question 8: Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?
Question 9: Over the last week, how much has your skin caused any sexual difficulties?
Question 10: Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time?

Repeat Table 14.2.5.2.1 for the following:

Table 14.2.5.2.2: Summary of Dermatology Life Quality Index (DLQI) – Individual Questions (Per-Protocol Population)

Table 14.2.6.1: Summary of Investigator's Global Assessment of Prurigo Nodularis Activity (IGA PN-A)
(Intent-to-Treat Population)
(Page 1 of 6)

IGA PN-A	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
N	xx	xx
Grade 0	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
Week 2		
n	xx	xx
Grade 0	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline. "Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.1: Summary of Investigator's Global Assessment of Prurigo Nodularis Activity (IGA PN-A)
(Intent-to-Treat Population)
(Page 2 of 6)

IGA PN-A	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 4		
n	xx	xx
Grade 0	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline. "Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.1: Summary of Investigator's Global Assessment of Prurigo Nodularis Activity (IGA PN-A)
(Intent-to-Treat Population)
(Page 3 of 6)

IGA PN-A	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 10		
n	xx	xx
Grade 0	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline. "Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.1: Summary of Investigator's Global Assessment of Prurigo Nodularis Activity (IGA PN-A)
(Intent-to-Treat Population)
(Page 4 of 6)

IGA PN-A	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
3-Week Follow-up		
n	xx	xx
Grade 0	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline. "Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.1: Summary of Investigator's Global Assessment of Prurigo Nodularis Activity (IGA PN-A)
(Intent-to-Treat Population)
(Page 5 of 6)

IGA PN-A	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
5-Week Follow-up		
n	xx	xx
Grade 0	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline. "Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.1: Summary of Investigator's Global Assessment of Prurigo Nodularis Activity (IGA PN-A)
(Intent-to-Treat Population)
(Page 6 of 6)

IGA PN-A	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Latest Follow-up		
n	xx	xx
Grade 0	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline. "Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.6.1 for the following:

Table 14.2.6.2: Summary of Investigator's Global Assessment of Prurigo Nodularis Activity (IGA PN-A) (Per-Protocol Population)

Table 14.2.7.1: Summary of Investigator's Global Assessment of Prurigo Nodularis Stage (IGA PN-S)
(Intent-to-Treat Population)
(Page 1 of 6)

IGA PN-S	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xx	xx
Grade 0	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
Week 2		
n	xx	xx
Grade 0	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline. "Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.1: Summary of Investigator's Global Assessment of Prurigo Nodularis Stage (IGA PN-S)
(Intent-to-Treat Population)
(Page 2 of 6)

IGA PN-S	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 4		
n	xx	xx
Grade 0	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline. "Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.1: Summary of Investigator's Global Assessment of Prurigo Nodularis Stage (IGA PN-S)
(Intent-to-Treat Population)
(Page 3 of 6)

IGA PN-S	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 10		
n	xx	xx
Grade 0	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline. "Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.1: Summary of Investigator's Global Assessment of Prurigo Nodularis Stage (IGA PN-S)
(Intent-to-Treat Population)
(Page 4 of 6)

IGA PN-S	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
3-Week Follow-up		
n	xx	xx
Grade 0	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline. "Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.1: Summary of Investigator's Global Assessment of Prurigo Nodularis Stage (IGA PN-S)
(Intent-to-Treat Population)
(Page 5 of 6)

IGA PN-S	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
5-Week Follow-up		
n	xx	xx
Grade 0	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline. "Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.1: Summary of Investigator's Global Assessment of Prurigo Nodularis Stage (IGA PN-S)
(Intent-to-Treat Population)
(Page 6 of 6)

IGA PN-S	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Latest Follow-up		
n	xx	xx
Grade 0	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline. "Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.7.1 for the following:

Table 14.2.7.2: Summary of Investigator's Global Assessment of Prurigo Nodularis Stage (IGA PN-S) (Per-Protocol Population)

Table 14.3.0.1: Summary of Extent of Exposure
(Intent-to-Treat Population)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total Number of Tablets Used[a]		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Total Number of Days of Exposure		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Compliant[b]		
n	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)

[a] Subjects were to dose with 3 tablets on Day 1/Date of First Dose.
[b] A subject was considered compliant with the dosing regimen if the subject took at least 80% but no more than 120% of expected doses.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.0.1 for the following:

Table 14.3.0.2: Summary of Extent of Exposure (Per-Protocol Population)
Table 14.3.0.3: Summary of Extent of Exposure (Safety Population)

Table 14.3.1.1.1: Overall Summary of Treatment-Emergent Adverse Events (TEAEs)
(Safety Population)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Subjects with any TEAE	xx (xx.x%)	xx (xx.x%)
Number of TEAEs	xx	xx
Subjects with any Related TEAE	xx (xx.x%)	xx (xx.x%)
Number of Related TEAEs	xx	xx
Subjects with any Serious TEAE	xx (xx.x%)	xx (xx.x%)
Number of Serious TEAEs	xx	xx
Subjects with any Related Serious TEAE	xx (xx.x%)	xx (xx.x%)
Number of Related Serious TEAEs	xx	xx
Subjects who Died	xx (xx.x%)	xx (xx.x%)
Subjects who Discontinued Study Drug Due to TEAE	xx (xx.x%)	xx (xx.x%)
Maximum Severity by Subject		
Grade 5	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Maximum Relationship by Subject		
Likely Related	xx (xx.x%)	xx (xx.x%)
Likely Unrelated	xx (xx.x%)	xx (xx.x%)

Note: TEAEs are AEs with an onset after first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.2: Summary of Subjects Reporting Treatment-Emergent Adverse Events (TEAEs) by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more TEAEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.

Note: TEAEs are AEs with an onset date after first dose of study drug.
MedDRA Version 21.1.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.3: Summary of Treatment-Emergent Adverse Events (TEAEs) Leading to Discontinuation of Study Drug
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more TEAEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.

Note: TEAEs are AEs with an onset date after first dose of study drug.
MedDRA Version 21.1.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.4: Summary of Subjects Reporting Treatment-Emergent Adverse Events (TEAEs) by Severity
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity[b]	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	Grade 5	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)
System Organ Class	Grade 5	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)
Preferred Term	Grade 5	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more TEAEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.
[b] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: TEAEs are AEs with an onset after first dose of study drug.
MedDRA Version 21.1.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.5: Summary of Subjects Reporting Treatment-Emergent Adverse Events (TEAEs) by Relationship to Study Drug
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)
System Organ Class	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more TEAEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported relationship.

Note: TEAEs are AEs with an onset after first dose of study drug.
MedDRA Version 21.1.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2.1.1: Overall Summary of Post-Drug Adverse Event (AEs)
(Safety Population)

	Placebo			Serlopitant 5 mg		
	Males (N=xxx)	Females (N=xxx)	Overall (N=xxx)	Males (N=xxx)	Females (N=xxx)	Overall (N=xxx)
Subjects with any Post-Drug AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Post-Drug AEs	xx	xx	xx	xx	xx	xx
Subjects with any Related Post-Drug AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Related Post-Drug AEs	xx	xx	xx	xx	xx	xx
Subjects with any Serious Post-Drug AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Serious Post-Drug AEs	xx	xx	xx	xx	xx	xx
Subjects with any Related Serious Post-Drug AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Related Serious Post-Drug AEs	xx	xx	xx	xx	xx	xx
Subjects who Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Severity by Subject						
Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Relationship by Subject						
Likely Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Likely Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Table includes AEs with an onset after last dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2.1.2: Overall Summary of Post-Drug Adverse Events (AEs) Occurring 1-7 Days Post Last Dose
(Safety Population)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Subjects with any Post-Drug AE	xx (xx.x%)	xx (xx.x%)
Number of Post-Drug AEs	xx	xx
Subjects with any Related Post-Drug AE	xx (xx.x%)	xx (xx.x%)
Number of Related Post-Drug AEs	xx	xx
Subjects with any Serious Post-Drug AE	xx (xx.x%)	xx (xx.x%)
Number of Serious Post-Drug AEs	xx	xx
Subjects with any Related Serious Post-Drug AE	xx (xx.x%)	xx (xx.x%)
Number of Related Serious Post-Drug AEs	xx	xx
Subjects who Died	xx (xx.x%)	xx (xx.x%)
Maximum Severity by Subject		
Grade 5	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Maximum Relationship by Subject		
Likely Related	xx (xx.x%)	xx (xx.x%)
Likely Unrelated	xx (xx.x%)	xx (xx.x%)

Note: Table includes AEs with an onset date within 1 to 7 days after last dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.1.2.1.2 for the following, with adjusted foonotes:

Table 14.3.1.2.1.3: Overall Summary of Post-Drug Adverse Events (AEs) Occurring 8-14 Days Post Last Dose (Safety Population)

Note: Table includes AEs with an onset date within 8 to 14 days after last dose of study drug.

