Statistical Analysis Plan

Title: A Randomized, Controlled, Double-blind, Continuation Study Comparing the Long-term Safety and Efficacy of Orelvo (voclosporin) (23.7 mg Twice Daily) with Placebo in Subjects with Lupus Nephritis

Protocol Number: AUR-VCS-2016-02

Protocol Version: 1.0 (13OCT2017), 2.0 (10OCT2018), 3.0 (21DEC2018)

SAP Version 1.0

SAP Issue Date: 11-May-2021

SAP Author: [redacted]

Previous SAP Versions

N/A

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SAP Amendments before database lock

Version	Issue Date	Section	Revision / Addition	Rationale

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LIST OF ABBREVIATIONS

AE	Adverse event
Anti-dsDNA	Anti-double-stranded deoxyribonucleic acid
AR	Auto Regressive
ATC	Anatomical Therapeutic Chemical Classification System
AURORA 1	**Aur**inia **O**relvo **R**enal **A**ssessments 1: Aurinia Renal Response in Active Lupus with Orelvo (voclosporin)
AURORA 2	**Aur**inia **O**relvo **R**enal **A**ssessments 2: Aurinia Renal Response in Lupus with Orelvo (voclosporin)
Aurinia	Aurinia Pharmaceuticals Inc.
BID	Twice daily
C3 / C4	Complement 3 / complement 4
CEC	Clinical Endpoints Committee
CI	Confidence interval
CTCAE	Common Terminology Criteria for Adverse Events
EAIR	Exposure-adjusted incidence rates
EDC	Electronic data capture
ECG	Electrocardiogram
eCRF	Electronic case report form
eGFR	Estimated glomerular filtration rate
FAS	Full analysis set
FMV	First morning void
HRQoL	Health-related quality of life
ITT	Intent-to-treat
IV	Intravenous
LN	Lupus nephritis
LS	Least Squares
MMF	Mycophenolate mofetil
MMRM	Mixed Effect Model Repeated Measures
OR	Odds ratio
Orelvo	Voclosporin (for Phase 3 lupus nephritis indication)
PK	Pharmacokinetic
QTc	Corrected QT interval
QTcF	QT interval duration corrected for heart rate using method of Fridericia
SAE	Serious adverse event
SAP	Statistical analysis plan
SELENA	Safety of Estrogens in Lupus Erythematosus National Assessment

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SLE	Systemic lupus erythematosus
SLEDAI	Systemic Lupus Erythematosus Disease Activity Index
TEAE	Treatment-emergent adverse event
UPCR	Urine protein creatinine ratio
[redacted]	[redacted]

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1 INTRODUCTION

This document details the planned statistical analyses for the Aurinia Pharmaceuticals Inc. AUR-VCS-2016-02 (AURORA 2) study titled "A Randomized, Controlled, Double-blind Continuation Study Comparing the Long term Safety and Efficacy of Orelvo (voclosporin) (23.7 mg Twice Daily) with Placebo in Subjects with Lupus Nephritis".

The proposed analyses are based on the contents of the final version of the protocol (Amendment 2, dated 21-DEC-2018).

Subjects who have completed 52 weeks of treatment with study drug in the AURORA 1 study will continue to receive the same treatment as assigned by randomization in the AURORA 1 study (either voclosporin or matching placebo) for up to an additional 24 months in AURORA 2.

After 12 months treatment in the AURORA 2 study (i.e., after 24 months treatment in total), subjects taking the 23.7 mg (3 capsules) twice daily (BID) dose will be permitted to reduce the dose of voclosporin to 15.8 mg (2 capsules) BID if considered appropriate by the Investigator and after consultation with the Medical Monitor.

Where a dose reduction is considered, the following guidance should be considered:

AURORA 2: Week 52 Dose	AURORA 2: Reduced Dose
23.7 mg BID and urine protein creatinine ratio (UPCR) ≥1.5 mg/mg	No reduction
23.7 mg BID and UPCR <1.5 mg/mg	15.8 mg BID
<23.7 mg BID	No reduction

2 STUDY OBJECTIVES

2.1 Primary Objective

To assess the long-term safety and tolerability of voclosporin compared with placebo for up to an additional 24 months following completion of treatment in the AURORA 1 study in subjects with Lupus Nephritis (LN).