Table 14.3.1.2.1.4: Overall Summary of Post-Drug Adverse Events (AEs) Occurring 15-21 Days Post Last Dose (Safety Population)

Note: Table includes AEs with an onset date within 15 to 21 days after last dose of study drug.

Table 14.3.1.2.1.5: Overall Summary of Post-Drug Adverse Events (AEs) Occurring 22-28 Days Post Last Dose (Safety Population)

Note: Table includes AEs with an onset date within 22 to 28 days after last dose of study drug.

Table 14.3.1.2.1.6: Overall Summary of Post-Drug Adverse Events (AEs) Occurring 29-35 Days Post Last Dose (Safety Population)

Note: Table includes AEs with an onset date within 29 to 35 days after last dose of study drug.

Table 14.3.1.2.2.1: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

	Placebo			Serlopitant 5 mg		
System Organ Class[a] Preferred Term	Males (N=xxx)	Females (N=xxx)	Overall (N=xxx)	Males (N=xxx)	Females (N=xxx)	Overall (N=xxx)
Total	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more AEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.

Note: Table includes AEs with an onset after last dose of study drug.
MedDRA Version 21.1.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2.2.2: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) Occurring 1-7 Days Post Last Dose
by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more AEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.

Note: Table includes AEs with an onset date within 1 to 7 days after last dose of study drug.
MedDRA Version 21.1.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.1.2.2.2 for the following, with adjusted foonotes:

Table 14.3.1.2.2.3: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) Occurring 8-14 Days Post Last Dose by MedDRA System Organ Class and Preferred Term (Safety Population)

Note: Table includes AEs with an onset date within 8 to 14 days after last dose of study drug.

Table 14.3.1.2.2.4: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) Occurring 15-21 Days Post Last Dose by MedDRA System Organ Class and Preferred Term (Safety Population)

Note: Table includes AEs with an onset date within 15 to 21 days after last dose of study drug.

Table 14.3.1.2.2.5: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) Occurring 22-28 Days Post Last Dose by MedDRA System Organ Class and Preferred Term (Safety Population)

Note: Table includes AEs with an onset date within 22 to 28 days after last dose of study drug.

Table 14.3.1.2.2.6: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) Occurring 29-35 Days Post Last Dose by MedDRA System Organ Class and Preferred Term (Safety Population)

Note: Table includes AEs with an onset date within 29 to 35 days after last dose of study drug.

Table 14.3.1.2.3.1: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) by Severity
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity[b]	Placebo Males (N=xxx)	Placebo Females (N=xxx)	Placebo Overall (N=xxx)	Serlopitant 5 mg Males (N=xxx)	Serlopitant 5 mg Females (N=xxx)	Serlopitant 5 mg Overall (N=xxx)
Total	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Grade 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more AEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.
[b] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: Table includes AEs with an onset after last dose of study drug.
MedDRA Version 21.1.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2.3.2: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) Occurring 1-7 Days Post Last Dose by Severity
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity[b]	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	Grade 5	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)
System Organ Class	Grade 5	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)
Preferred Term	Grade 5	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more AEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.
[b] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: Table includes AEs with an onset date within 1 to 7 days after last dose of study drug.
MedDRA Version 21.1.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.1.2.3.2 for the following, with adjusted foonotes:

Table 14.3.1.2.3.3: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) Occurring 8-14 Days Post Last Dose by Severity (Safety Population)
Note: Table includes AEs with an onset date within 8 to 14 days after last dose of study drug.

Table 14.3.1.2.3.4: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) Occurring 15-21 Days Post Last Dose by Severity (Safety Population)
Note: Table includes AEs with an onset date within 15 to 21 days after last dose of study drug.

Table 14.3.1.2.3.5: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) Occurring 22-28 Days Post Last Dose by Severity (Safety Population)
Note: Table includes AEs with an onset date within 22 to 28 days after last dose of study drug.

Table 14.3.1.2.3.6: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) Occurring 29-35 Days Post Last Dose by Severity (Safety Population)
Note: Table includes AEs with an onset date within 29 to 35 days after last dose of study drug.

Table 14.3.1.2.4.1: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) by Relationship to Study Drug
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	Placebo Males (N=xxx)	Placebo Females (N=xxx)	Placebo Overall (N=xxx)	Serlopitant 5 mg Males (N=xxx)	Serlopitant 5 mg Females (N=xxx)	Serlopitant 5 mg Overall (N=xxx)
Total	Likely Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	Likely Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more AEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported relationship.

Note: Table includes AEs with an onset after last dose of study drug.
MedDRA Version 21.1.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2.4.2: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) Occurring 1-7 Days Post Last Dose by Relationship to Study Drug
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)
System Organ Class	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more AEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported relationship.

Note: Table includes AEs with an onset date within 1 to 7 days after last dose of study drug.
MedDRA Version 21.1.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.1.2.4.2 for the following, with adjusted foonotes:

Table 14.3.1.2.4.3: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) Occurring 8-14 Days Post Last Dose by Relationship to Study Drug (Safety Population)

Note: Table includes AEs with an onset date within 8 to 14 days after last dose of study drug.

Table 14.3.1.2.4.4: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) Occurring 15-21 Days Post Last Dose by Relationship to Study Drug (Safety Population)

Note: Table includes AEs with an onset date within 15 to 21 days after last dose of study drug.

Table 14.3.1.2.4.5: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) Occurring 22-28 Days Post Last Dose by Relationship to Study Drug (Safety Population)

Note: Table includes AEs with an onset date within 22 to 28 days after last dose of study drug.

Table 14.3.1.2.4.6: Summary of Subjects Reporting Post-Drug Adverse Events (AEs) Occurring 29-35 Days Post Last Dose by Relationship to Study Drug (Safety Population)

Note: Table includes AEs with an onset date within 29 to 35 days after last dose of study drug.

Table 14.3.1.3.1: Summary of Subjects Reporting Serious Treatment-Emergent Adverse Events (TEAEs) by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more TEAEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.

Note: TEAEs are AEs with an onset date after first dose of study drug.
MedDRA Version 21.1.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.3.2: Summary of Subjects Reporting Serious Treatment-Emergent Adverse Events (TEAEs) by Severity
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	Grade 5	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)
System Organ Class	Grade 5	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)
Preferred Term	Grade 5	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more serious TEAEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.
[b] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: TEAEs are AEs with an onset after first dose of study drug.
MedDRA Version 21.1.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.3.3: Summary of Subjects Reporting Serious Treatment-Emergent Adverse Events (TEAEs) by Relationship to Study Drug
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)
System Organ Class	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more TEAEs that map to the MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported relationship.

Note: TEAEs are AEs with an onset after first dose of study drug.
MedDRA Version 21.1.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.1.1: Summary of Hematology Laboratory Results
(Safety Population)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Test Name> (<units>)		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 2		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
"Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include post-baseline visits of "Week 2", "Week 10", "3-Week Follow-up", "5-Week Follow-up", "Latest Follow-up".

Table to include following lab tests: "BASOPHILS", "EOSINOPHILS", "HCT", "HGB", "LYMPHOCYTES", "MCH", "MCHC", "MCV", "MONOCYTES", "NEUTROPHILS", "PLATELET COUNT", "RBC", "WBC".