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2.2 Secondary Objective

To assess the long-term efficacy of voclosporin compared with placebo for up to an additional 24 months following completion of treatment in the AURORA 1 study in subjects with LN.

3 ENDPOINTS

All estimands are assessed in all subjects who continued into the continuation study. Additional analyses will be performed to compare subjects who did not participate in AURORA 2 with those who participated.

3.1 Primary Endpoint

Adverse event (AE) profile and routine biochemical and hematological assessments. Estimand for AEs is the proportion of subjects reporting AEs in the Safety Population when comparing voclosporin and placebo at each visit. Estimands for biochemical and hematological assessments are the mean absolute values and mean changes from AURORA 1 baseline in the Safety Population when comparing voclosporin and placebo at each visit.

3.2 Secondary Endpoints

3.2.1 Key Secondary Endpoints

- Renal response at Months 12, 18, 24, 30 and 36. Estimand is the proportion of subjects showing renal response (programmed response) in the Intention-To-Treat (ITT) Population when comparing voclosporin and placebo at each visit. Renal response is defined as:
  - UPCR of ≤0.5 mg/mg
  - Estimated glomerular filtration rate (eGFR) ≥60 mL/min/1.73 m^2 or eGFR <60 mL/min/1.73 m^2 with no confirmed decrease >20% or eGFR <60 mL/min/1.73 m^2 with confirmed decrease >20% but with no disease-related or treatment-related eGFR associated AE present at time of assessment
  - Received no rescue medication for LN
  - Did not receive more than 10 mg prednisone for ≥3 consecutive days or for ≥7 days in total during the 8 weeks prior to the renal response assessment.
  - Subjects who withdraw from the study prior to the response assessment will be defined as non-responders.

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- Partial renal response at Months 12, 18, 24, 30 and 36 defined as a 50% reduction from baseline in UPCR. Estimand is the proportion of subjects showing partial renal response (programmed response) in the ITT Population when comparing voclosporin and placebo at each visit.
- Renal flare as adjudicated by the Clinical Endpoints Committee (CEC). Estimand is the proportion of subjects showing renal flare (CEC adjudicated response) in the ITT Population when comparing voclosporin and placebo at each visit.
- Extra-renal flare as adjudicated by the CEC. Estimand is the proportion of subjects showing extra-renal flare (CEC adjudicated response) in the ITT Population when comparing voclosporin and placebo at each visit.
- Safety of Estrogens in Lupus Erythematosus National Assessment- Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) scores by visit. Estimand is the mean change from AURORA 1 baseline in Total SELENA-SLEDAI score in the ITT Population when comparing voclosporin and placebo at each visit.
- Change in UPCR, eGFR, urine protein, and serum creatinine from AURORA 1 baseline by visit. Estimand is the mean change from AURORA 1 baseline in the ITT Population when comparing voclosporin and placebo at each visit.

3.2.2 Other Secondary Endpoints

- Change in immunology parameters complement 3 (C3), complement 4 (C4), and anti-double-stranded deoxyribonucleic acid (anti-dsDNA) from AURORA 1 baseline by visit. Estimand is the mean change from AURORA 1 baseline in the ITT Population when comparing voclosporin and placebo at each visit. It is assessed in all subjects who continued into the continuation study.
- Change in health-related quality of life (HRQoL) (SF-36) from AURORA 1 baseline by visit. Estimand is the mean change from AURORA 1 baseline in the ITT Population when comparing voclosporin and placebo at each visit. It is assessed in all subjects who continued into the continuation study.
- Healthcare Resource Utilization (HRU). Estimand is the proportion of subjects reporting healthcare resource utilization in the ITT Population when comparing voclosporin and placebo at each visit. It is assessed in all subjects who continued into the continuation study.

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4 SAMPLE SIZE

Eligible subjects will enter this study from the AURORA 1 study in order to provide the opportunity of an additional 24 months of treatment (total of 36 months of treatment); no sample size calculation is required.

5 RANDOMIZATION

Subjects continue on the same treatment which they received in AURORA 1.

6 PLANNED ANALYSES

No statistical analysis plan (SAP) prepared in advance of the data can be absolutely definitive and the final Clinical Study Report (CSR) may contain additional tables or statistical tests if warranted by the data obtained. The justification for any such additional analyses will be fully documented in the final CSR.

6.1 Analysis Populations

6.1.1 Intent-to-Treat Population

The ITT population will be based on ITT principles and will consist of all subjects who are consented to treatment in AURORA 2 (n=216). This group will be analyzed based on the treatment to which the subject was randomized in the AURORA 1 study.

6.1.2 Safety Population

The safety population will consist of all subjects who receive at least 1 dose of study drug in the AURORA 2 study (n=216). The subjects in this group will be analyzed based on the treatment they received. Subjects who receive voclosporin treatment for more than 14 days will be assigned to the voclosporin arm irrespective of the arm they were randomized to.

Additional safety populations will be defined as follows:

- AURORA 1 safety population (all subjects who were treated in core study, n=356) and
- subjects who did not participate in AURORA 2 (n=140).

6.2 Derived Data

This section describes the derivations required for statistical analysis. Unless otherwise stated, variables derived in the source data will not be re-calculated.

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6.2.1 Race

Where more than one race category has been selected for a subject, these race categories will be combined into a single category labeled "Multiple Race" in the summary tables. For black race category 'Black (including mixed black)' will be used. [redacted]

6.2.2 Baseline

Except for parameters detailed later in this section, baseline is defined as the last non-missing value (either scheduled, unscheduled or repeat) before the subject receives the first dose of study drug on Day 1 in AURORA 1. As assessments on Day 1 in AURORA 1 are scheduled to be undertaken prior to taking study drug, Day 1 assessments can be defined as baseline.

eGFR baseline will be calculated as the lowest measurement available prior to dosing in AURORA 1.

Urine creatinine baseline will be calculated as the mean of the latest 2 pre-randomization values in AURORA 1. Should only 1 value be available, it will be used as the baseline value.

Urine protein baseline will be calculated as the mean of the latest 2 pre-randomization values in AURORA 1. Should only 1 value be available, it will be used as the baseline value.

UPCR values are calculated by the laboratory as the ratio of urine protein to creatinine. The ratio is only calculated where laboratory tests produce a result for both the creatinine and the protein. UPCR baseline will be calculated as the mean of the latest 2 pre-randomization values. Should only 1 value be available, it will be used as the baseline value.

For the endpoints of change from baseline in UPCR and also for partial response endpoints (that incorporate a 50% reduction from baseline in UPCR), a second definition of baseline (alternative baseline) UPCR will be defined as the lowest measurement available prior to dosing.

6.2.3 Early Terminations Assessments

Data collected at Early Termination (ET) assessments will be mapped to the visits closest to the date of termination.

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6.2.4 Duration / Study Day / Time

Study day will be calculated as the number of days from first dose of study drug (Day 1) in AURORA 1.

- Date of event – date of first dose of study drug (in AURORA 1) + 1, for events on or after first dose
- Date of event – date of first dose of study drug (in AURORA 1), for events before first dose

To this end, Day 0 remains undefined.

For all time to event analyses, subjects not reporting the specified endpoint will be censored at the time that the subjects were last known not to have experienced the endpoint. For all endpoints not encompassing death, all deaths will be treated as censoring events. In complex cases where the censoring time of the subject is uncertain, the case will be reviewed by the [redacted] statistician and a censoring time will be assigned and programmed prior to database lock.

6.2.5 Conventions for Missing and Partial Dates

All rules explained below for partial/missing dates will be followed unless contradicted by any other data recorded on the electronic Case Report Form (eCRF).

All dates presented in the individual subject listings will be as recorded on the eCRF (i.e., not completed as per the below rules).

6.2.6 Missing / Partial Start / Stop Date of Adverse Events (AE) and Concomitant Medications

Missing and partial start and stop dates will be imputed for analysis purposes as follows:

<u>Partial or missing stop date will be imputed as follows:</u>

- If the stop date is completely missing and the event has resolved or the subject has stopped taking the concomitant medication, the stop date will be imputed as the date of the subject's last clinic visit in the study.
- If only the year is known, the stop date will be imputed as "31-Dec" of that year or as the date of the subject's last clinic visit in the study if in the same year.