Table 14.3.1.4.1.2: Shift Summary of Hematology Laboratory Results
(Safety Population)
(Page 1 of xx)

<Test Name> (<units>)		Placebo (N=xxx)			Serlopitant 5 mg (N=xxx)		
		Week 2			**Week 2**		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Week 10			**Week 10**		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		3-Week Follow-up			**3-Week Follow-up**		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		5-Week Follow-up			**5-Week Follow-up**		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Latest Follow-up			**Latest Follow-up**		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: BNL=Below Normal Limit, WNL=Within Normal Limits, ANL=Above Normal Limit.
No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. “Latest Follow-up” visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include the same lab tests used in Table 14.3.1.4.1.1.

Table 14.3.1.4.2.1: Summary of Chemistry Laboratory Results
(Safety Population)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Test Name> (<units>)		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 2		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
"Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include post-baseline visits of "Week 2", "Week 10", "3-Week Follow-up", "5-Week Follow-up", "Latest Follow-up".

Table to include following lab tests: "ALBUMIN", "ALKALINE PHOSPHATASE", "ALT", "AST", "BICARBONATE", "BILIRUBIN, TOTAL", "BUN", "CALCIUM", "CHLORIDE", "CHOLESTEROL, TOTAL", "CREATININE", "GLUCOSE, RANDOM", "HDL-CHOLESTEROL", "LDH", "LDL-CHOLESTEROL", "MAGNESIUM", "PHOSPHORUS", "POTASSIUM", "PROTEIN, TOTAL", "SODIUM", "TRIGLYCERIDES", "URIC ACID".

Table 14.3.1.4.2.2: Shift Summary of Chemistry Laboratory Results
(Safety Population)
(Page 1 of xx)

<Test Name> (<units>)		Placebo (N=xxx)			Serlopitant 5 mg (N=xxx)		
		Week 2			**Week 2**		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Week 10			**Week 10**		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		3-Week Follow-up			**3-Week Follow-up**		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		5-Week Follow-up			**5-Week Follow-up**		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Latest Follow-up			**Latest Follow-up**		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: BNL=Below Normal Limit, WNL=Within Normal Limits, ANL=Above Normal Limit.
No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. “Latest Follow-up” visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include the same lab tests used in Table 14.3.1.4.2.1.

Table 14.3.1.4.3.1.1: Summary of Endocrine/Reproductive Endocrine Laboratory Results
(Safety Population)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Test Name> (<units>)		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 10		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
"Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include post-baseline visits of "Week 10", "3-Week Follow-up", "5-Week Follow-up", "Latest Follow-up".

Table to include following lab tests: "TSH ULTRASENSITIVE", "THYROXINE, FREE", "CORTISOL, SERUM RANDOM", "ACTH, PLASMA", "ANTI-MULLERIAN HORMONE", "FSH", "ESTRADIOL", "LUTEINIZING HORMONE", "PROGESTERONE".

Table 14.3.1.4.3.1.2: Summary of Reproductive Endocrine Laboratory Results
(Safety Population – Females Using Hormonal Contraception/Therapy)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Test Name> (<units>)		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 10		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
"Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include post-baseline visits of "Week 10", "3-Week Follow-up", "5-Week Follow-up", "Latest Follow-up".

Table to include following lab tests: "ANTI-MULLERIAN HORMONE", "FSH", "ESTRADIOL", "LUTEINIZING HORMONE", "PROGESTERONE".

Table 14.3.1.4.3.1.3: Summary of Reproductive Endocrine Laboratory Results
(Safety Population – Females Not Using Hormonal Contraception/Therapy)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Test Name> (<units>)		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 10		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
"Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include post-baseline visits of "Week 10", "3-Week Follow-up", "5-Week Follow-up", "Latest Follow-up".

Table to include following lab tests: "ANTI-MULLERIAN HORMONE", "FSH", "ESTRADIOL", "LUTEINIZING HORMONE", "PROGESTERONE".

Table 14.3.1.4.3.2: Shift Summary of Endocrine/Reproductive Endocrine Laboratory Results
(Safety Population)
(Page 1 of xx)

<Test Name> (<units>)		Placebo (N=xxx)			Serlopitant 5 mg (N=xxx)		
		Week 10			Week 10		
Baseline		BNL	WNL	ANL	BNL	WNL	ANL
BNL		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
WNL		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ANL		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		3-Week Follow-up			3-Week Follow-up		
Baseline		BNL	WNL	ANL	BNL	WNL	ANL
BNL		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
WNL		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ANL		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		5-Week Follow-up			5-Week Follow-up		
Baseline		BNL	WNL	ANL	BNL	WNL	ANL
BNL		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
WNL		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ANL		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Latest Follow-up			Latest Follow-up		
Baseline		BNL	WNL	ANL	BNL	WNL	ANL
BNL		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
WNL		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ANL		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: BNL=Below Normal Limit, WNL=Within Normal Limits, ANL=Above Normal Limit.
No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. “Latest Follow-up” visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include following lab tests: “TSH ULTRASENSITIVE”, “THYROXINE, FREE”, “CORTISOL, SERUM RANDOM”, “ACTH, PLASMA”, “ANTI-MULLERIAN HORMONE”.

Table 14.3.1.5.1.1: Summary of Treatment-Emergent Electrocardiogram (ECG) Parameter Abnormalities
(Safety Population)
(Page 1 of 2)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Number of Subjects with Treatment-Emergent ECG Results	xxx	xxx
PR Interval		
> 200 msec	xx (xx.x%)	xx (xx.x%)
> 220 msec	xx (xx.x%)	xx (xx.x%)
Change from Baseline in PR Interval		
>= 25% and > 200 msec	xx (xx.x%)	xx (xx.x%)
QRS Interval		
> 110 msec	xx (xx.x%)	xx (xx.x%)
> 120 msec	xx (xx.x%)	xx (xx.x%)
Change from Baseline in QRS Interval		
>= 25% and > 110 msec	xx (xx.x%)	xx (xx.x%)
>= 25% and > 120 msec	xx (xx.x%)	xx (xx.x%)
QTcF Interval		
> 450 - 470 msec	xx (xx.x%)	xx (xx.x%)
> 470 - 500 msec	xx (xx.x%)	xx (xx.x%)
> 500 msec	xx (xx.x%)	xx (xx.x%)
Change from Baseline in QTcF Interval		
> 30 - 60 msec	xx (xx.x%)	xx (xx.x%)
> 60 msec	xx (xx.x%)	xx (xx.x%)
QTcF Interval > 500 msec and Change from Baseline > 60 msec	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.5.1.1: Summary of Treatment-Emergent Electrocardiogram (ECG) Abnormalities
(Safety Population)
(Page 2 of 2)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Number of Subjects with Treatment-Emergent ECG Results	xxx	xxx
QTcB Interval		
> 450 - 470 msec	xx (xx.x%)	xx (xx.x%)
> 470 - 500 msec	xx (xx.x%)	xx (xx.x%)
> 500 msec	xx (xx.x%)	xx (xx.x%)
Change from Baseline in QTcB Interval		
> 30 - 60 msec	xx (xx.x%)	xx (xx.x%)
> 60 msec	xx (xx.x%)	xx (xx.x%)
QTcB Interval > 500 msec and Change from Baseline > 60 msec	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.5.1.2: Summary of Electrocardiogram Parameters
(Safety Population)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Parameter> (<units>)		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 2		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
"Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include parameters "ECG Mean Heart Rate (beats/min)", "PR Interval, Aggregate (msec)", "QRS Duration, Aggregate (msec)", "QT Interval, Aggregate (msec)", "QTcB Interval, Aggregate (msec)", "QTcF Interval, Aggregate (msec)", "RR Interval, Aggregate (msec)".

Table to include post-baseline visits of "Week 2", "Week 4", "Week 10", "3-Week Follow-up", "5-Week Follow-up", "Latest Follow-up".

Table 14.3.1.5.1.3: Shift Summary of Overall Electrocardiogram (ECG) Assessments
(Safety Population)
(Page 1 of 2)

Overall ECG Assessment (per Investigator)	Placebo (N=xxx)			Serlopitant 5 mg (N=xxx)		
	Week 2			**Week 2**		
Baseline	Normal	Abnormal, NCS	Abnormal, CS	Normal	Abnormal, NCS	Abnormal, CS
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Week 4			**Week 4**		
Baseline	Normal	Abnormal, NCS	Abnormal, CS	Normal	Abnormal, NCS	Abnormal, CS
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Week 10			**Week 10**		
Baseline	Normal	Abnormal, NCS	Abnormal, CS	Normal	Abnormal, NCS	Abnormal, CS
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	3-Week Follow-up			**3-Week Follow-up**		
Baseline	Normal	Abnormal, NCS	Abnormal, CS	Normal	Abnormal, NCS	Abnormal, CS
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	5-Week Follow-up			**5-Week Follow-up**		
Baseline	Normal	Abnormal, NCS	Abnormal, CS	Normal	Abnormal, NCS	Abnormal, CS
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. “Latest Follow-up” visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
NCS=Not Clinically Significant; CS=Clinically Significant.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.5.1.3: Shift Summary of Overall Electrocardiogram (ECG) Assessments
(Safety Population)
(Page 2 of 2)

Overall ECG Assessment (per Investigator)	Placebo (N=xxx)			Serlopitant 5 mg (N=xxx)		
	Latest Follow-up			**Latest Follow-up**		
Baseline	Normal	Abnormal, NCS	Abnormal, CS	Normal	Abnormal, NCS	Abnormal, CS
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. “Latest Follow-up” visit includes the latest available follow-up information for each subject from the 3-Week or 5-Week Follow-up visits.
NCS=Not Clinically Significant; CS=Clinically Significant.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.5.2.1: Summary of Post-Drug Electrocardiogram (ECG) Parameter Abnormalities
(Safety Population Consenting to Protocol Version 3.0)
(Page 1 of 2)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Number of Subjects with Post-Drug ECG Results	xxx	xxx
PR Interval		
> 200 msec	xx (xx.x%)	xx (xx.x%)
> 220 msec	xx (xx.x%)	xx (xx.x%)
Change from On-Drug Baseline in PR Interval		
>= 25% and > 200 msec	xx (xx.x%)	xx (xx.x%)
QRS Interval		
> 110 msec	xx (xx.x%)	xx (xx.x%)
> 120 msec	xx (xx.x%)	xx (xx.x%)
Change from On-Drug Baseline in QRS Interval		
>= 25% and > 110 msec	xx (xx.x%)	xx (xx.x%)
>= 25% and > 120 msec	xx (xx.x%)	xx (xx.x%)
QTcF Interval		
> 450 - 470 msec	xx (xx.x%)	xx (xx.x%)
> 470 - 500 msec	xx (xx.x%)	xx (xx.x%)
> 500 msec	xx (xx.x%)	xx (xx.x%)
Change from On-Drug Baseline in QTcF Interval		
> 30 - 60 msec	xx (xx.x%)	xx (xx.x%)
> 60 msec	xx (xx.x%)	xx (xx.x%)
QTcF Interval > 500 msec and Change from On-Drug Baseline > 60 msec	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values. On-Drug Baseline is the latest recorded value prior to last dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.5.2.1: Summary of Post-Drug Electrocardiogram (ECG) Abnormalities
(Safety Population Consenting to Protocol Version 3.0)
(Page 2 of 2)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Number of Subjects with Post-Drug ECG Results	xxx	xxx
QTcB Interval		
> 450 - 470 msec	xx (xx.x%)	xx (xx.x%)
> 470 - 500 msec	xx (xx.x%)	xx (xx.x%)
> 500 msec	xx (xx.x%)	xx (xx.x%)
Change from On-Drug Baseline in QTcB Interval		
> 30 - 60 msec	xx (xx.x%)	xx (xx.x%)
> 60 msec	xx (xx.x%)	xx (xx.x%)
QTcB Interval > 500 msec and Change from On-Drug Baseline > 60 msec	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values. On-Drug Baseline is the latest recorded value prior to last dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.5.2.2: Summary of Post-Drug Electrocardiogram Parameters
(Safety Population Consenting to Protocol Version 3.0)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Parameter> (<units>)		
On-Drug Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
5-Week Follow-up		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from On-Drug Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. On-Drug Baseline is the latest recorded value prior to last dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include parameters "ECG Mean Heart Rate (beats/min)", "PR Interval, Aggregate (msec)", "QRS Duration, Aggregate (msec)", "QT Interval, Aggregate (msec)", "QTcB Interval, Aggregate (msec)", "QTcF Interval, Aggregate (msec)", "RR Interval, Aggregate (msec)".

Table 14.3.1.5.2.3: Shift Summary of Post-Drug Overall Electrocardiogram (ECG) Assessments
(Safety Population Consenting to Protocol Version 3.0)

Overall ECG Assessment (per Investigator)	Placebo (N=xxx)			Serlopitant 5 mg (N=xxx)		
	5-Week Follow-up			**5-Week Follow-up**		
On-Drug Baseline	Normal	Abnormal, NCS	Abnormal, CS	Normal	Abnormal, NCS	Abnormal, CS
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal, CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values. On-Drug Baseline is the latest recorded value prior to last dose of study drug.
NCS=Not Clinically Significant; CS=Clinically Significant.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.6.1: Summary of Vital Signs
(Safety Population)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Parameter> (<units>)		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 2		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline. "Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week, 4-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include parameters in following order: "Temperature (degrees Celsius)", "Respiration Rate (breaths/min)", "Heart Rate (beats/min)", "Systolic Blood Pressure (mmHg)", "Diastolic Blood Pressure (mmHg)".

Table to include post-baseline visits of "Week 2", "Week 4", "Week 6", "Week 10", "3-Week Follow-up", '"5-Week Follow-up", "Latest Follow-up".

Table 14.3.1.6.2: On-Drug Summary of Vital Signs
(Safety Population Consenting to Protocol Version 3.0)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Parameter> (<units>)		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 2		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include parameters in following order: "Temperature (degrees Celsius)", "Respiration Rate (breaths/min)", "Heart Rate (beats/min)", "Systolic Blood Pressure (mmHg)", "Diastolic Blood Pressure (mmHg)".

Table to include post-baseline visits of "Week 2", "Week 4", "Week 6", "Week 10".

Table 14.3.1.6.3: Post-Drug Summary of Vital Signs
(Safety Population Consenting to Protocol Version 3.0)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Parameter> (<units>)		
On-Drug Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
3-Day Follow-up		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from On-Drug Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: On-Drug Baseline is the latest recorded value prior to last dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include parameters in following order: "Temperature (degrees Celsius)", "Respiration Rate (breaths/min)", "Heart Rate (beats/min)", "Systolic Blood Pressure (mmHg)", "Diastolic Blood Pressure (mmHg)".

Table to include post-drug observation visits of "3-Day Follow-up", "1-Week Follow-up", "2-Week Follow-up", "3-Week Follow-up", "4-Week Follow-up", "5-Week Follow-up".

Table 14.3.1.7.1: Summary of Hospital Anxiety and Depression Scale (HADS)
(Safety Population)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Subscale>		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline. "Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week, 4-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include subscales in following order: "Anxiety Subscale", "Depression Subscale".

Table to include post-baseline visits of "Week 4", "Week 10", "3-Week Follow-up", '"5-Week Follow-up", "Latest Follow-up".

Table 14.3.1.7.2: On-Drug Summary of Hospital Anxiety and Depression Scale (HADS)
(Safety Population Consenting to Protocol Version 3.0)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Subscale>		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include subscales in following order: "Anxiety Subscale", "Depression Subscale".

Table to include post-baseline visits of "Week 4", "Week 10"

Table 14.3.1.7.3: Post-Drug Summary of Hospital Anxiety and Depression Scale (HADS)
(Safety Population Consenting to Protocol Version 3.0)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Subscale>		
On-Drug Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
3-Day Follow-up		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from On-Drug Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: On-Drug Baseline is the latest recorded value prior to last dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include subscales in following order: "Anxiety Subscale", "Depression Subscale".

Table to include post-drug observation visits of "3-Day Follow-up", "1-Week Follow-up", "2-Week Follow-up", "3-Week Follow-up", "4-Week Follow-up", "5-Week Follow-up".