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- If the month and year are known, the stop date will be imputed as the last day of that month unless the stop date corresponds to the same month as the subject's last clinic visit in which case the date of subject's last clinic visit in the study will be used instead.

Missing start date will be imputed as follows:

- If the stop date occurs on or after the start of study drug in AURORA 2 or the event/concomitant medication is ongoing, the start date will be imputed as the date of the first dose of study drug in AURORA 2.
- If the stop date occurs before the start of study drug in AURORA 2, the start date of the event/concomitant medication will be imputed as the subject's AURORA 1 Visit 15 (Week 52) date or the stop date of the event/concomitant medication whichever the earlier.

Partial start date (year present, but month and day missing)

- If the stop date occurs on or after the start of study drug in AURORA 2 or the event/concomitant medication is ongoing at the end of AURORA 1, and the year is the same as the year of first dosing in AURORA 2 the start date will be imputed as "01-Jan" of the same year or the date of the first dose of study drug in AURORA 2 whichever is latest. If the year is different from the year of first dosing "01-Jan" will be used.

If the stop date occurs before the start of study drug in AURORA 2, the start date of the event/concomitant medication will be imputed as the "01-Jan" of the same year.

Partial start date (month and year present, but day missing)

- If the stop date occurs on or after the start of study drug in AURORA 2 or the event/concomitant medication is ongoing, the start date will be imputed as the first day of the same month and year unless this partial start date is in same month as the first dose of study drug in AURORA 2 in which case the date of first dose of study drug in AURORA 2 will be used.

If the stop date occurs before the start of study drug in AURORA 2, the start date will be imputed as the first day of the month and year of the partial stop date.

6.2.7 Missing Last Dates of Study Drug Dosing

If the date of last dose of study drug is completely missing, then the date of last dose of study drug will be taken for analysis purposes as the date when the subject would have run out of study

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drug assuming full compliance from the date the study drug was last dispensed or the date of subject's last clinic visit in the study or early withdrawal or death whichever is earlier.

If only the month and year of the last dose was recorded, then the date of last dosing will be taken for analysis purposes as the date the subject would have run out of study drug assuming full compliance from the date the study drug was last dispensed, the last day of the month of the recorded last dose or the date of subject's last clinic visit in the study or early withdrawal or death whichever the earlier.

6.2.8 Missing Diagnosis Dates

If the month and year are present but the day is missing, the diagnosis date will be set to first day of the relevant month. If only the year is recorded the diagnosis date will be set as "01-Jan" for that year.

6.2.9 Exposure to Study Drug

Exposure to study drug will be calculated from the date of last dosing minus the first day of dosing (in AURORA 2) + 1 for each prescribing record. Exposure will be summarized as the number of days on medication and mean daily dose. Mean daily dose will take into account periods where zero dose was prescribed.

6.2.10 Inexact Values

In the case where a variable is recorded as "> x", "≥ x", "< x" or "≤ x", a value of x will be taken for analysis purposes.

6.2.11 Electrocardiogram (ECG) Data

For ECG data recorded on continuous scales, if more than one value is recorded at a time point, the mean value rounded to the integer will be presented. For overall interpretation if more than one value is recorded, the most severe (worst case) of the respective readings will be taken.

6.2.12 Unscheduled Visits

All visits whether scheduled or unscheduled will be mapped to the closest scheduled protocol visit according to the protocol schedule of assessments. However, visits, when sorted by visit number and visit date, must remain in chronological order. In summary tables by visit, a subject's latest observation per visit will be tabulated.

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6.2.13 Randomization Strata

The randomization will be stratified by biopsy class (Class V only versus Others) and by prior mycophenolate mofetil (MMF) use at time of screening. A regional blocking factor will also be used for supply purposes ensuring balance within region. The stratification factors and the regional blocking factor will be used as covariates in the primary analyses.

Variables for biopsy class data and prior MMF use will be taken from AURORA 1 data.

6.2.14 eGFR

For the purposes of all eGFR summary tables and endpoints incorporating eGFR measures, an eGFR ceiling will be set at 90 mL/min/1.73 m^2. In doing so, all values greater than 90 will be constrained to 90, thereby removing the reductions from renal hyperfiltration to normal renal function. These eGFR values will be labelled as 'Corrected eGFR'. Original, raw- eGFR measures will be displayed in listings. In addition, eGFR change from baseline tables will be produced using raw-eGFR values.

6.2.15 FMV and 24-hour Urine

UPCR values will be determined using first morning void (FMV) urinalysis samples. In the event that the Investigator determines that the Month 12, Month 18, Month 24, Month 30 or Month 36 FMV urinalysis sample was invalid, the UPCR values from the 24-hour urinalysis at the corresponding visit will be used instead of the FMV urinalysis in the calculation of efficacy endpoints. FMV analysis results will still be used for all other timepoints.

6.2.16 Adverse Events

An AE with missing intensity of AE will be coded "Severe" which is the worst case. An AE with a missing relationship to Study Drug will be coded as "Related". An AE with missing relationship to disease under Study will be coded as "Related" to the disease unless the AE is recorded as being related to treatment.

6.2.17 SELENA-SLEDAI Index Score

The SELENA-SLEDAI assesses disease activity within the last 10 days. Twenty-four items are scored for 9 organ systems and summed to a maximum of 105 points. A score of 6 is considered clinically significant. Assessments for SELENA-SLEDAI will be conducted at AURORA 1 baseline and Week 52, and Months 18, 24 and 36.

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While the total score is populated on the database, it will be re-calculated as the sum of all individual items and added to the efficacy ADaM. Any missing items will lead to a missing total.

A patient's SELENA-SLEDAI total score at a given visit is the sum of the weighted scores of all marked SLE-related descriptors. A total score can fall between 0 and 105, with a higher score representing a more significant degree of disease activity.

6.2.18 Short Form Health Survey (SF-36)

The SF-36 HRQoL assessment is a 36-question subject HRQoL questionnaire. The SF-36 responses will be weighted as follows:

Item number	Original Response	Weight
1, 2, 20, 22, 34, 36	1 →	100
	2 →	75
	3 →	50
	4 →	25
	5 →	0
3, 4, 5, 6, 7, 8, 9, 10, 11, 12	1 →	0
	2 →	50
	3 →	100
13, 14, 15, 16, 17, 18, 19	1 →	0
	2 →	100
21, 23, 26, 27, 30	1 →	100
	2 →	80
	3 →	60
	4 →	40
	5 →	20
	6 →	0

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Item number	Original Response	Weight
24, 25, 28, 29, 31	1 →	0
	2 →	20
	3 →	40
	4 →	60
	5 →	80
	6 →	100
32, 33, 35	1 →	0
	2 →	25
	3 →	50
	4 →	75
	5 →	100

These items will be further grouped into the following scales:

Scales	Number of items	Mean of Items
Physical functioning	10	3, 4, 5, 6, 7, 8, 9, 10, 11, 12
Role limitations due to physical health	4	13, 14, 15, 16
Role limitations due to emotional problems	3	17, 18, 19
Energy/fatigue	4	23, 27, 29, 31
Emotional well-being	5	24, 25, 26, 28, 30
Social functioning	2	20, 32
Pain	2	21, 22
General health	5	1, 33, 34, 35, 36
Total mean score	36	All 36 items

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Each scale will be calculated for each subject by taking the mean of its corresponding item.

Only scheduled post-baseline laboratory and vital signs values will be tabulated. Post-baseline repeat / unscheduled assessments will be disregarded, although these post-baseline assessments will be listed in the relevant appendices to the CSR.

6.3 Conventions

All data listings, summaries, figures and statistical analyses will be generated using SAS version 9.4 or higher[1].

Summaries will be presented by treatment group for all subjects. Treatment group labels will be displayed as follows:

- Placebo
- Voclosporin
- Overall

Columns to be included within the table shells are as follows:

Demography	Treatment group and overall
Baseline	Treatment group and overall
Disposition	Treatment group and overall
Efficacy	Treatment group
TEAEs	Treatment group
Other safety	Treatment group

Tables of events or medications will be ordered in descending frequency of subjects followed by (where applicable) events for the system organ class (or Anatomical Therapeutic Chemical Classification System [ATC] level 2 for medications) followed by the preferred term. Ordering will be for the voclosporin treatment group first followed by the placebo group and alphabetical thereafter.