Table 14.3.1.8.1: Summary of Epworth Sleepiness Scale (ESS)
(Safety Population)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
ESS		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline. "Latest Follow-up" visit includes the latest available follow-up information for each subject from the 3-Week, 4-Week or 5-Week Follow-up visits.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include post-baseline visits of "Week 4", "Week 10", "3-Week Follow-up", '"5-Week Follow-up", "Latest Follow-up".

Table 14.3.1.8.2: On-Drug Summary of Epworth Sleepiness Scale (ESS)
(Safety Population Consenting to Protocol Version 3.0)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
ESS		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include post-baseline visits of "Week 4", "Week 10".

Table 14.3.1.8.3: Post-Drug Summary of Epworth Sleepiness Scale (ESS)
(Safety Population Consenting to Protocol Version 3.0)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
ESS		
On-Drug Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
3-Day Follow-up		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from On-Drug Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: On-Drug Baseline is the latest recorded value prior to last dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include post-drug observation visits of "3-Day Follow-up", "1-Week Follow-up", "2-Week Follow-up", "3-Week Follow-up", "4-Week Follow-up", "5-Week Follow-up".

Table 14.3.1.9: Summary of Pharmacokinetic Concentrations
(Safety Population)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Analyte> (<units>)		
Week 2		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 10		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include analytes in following order: “M1/M1a”, “M2/M2a”, “M3”, “Serlopitant”.

Table 14.3.1.10: Summary of Menstrual Cycles
(Safety Population)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Number of Menstrual Cycles		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Duration of Menstrual Cycles		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

11. INDEX OF PLANNED LISTINGS

Listing 16.1.7: Randomization Scheme
(Page xx of yy)

Subject	Age/Sex	Evaluable	Randomization Strata	Randomization Date	Assigned Treatment Group	Was the subject previously a Screen Fail?	Previous Screening Subject Number
xxxxxx	xxxx	xxxxxxxxx	xxxx	xxxxxxxxxx	xxxxxxx xxxxxx	xxx	xxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxx	xxxxxxxxxx	xxxxxxx xxxxxx	xxx	xxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxx	xxxxxxxxxx	xxxxxxx xxxxxx	xxx	xxxxxx

Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject.

Listing 16.2.1.1: Subject Disposition Information
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	F: Date of First Dose L: Date of Last Dose	R: Reason for Treatment Discontinuation P: Primary AE Number/Specify	E: Follow-up Discontinuation Date (Day)[1] R: Reason for Follow-up Discontinuation	D: Date of Last Contact P: Primary AE Number/Specify C: Continuing into MTI-107?
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx	R: xxxxxxxxxx xx xxxxxxxxxxxxxx P: xxxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxxxxxxxx xx xxxxxxxxxx	D: xxxx-xx-xx P: xxxxxxxxxxx C: xxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx	R: xxxxxxxxxx xx xxxxxxxxxxxxxx P: xxxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxxxxxxxx xx xxxxxxxxxx	D: xxxx-xx-xx P: xxxxxxxxxxx C: xxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx	R: xxxxxxxxx xxxx xxxxxxxx xxxxx P: xxxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxx xx xxxxxxxxx	D: P: xxxxxxxxxxx C: xxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject.

Listing 16.2.1.2: Discontinued Subjects
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	F: Date of First Dose L: Date of Last Dose	R: Reason for Treatment Discontinuation P: Primary AE Number/Specify	E: Follow-up Discontinuation Date (Day)[1] R: Reason for Follow-up Discontinuation	D: Date of Last Contact P: Primary AE Number/Specify C: Continuing into MTI-107?
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx	R: xxxxxxxxxx xx xxxxxxxxxxxxxx P: xxxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxxxxxxxx xx xxxxxxxxxx	D: xxxx-xx-xx P: xxxxxxxxxxx C: xxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx	R: xxxxxxxxxx xx xxxxxxxxxxxxxx P: xxxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxxxxxxxx xx xxxxxxxxxx	D: xxxx-xx-xx P: xxxxxxxxxxx C: xxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx	R: xxxxxxxxx xxxx xxxxxxxx xxxxx P: xxxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxx xx xxxxxxxxx	D: P: xxxxxxxxxxx C: xxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject.

Listing 16.2.2.1: Inclusion/Exclusion Criteria Not Met
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Criterion Failed	Description
xxxxxx	xxxx	xxxxxxxxx	xxxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx
			xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx
			xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxxxxx xxxxxxxxx x xxxxxxxxxxxxxxxx xxx

Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject and Criterion Failed.

Listing 16.2.3: Analysis Populations
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Population	Included	Reason(s) Excluded	Exception(s)
xxxxxx	xxxx	Intent-to-Treat	xxx		
		Safety	xxx		
		Per-Protocol	xx	xxxxxxxxxxx xxxxxxx xxxxxxxxx xxxxxxxxxxx xxxxxxx xxxxxxxxx	
xxxxxx	xxxx	Intent-to-Treat	xxx		
		Safety	xxx		
		Per-Protocol	xxx		
xxxxxx	xxxx	Intent-to-Treat	xxx		
		Safety	xxx		
		Per-Protocol	xx	xxxxxxxxxxx xxxxxxx xxxxxxxxx xxxxxxxxxxx xxxxxxx xxxxxxxxx	xxxxxxxxxxx xxxxxxx xxxxxxxxx
xxxxxx	xxxx	Intent-to-Treat	xxx		
		Safety	xx	xxxxxxxxxxx xxxxxxx xxxxxxxxx	
		Per-Protocol	xx	xxxxxxxxxxx xxxxxxx xxxxxxxxx xxxxxxxxxxx xxxxxxx xxxxxxxxx	

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject and Population (as ordered above).

Listing 16.2.4.1: Subject Demographic Information
Treatment Group
(Page xx of yy)

Subject	Evaluable	B: Date of Birth A: Age S: Sex	R: Race E: Ethnicity	C: Childbearing Potential M: Method of Contraception	I: Informed Consent Date/Protocol Version P: Did subject consent to photography?
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxxxx	R: xxxxxx xxxxxxxx xx xxxxx xxxxxxx xxxxxxxx xxxxxxxxxx E: xxx xxxxxxxx xx xxxxxx	C: xxx M: xxxxxxxxx xxxxxxxxxx xxxxxxxxxxxx xxxxxxxxx xxxx x xxxxxxxxxx xx xxxxxxxxx xxxxxxxxxx xxxx xxxxxxx	I: V2.1/xxxx-xx-xx V3/xxxx-xx-xx P: xxx
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxx	R: xxxxx E: xxxxxxxx xx xxxxxx	C: xx M:	I: V2/xxxx-xx-xx P: xxx
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxxxx	R: xxxxx E: xxxxxxxx xx xxxxxx	C: xxx M: xxxxxxxx xxxxxxxxxxxx	I: V3/xxxx-xx-xx P: xxx

Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject. Include all instances of informed consents and associated protocol versions.

Listing 16.2.4.2.1: Unique Medical History Coded to MedDRA System Organ Classes and Preferred Terms
(Page xx of yy)

MedDRA System Organ Class	MedDRA Preferred Term	Medical History Verbatim Term
xxxx xxx xxxxx	xxxx xxx xxxxx	xxxx
		xxxxxx xxxxxxxxxx xx xxxxxx
		xxxxxx xxxxxxxxxx xx xxxxx
xxxx xxx xxxxx	xxxx xxx xxxxx	xxxx
		xxxxxx xxxxxxxxxx xx xxxxxx
		xxxxxx xxxxxxxxxx xx xxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by MedDRA System Organ Class, MedDRA Preferred Term, and Medical History Verbatim Term.