Listings will be sorted in the following order: treatment group, subject, parameter, and visit unless otherwise stated. All data will be listed.

Continuous variables will be summarized by the number of non-missing observations, mean, median, standard deviation, and minimum and maximum. For all tabulations of changes from baseline data, the lower and upper 95% confidence limits for the mean for the individual treatments will be given.

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Categorical variables will be summarized by presenting the frequency and percent. Percentages will be based on the number of non-missing observations out of the subject population unless otherwise specified. For each variable, all categories will be shown. Zero frequencies (but not the percent) within a category will be presented.

6.3.1 Decimal Places

Means, medians and percentiles will be displayed to one more decimal place than the data, dispersion statistics (e.g., standard deviation) will have two more decimal places, and the minimum and maximum will be displayed to the same number of decimal places as reported in the raw data. Percentages will be displayed with one decimal place.

P-values will be quoted to 3 decimal places. P-values < 0.001 will be presented as $p<0.001$.

6.4 Subject Disposition

Subject disposition will be summarized as follows:

- The number of continuation subjects who entered the study from AURORA 1 and who are in each analysis population will be summarized by treatment group and overall for the ITT population. This summary will be repeated for individual levels of the stratification and blocking variables used in AURORA 1.
- The number of early withdrawals and the reasons for withdrawals will be tabulated by treatment group and overall for the ITT population.
- The number of subjects that discontinue study drug will be presented by treatment group and visit for the ITT population.

6.5 Protocol Deviations

Major protocol deviations will be grouped into categories and summarized by treatment group and overall for the Safety and ITT populations. A listing of protocol deviations will be provided.

6.6 Baseline Comparability

The comparability of treatment groups with respect to subject demographics and baseline characteristics will be assessed in a descriptive manner for the Safety population, but no formal statistical testing will be performed. Similar baseline tables to those presented in AURORA 1 will be presented for the continuation subjects in AURORA 2.

Standard continuous or categorical variable summaries will be presented for the following variables based on the safety population.

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- Demographic data (summarized additionally by country and region)
- Disease history (including eGFR and UPCR measures)
- Medical / Surgical / Systemic Lupus Erythematosus / Renal history

Demography and disease history will also be summarized for the ITT population.

Additionally, baseline comparability will be summarized for subjects who did not continue to AURORA 2.

6.7 Medical History

Medical conditions from AURORA 1 will be presented by treatment group for the safety population. Conditions will be presented by Medical Dictionary of Regulatory Activities (MedDRA) primary system organ class and preferred term.

All variables will also be listed.

Additionally, medical history will be summarized for subjects who did not continue to AURORA 2.

6.8 Prior and Concomitant Medications

Separate tabulations will be produced for prior and concomitant medications presented by treatment group and overall for the safety population. Medications will be summarized using ATC Level 2.

Additionally, prior and concomitant medications will be summarized for subjects who did not continue to AURORA 2.

Prior medications are defined as all medications starting and stopping before the date of first dose of study drug in AURORA 1.

Prior and concomitant medications are defined as both:

- **Concomitant Medications Ongoing at the First Dose of AURORA 1:** medications starting before AURORA 1 and continuing at the time of starting AURORA 1.
- **Concomitant Medications Ongoing at the end of AURORA 1:** medication starting before AURORA 2 and continuing at the time of starting AURORA 2.

Concomitant medications are defined as medications starting on or after the date of first dose of study drug in AURORA 2.

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The following previous LN therapies will also be summarized: MMF, Intravenous Cyclophosphamide, Corticosteroids, Methotrexate, Calcineurin Inhibitors, Biologics, Azathioprine, Antimalarials, other. The responses for these LN therapies are Yes or No.