Listing 16.2.4.2.2: Medical History
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	M: Medical Condition A: Pruritic Condition Associated with Prurigo Nodularis	P: MedDRA Preferred Term S: MedDRA System Organ Class	S: Onset Date E: End Date
xxxxxx	xxxx	xxxxxxxx	M: xxxx xxxxxxx (xxxxxxxx xxxxx) A: xxx	P: xxxxxx xxxxxxxxxx S: xxxxxxxxxxx xxxxxxx	S: xxxx-xx-xx E:
			M: xxxx xxxxxxx (xxxxxxxx xxxxx) A: xxx	P: xxxxxx xxxxxxxxxx S: xxxxxxxxxxx xxxxxxx	S: xxxx-xx-xx E:

Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
System Organ Class and Preferred Term map to MedDRA (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Medical Condition/Surgery Verbatim Term, Onset Date, and End Date.

Listing 16.2.4.3.1: Prurigo Nodularis History
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Date of Prurigo Nodularis Diagnosis	Body Locations of Prurigo Nodularis	In the 7 days prior to screening, have you had sensation of stinging or burning with your prurigo nodularis?
xxxxxx	xxxx	xxxxxxxx	xxxx-xx-xx	xxxxxxxxx xxxxx; xxxxxx; xxxx xxx xxxx; xxxxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxx-xx-xx	xxxxxxxxx xxxxx; xxxxx xxxxx; xxxxx; xxxxxxxxx	xx

Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject.

Listing 16.2.4.3.2: Prior Therapies
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Therapy Type	Name	Estimated Duration (unit)	Route	Reason for Discontinuing Therapy
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxxx xxxx	xxxxxxxxxxxxxxx	xx	xxxxxxxxxxxxx	xxxx xx xxxxxxxx
			xxxxxx xxxxxxx	xxxxx	xxxx	xxxxxxxxxxxxx	xxxxxxxxxxx
			xxxx xx xxxxxx xxxxxxxx	xxxxxxxx xxxxx	xxxxxxxxx	xxxxxxxxxxxxxx	xxxxxx

Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Therapy Type, Name.

Listing 16.2.4.4.1: Unique Medication Names Coded to WHO DDE ATC Level 2 Terms and Preferred Names
(Page xx of yy)

ATC Level 2 Term	Standardized Medication Name	Medication Name	I: Indication R: Route
xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
		xxxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
		xxxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx

Note: Standardized Medication Name and ATC Level 2 Term map to the WHO DDE (Version September 1, 2018).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by ATC Level 2 Term, Standardized Medication Name, Medication Name, Indication, and Route.

Note to Programmer: If Indication or Route is 'Other' then the applicable variable is 'OTHER: <specification of other>'.

Listing 16.2.4.4.2: Concomitant Medications
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	M: Medication Name P: Standardized Medication Name A: ATC Level 2 Term I: Indication	T: Prior/Concomitant F: Date of First Dose S: Start Date (Day)[1] E: End Date (Day)[1]	D: Dose U: Units F: Frequency R: Route
xxxxxx	xxxx	xxxxxxxxxx	M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	T: xxxxxxxxxx F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	D: xx U: xx F: xxxx R: xxxxxx
			M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	T: xxxxxxxxxx F: xxxx-xx-xx S: xxxx-xx E:	D: xxxxx U: xx F: xx R: xxxx
xxxxxx	xxxx	xxxxxxxxxx	M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	T: xxxxxxxxxx F: xxxx-xx-xx S: xxxx-xx-xx (x) E: xxxx-xx-xx (xx)	D: xxx U: xx F: xx R: xxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
Standardized Medication Name and ATC Level 2 Term map to the WHO DDE (Version September 1, 2018).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, Medication Name, Indication, and Route. If ongoing, include 'Ongoing' in place of End Date.

Note to Programmer: If Units, Frequency, Indication, or Route is 'Other' then the applicable variable is 'OTHER: <specification of other>'.

Listing 16.2.4.5: Concomitant Procedures/Therapies
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	T: Procedure/Therapy P: MedDRA Preferred Term S: MedDRA System Organ Class	F: Date of First Dose S: Start Date (Day)[1] E: End Date (Day)[1]	Reason for Procedure or Therapies
xxxxxx	xxxx	xxxxxxxxxx	T: xxxxxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxxxxxxxxxxxxx S: xxxxxxxxxxxxxxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	x xxxxxx xxxx xxxxxx xxxxxxxxx
xxxxxx	xxxx	xxxxxxxxxx	T: xxxxxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxxxxxxxxxxxxx S: xxxxxxxxxxxxxxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	x xxxxxx xxxx xxxxxx xxxxxxxxx
xxxxxx	xxxx	xxxxxxxxxx	T: xxxxxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxxxxxxxxxxxxx S: xxxxxxxxxxxxxxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	x xxxxxx xxxx xxxxxx xxxxxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
System Organ Class and Preferred Term map to MedDRA (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, and Procedure/Therapy. If ongoing, include 'Ongoing' in place of End Date.

Listing 16.2.4.6: Physical Examination
Treatment Group
(Page x of xx)

Subject	Age/Sex	Evaluable	Visit	Date of Assessment (Day)[1]	Physical Exam Completed
xxxxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxx-xx-xx (xx)	xxxxxxxx
xxxxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxx-xx-xx (xx)	xxxxxxxx
xxxxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxx-xx-xx (xx)	xxxxxxxx
xxxxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxx-xx-xx (x)	xxxxxxxx
xxxxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxx-xx-xx (xx)	xxxxxxx
xxxxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxx-xx-xx (xx)	xxxxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, and Date of Assessment.

Listing 16.2.5.1: Study Visit/Phone Call Compliance
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Visit	Visit Date	Study Day[1]	Within Visit Window	Continuing into MTI-107?	Visit Not Done/ Reason for Unscheduled Visit
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxx-xx-xx	xx	xxx	xxx	
			xxxxxxxx	xxxx-xx-xx	xx	xxx	xxx	
			xxxxxx	xxxx-xx-xx	xx	xxx	xxx	
			xxxxxx	xxxx-xx-xx	xx	xxx	xxx	xxxxxxx x xxxxxx xxxxxxx xxxxx xxxxxx xx xxxx xxx xxxx xx xxx xxxx
			xxxxxx	xxxx-xx-xx	xx	xxx	xxx	
			xxxxxxxxxxxxxx	xxxx-xx-xx	xx	xxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxx-xx-xx	xx	xxx	xxx	
			xxxxxx	xxxx-xx-xx	xx	xxx	xxx	
			xxxxxxxxxxxxxx	xxxx-xx-xx	xx	xxx	xxx	

[1] Day is calculated as date – baseline date for dates prior to baseline date. Otherwise, day is calculated as date – baseline date + 1 for dates on or after baseline date. For follow-up visits, Week 10 date is used in place of baseline.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, and Visit Date.

Note to Programmer: If a visit is ranged present the 'Visit Date' column as '<Start Date> to <End Date>' same with the Study Day column.

Listing 16.2.5.2: Study Drug Dispensing and Return
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Bottle Number	Date Bottle Dispensed	Date Bottle Returned	Number of Tablets Dispensed	Number of Tablets Returned	Tablets Used
xxxxxx	xxxx	xxxxxxxxx	xxxxxx	xxxx-xx-xx	xxxx-xx-xx	xx	xx	xx
			xxxxxx	xxxx-xx-xx	xxxx-xx-xx	xx	xx	xx
xxxxxx	xxxx	xxxxxxxxx	xxxxxx	xxxx-xx-xx	xxxx-xx-xx	xx	xx	xx
			xxxxxx	xxxx-xx-xx	xxxx-xx-xx	xx	xx	xx

Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Date Bottle Dispensed, and Date Bottle Returned.

Listing 16.2.5.3: Dosing Deviations
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Date of Deviation	Reason for Deviation	Number of Tablets Taken
xxxxxx	xxxx	xxxxxxxxx	xxxx-xx-xx	xxxxxx	xxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxx-xx-xx	xxxxxx	x
			xxxx-xx-xx	xxxxxx	xxxxxxxxxxxxxxxxxxxxx
			xxxx-xx-xx	xxxxxx	xxxxxxxxxxxxxxxxxxxxx
			xxxx-xx-xx	xxxxxx	xxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxx-xx-xx	xxxx	
			xxxx-xx-xx	xxxxxx	x

Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Date of Deviation, Type of Deviation, and Number of Tablets Taken.

Listing 16.2.6.1.1: Worst Itch Numeric Rating Scale (WI-NRS) at Screening
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Date of Assessment (Day)[1]	WI-NRS[2] in the past 24 hours
xxxxxxxx	xxxx	xxxxxxxxx	xxxx-xx-xx (xx)	xx
xxxxxxxx	xxxx	xxxxxxxxx	xxxx-xx-xx (xx)	xx
xxxxxxxx	xxxx	xxxxxxxxx	xxxx-xx-xx (xx)	xx
xxxxxxxx	xxxx	xxxxxxxxx	xxxx-xx-xx (xx)	xx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Scaled from 0 - No Itch to 10 - Worst Itch Imaginable.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject and Date of Assessment.

Listing 16.2.6.1.2: Worst Itch Numeric Rating Scale (WI-NRS)
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Timepoint	Date of Assessment (Day)[1]	WI-NRS in past 24 hrs[2]	Change from Baseline[3]
xxxxxx	xxxx	xxxxxxxx		xxxx-xx-xxTxx:xx:xx (xxx)	x	
				xxxx-xx-xxTxx:xx:xx (xxx)	x	
				xxxx-xx-xxTxx:xx:xx (xxx)	x	
				xxxx-xx-xxTxx:xx:xx (xxx)	x	
				xxxx-xx-xxTxx:xx:xx (xxx)	x	
				xxxx-xx-xxTxx:xx:xx (xxx)	x	
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx (xxx)	x	
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx (xxx)	x	
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx (xxx)	x	
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx (xxx)	x	
			xxxxxxxx	Average	xxxxx	
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx (xxx)	x	xxxx
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx (xxx)	x	xxxx
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx (xxx)	x	xxxx
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx (xxx)	x	xxxx
			xxxxxxxx	Average	xxxxx	xxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Scaled from 0 – No Itch to 10 – Worst Itch Imaginable
[3] The WI-NRS Baseline is the average of the results for the week prior to starting the study drug (Timepoint = BASELINE).
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Date of Assessment, Timepoint (where the Average over a given Timepoint is presented in the order above), and WI-NRS in past 24 hours.

Listing 16.2.6.2: IGA PN-A and IGA PN-S Results
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Visit	Date of Assessment (Day)[1]	Investigator's Global Assessement of Prurigo Nodularis Activity	Investigator's Global Assessement of Prurigo Nodularis Stage
xxxxxxxx	xxxx	xxxxxxxxx	xxxxxxx	xxxx-xx-xx (xx)	xxxxx x	xxxxx x
				xxxx-xx-xx (xx)	xxxxx x	xxxxx x
				xxxx-xx-xx (xx)	xxxxx x	xxxxx x
				xxxx-xx-xx (xx)	xxxxx x	xxxxx x
				xxxx-xx-xx (xx)	xxxxx x	xxxxx x
				xxxx-xx-xx (xx)	xxxxx x	xxxxx x
xxxxxxxx	xxxx	xxxxxxxxx	xxxxxxx	xxxx-xx-xx (xx)	xxxxx x	xxxxx x
				xxxx-xx-xx (xx)	xxxxx x	xxxxx x
				xxxx-xx-xx (xx)	xxxxx x	xxxxx x
				xxxx-xx-xx (xx)	xxxxx x	xxxxx x
				xxxx-xx-xx (xx)	xxxxx x	xxxxx x
				xxxx-xx-xx (xx)	xxxxx x	xxxxx x

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, and Date of Assessment.

Listing 16.2.6.3: Dermatology Life Quality Index (DLQI)
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	V: Visit D: Date of Assessment (Day)[1]	Question Number	Question	Result
xxxxxxxx	xxxx	xxxxxxx	V: xxxxxxxxxx D: xxxx-xx-xx (xx)	1	Over the last week, how itchy, sore, painful or stinging has your skin been?	xxxxxx
				2	Over the last week, how embarrassed or self conscious have you been because of your skin?	xxxxxx
				3	Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden?	xxxxxx
				4	Over the last week, how much has your skin influenced the clothes you wear?	xxxxxx
				5	Over the last week, how much has your skin affected any social or leisure activities?	xxxxxx
				6	Over the last week, how much has your skin made it difficult for you to do any sport?	xxxxxx
				7	Over the last week, has your skin prevented you from working or studying?	xxxxxx
				7A	If "No", over the last week how much has your skin been a problem at work or studying?	xxxxxx
				8	Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?	xxxxxx
				9	Over the last week, how much has your skin caused any sexual difficulties?	xxxxxx
				10	Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time?	xxxxxx
					Questionnaire Score	xx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, and Date of Assessment.

Listing 16.2.6.4: Photography
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	V: Visit D: Date of Assessment (Day)[1]	Body Areas Photographed
xxxxxxxx	xxxx	xxxxxxx	V: xxxxxxxxxx D: xxxx-xx-xx (xx)	xxxxxxxx; xxxxxxxxxxx; xxxxxxxx
			V: xxxxxxxxxx D: xxxx-xx-xx (xx)	xxxxxxxx; xxxxxxxxxxx; xxxxxxxx
			V: xxxxxxxxxx D: xxxx-xx-xx (xx)	xxxxxxxx; xxxxxxxxxxx; xxxxxxxx
			V: xxxxxxxxxx D: xxxx-xx-xx (xx)	xxxxxxxx; xxxxxxxxxxx; xxxxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, and Date of Assessment.

Listing 16.2.7.1.1: Unique Adverse Events Coded to MedDRA System Organ Classes and Preferred Terms
(Page xx of yy)

MedDRA System Organ Class	MedDRA Preferred Term	Adverse Event
xxxxx xxxxx xxxxx	xxxxx xxxxx xxxxx	xxxxxxxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxx
	xxxxx xxxxx xxxxx	xxxxxxxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxx
	xxxxxxxxxx	xxxxx xxxxx xxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxx

Note: System Organ Class and Preferred Term map to MedDRA (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by MedDRA System Organ Class, Preferred Term, and Adverse Event.

Listing 16.2.7.1.2: Treatment-Emergent Adverse Events
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	A: Event C: System Organ Class P: Preferred Term	F: Date of First Dose S: Start Date (Day)[1] E: End Date (Day)[1]	S: Grade[2] R: Relationship to Study Treatment O: Outcome	S: Is AE Serious? R: Reason(s) for Serious T: Action Taken with Study Treatment A: Any Other Action(s)
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	S: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: xxxx xxx xxxxxxx T: xxx A: xxxxxxx
	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (x) E: xxxx-xx-xx (xx)	S: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: xxxx xxx xxxxxxx T: xxx A: xxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	S: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: xxxx xxx xxxxxxx T: xxx A: xxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	S: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: xxxx xxx xxxxxxx T: xxx A: xxxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
System Organ Class and Preferred Term map to MedDRA (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, and Adverse Event.

Listing 16.2.7.1.3: Serious Adverse Events
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	A: Event C: System Organ Class P: Preferred Term	F: Date of First Dose S: Start Date (Day)[1] E: End Date (Day)[1]	S: Grade[2] R: Relationship to Study Treatment O: Outcome	S: Is AE Serious? R: Reason(s) for Serious T: Action Taken with Study Treatment A: Any Other Action(s)
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	S: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: xxxx xxx xxxxxxx T: xxx A: xxxxxxx
	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (x) E: xxxx-xx-xx (xx)	S: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: xxxx xxx xxxxxxx T: xxx A: xxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	S: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: xxxx xxx xxxxxxx T: xxx A: xxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	S: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: xxxx xxx xxxxxxx T: xxx A: xxxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
System Organ Class and Preferred Term map to MedDRA (Version 21.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, and Adverse Event.

Listing 16.2.7.1.4: Subjects Who Permanently Discontinued Study Drug Due to Adverse Events
Treatment Group
(Page xx of yy)

		Completion/Discontinuation	Adverse Events	
S: Subject A: Age/Sex E: Evaluable	F: Date of First Dose L: Date of Last Dose	D: Date of Study Discontinuation (Day)[1] T: Primary Reason for Treatment Discontinuation S: Primary Reason for Study Discontinuation	A: Event S: Grade[2] R: Relationship to Study Treatment	S: Start Date (Day)[1] E: End Date (Day)[1] A: Action Taken with Study Treatment
S: xxxxxx A: xxxx E: xxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx	D: xxxx-xx-xx (xx) T: xxxxxx S: xxxxxxxxxxxxxx	A: xxxxxxxxxx S: xxxxxxx R: xxxxxxxxxxxxxxxx	S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx) A: xxxxxxxxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, and Adverse Event.

Listing 16.2.7.2.1: Hospital Anxiety and Depression Scale
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	V: Visit D: Date of Assessment (Day)[1]	Question	Result
xxxxxxxx	xxxx	xxxxxxx	V: xxxxxxxxxx D: xxxx-xx-xx (xx)	I feel tense or 'wound up'	xxxxxxxxxxxxxxxxxxx
				I still enjoy the things I used to enjoy	xxxxxxxxxxxxxxxxxxx
				I get a sort of frightened feeling as if something awful is about to happen	xxxxxxxxxxxxxxxxxxx
				I can laugh and see the funny side of things	xxxxxxxxxxxxxxxxxxx
				Worrying thoughts go through my mind	xxxxxxxxxxxxxxxxxxx
				I feel cheerful	xxxxxxxxxxxxxxxxxxx
				I can sit at ease and feel relaxed	xxxxxxxxxxxxxxxxxxx
				Depression Subscale	xx
				Anxiety Subscale	xx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.7.2.2: Epworth Sleepiness Scale
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	V: Visit D: Date of Assessment (Day)[1]	Situation	Result
xxxxxxxx	xxxx	xxxxxxx	V: xxxxxxxxxx D: xxxx-xx-xx (xx)	Sitting and reading	xxxxxxxxxxxxxxxxxxx
				Watching TV	xxxxxxxxxxxxxxxxxxx
				Sitting, inactive in a public place (e.g. a theatre or a meeting)	xxxxxxxxxxxxxxxxxxx
				As a passenger in a car for an hour without a break	xxxxxxxxxxxxxxxxxxx
				Lying down to rest in the afternoon when circumstances permit	xxxxxxxxxxxxxxxxxxx
				Sitting and talking to someone	xxxxxxxxxxxxxxxxxxx
				Sitting quietly after a lunch without alcohol	xxxxxxxxxxxxxxxxxxx
				In a car, while stopped for a few minutes in the traffic	xxxxxxxxxxxxxxxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.7.3: Menstrual Diary
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Childbearing Potential	Start Date of Period (Day)[1]	End Date of Period (Day)[1]
xxxxxxxx	xxxx	xxxxxxx	xxxxxxxxxxxx	xxxx-xx-xx (xx)	xxxx-xx-xx (xx)
				xxxx-xx-xx (xx)	xxxx-xx-xx (xx)
				xxxx-xx-xx (xx)	xxxx-xx-xx (xx)

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.8.1: Pregnancy Test Results
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	V: Visit D: Date (Day)[1]	S: Specimen[2] R: Result	S: Was a Serum Pregnancy Test Ordered? E: If no, but was required, explain	Comments
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxxx D: xxxx-xx-xx (xxx)	S: xxxxx R: xxxxxxxx	S: xxx E:	xxxxxxxxxxxxx
	V: xxxxxxxxx D: xxxx-xx-xx (xxx)	S: xxxxx R: xxxxxxxx	S: xx E:	
	V: xxxxxxxxx D: xxxx-xx-xx (xxx)	S: xxxxx R: xxxxxxxx	S: xx E:	
	V: xxxxxxxxx D: xxxx-xx-xx (xxx)	S: xxxxx R: xxxxxxxx	S: xx E:	
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxxx D: xxxx-xx-xx (xxx)	S: xxxxx R: xxxxxxxx	S: xx E: xxxxxxxxxxxxxxxxxxxxxxxxx	

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] For Serum pregnancy results: HCG levels less than 10 mIU/mL are considered negative for pregnancy. Levels between 10 - 24.9 mIU/mL are equivocal and a redraw of the patient after 48 hours is suggested. Levels greater than or equal to 25 mUI/mL are considered positive for pregnancy.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date, and Specimen. NOTE: Serum Pregnancy Questions (S: E:) are only applicable to Urine Pregnancy test records.

Listing 16.2.8.2.1: Laboratory Test Results
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	V: Visit D: Date (Day)[1] C: Category	Laboratory Test	Results (Units)	Reference Range Low	Reference Range High	Reference Range Indicator(CS[2])	Comments
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xxx) C: xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx (xxxxxx)				xxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxx xxxxxxxxxxxxxx
	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xxx) C: xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx (xxxxxx)	x	xx	xxxxxxxxxxx (xxx)	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxx xxxxxxxxxxxxxx
	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xxx) C: xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx (xxxxxx)	x	xx	xxxxxxxxxxx (xxx)	

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Clinical significance based on Investigator interpretation. CS = Clinically Significant; NCS = Not Clinically Significant.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date, Category, and Lab Test.

Listing 16.2.8.2.2: Out of Range Laboratory Results
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	V: Visit D: Date (Day)[1] C: Category	Laboratory Test	Results (Units)	Reference Range Low	Reference Range High	Reference Range Indicator(CS[2])	Comments
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xxx) C: xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx (xxxxxx)				xxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxx xxxxxxxxxxxxxx
	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xxx) C: xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx (xxxxxx)	x	xx	xxxxxxxxxxx (xxx)	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxx xxxxxxxxxxxxxx
	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xxx) C: xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx (xxxxxx)	x	xx	xxxxxxxxxxx (xxx)	

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Clinical significance based on Investigator interpretation. CS = Clinically Significant; NCS = Not Clinically Significant.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date, Category, and Lab Test.

Listing 16.2.8.2.3: Common Laboratory Comments Including Reference Ranges for Specific Laboratory Tests
(Page 1 of 1)

Category	Laboratory Test	Comments
xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Category and Lab Test.

Listing 16.2.8.3: Electrocardiogram Test Results
Treatment Group
(Page x of xx)

S: Subject A: Age/Sex E: Evaluable	Category	ECG Parameter	V: Visit D: Date/Time of ECG (Day)[1]	Result (unit)	Clinical Significance[2]	Comments
S: xxxxxxxxx A: xxxx E: xxx/xx/xxx	xxxxxxxxxx	xxxxxxxxxx	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xx)	xxxx xxxxx xx (xxx)	xxx	

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Clinical significance based on Investigator interpretation. CS = Clinically Significant; NCS = Not Clinically Significant.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Category, Parameter, Visit, and Date. **Note: for interpretation records, EGEVAL should be concatenated into ECG Parameter as EGTEST (EGEVAL).**

Listing 16.2.8.4: Vital Signs
Treatment Group
(Page x of xx)

Subject	Age/Sex	Evaluable	Visit	Date of Measurements (Day)[1]	Vital Sign	Result	Units
xxxxxxxxx	xxxx	xxxxx	xxxxxxxxxx	xxxx-xx-xx (xxx)	xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
			xxxxxxxxxx	xxxx-xx-xx (xxx)	xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
xxxxxxxxx	xxxx	xxxxx	xxxxxxxxxx	xxxx-xx-xx (xxx)	xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
			xxxxxxxxxx	xxxx-xx-xx (xxx)	xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date, and Vital Sign (ordered as: Height, Weight, Temperature, Respiration Rate, Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure).

Listing 16.2.8.5: Pharmacokinetics Blood Sample Collection and Plasma Concentrations
Treatment Group
(Page x of xx)

S: Subject A: Age/Sex E: Evaluable	Analyte	Visit	Date/Time of Pre-PK Study Drug Dose	Date/Time PK Sample Obtained	Concentration (ng/mL)	Reason Not Done
S: xxxxxx A: xxxx E: xxxxx	xxxxxxxxxxx	xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx
		xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx
		xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx
		xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx
	xxxxxxxxxxx	xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx
		xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx
S: xxxxxx A: xxxx E: xxxxx	xxxxxxxxxxx	xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx
		xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx
		xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx

Note: ITT = Intent-to-Treat Population; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Analyte, Visit, Date.