6.9 Exposure to Study Drug

Overall exposure to study drugs (number of days of exposure to study drugs and mean dose) will be presented for both the safety populations. Exposure will be based on prescribed dose. Exposure will not be summarized by visit but for the overall study duration in AURORA 1 and AURORA 2. Overall study drug exposure will be calculated from the first dose date in AURORA 1 to the last dose date in AURORA 2 plus 1. Care should be taken to not double-count days. It is expected that prescription records will cover each study day between randomization and the end of study (or early termination). Periods of zero dose will be assigned as such.

The following gives an example of a subject with 5 prescription records over the 3-year (1095 day) period.

Final prescription records that detail a zero dose will be removed.

Table 5.1 Exposure calculation example

Start Day	End Day	Dose (bid)	Duration
1	364	3	364 days
365	500	3	136 days
501	600	0	100 days
601	750	2	150 days
751	1095	3	345 days

For the purposes of analysis this subject will have 'days on treatment' calculated as 364+136+100+150+345=1095 days. Their mean daily dose will be:

(364*3 + 136*3 + 100*0 + 150*2 + 345*3) / 1095 = 2.34 caps BID (converted to 37.03mg per day).

Gaps between dosing records will be counted as a zero dose.

For subjects who are lost to follow-up, and for whom the last dose date from the termination record is unknown, the date of the last available visit will be used as the last dose date.

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Exposure to study drug will be summarized for the following:

- Voclosporin
- MMF
- Oral Corticosteroids.

Prescribed dose changes at visit intervals and overall will be summarized for voclosporin/placebo and for MMF.

6.10 Treatment Compliance

All unused study treatments (and any empty containers) dispensed to the subject will be returned at each study visit for capsule counts to check compliance. The Investigator will count the returned study treatment and this information will be used to assess subject compliance. Subjects will continue on the same dose they are on at the end of AURORA 1. Each softgel capsule = 7.9 mg. It should be noted that compliance will not be summarized by visit but for the overall study period.

Subject compliance with study drug (voclosporin / placebo) will be summarized by treatment group. Counts of the returned study treatment will be used to assess subject compliance. The study treatment count will be documented in the eCRF and source documentation.

Subject compliance will be calculated as:

$$\text{Compliance (\%)} = \frac{\text{Number of dispensed capsules} - \text{Number of lost or returned capsules}}{\text{Number of prescribed capsules}} * 100$$

Note : dispensed capsules includes those carried over from AURORA 1

The number of prescribed doses (number of doses expected to receive in treatment period) will be calculated as per the exposure calculation.

6.11 Efficacy Analyses

All the secondary efficacy analyses will be performed on the ITT population using data from the start of AURORA 1 through to the completion of AURORA 2. All statistical tests will be performed using a two-tailed 5% overall significance level, unless otherwise stated. All comparisons between treatments will be reported with 95% confidence intervals for the odds ratio, hazard ratio or difference as applicable.

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6.11.1 Efficacy Endpoint

Renal response is defined as:

- UPCR of ≤0.5 mg/mg
- eGFR criteria:
  - eGFR ≥60 mL/min/1.73 m^2 or
  - eGFR <60 mL/min/1.73 m^2 with no confirmed decrease >20% or
  - eGFR <60 mL/min/1.73 m^2 with confirmed decrease >20% but with no disease-related or treatment-related eGFR associated AE present at time of assessment
- Received no rescue medication for LN
- Did not receive more than 10 mg prednisone for ≥3 consecutive days or for ≥7 days in total during the 8 weeks prior to the renal response assessment.

6.11.2 Efficacy Analysis

6.11.2.1 Proportion of subjects in renal response

The number of subjects that meet all four criteria in the above definition of renal response will be summarized by treatment group. The number of subjects who meet each of the four individual criteria will also be summarized by treatment group. These summaries will be presented for Months 6, 12, 18, 24, 30 and 36. Subjects who withdraw from the study prior to the response assessment will be defined as non-responders. The analysis of overall renal response and each of the components will be conducted on the ITT population using a logistic regression model with terms for treatment, baseline UPCR, biopsy class, MMF use at baseline and region, and renal response (Yes/No) at Months 6, 12, 18, 24, 30 and 36 as the response variable.

The results will be expressed as an odds ratio (and associated two sided- 95% confidence interval [CI]) for voclosporin compared to placebo. Odds ratios greater than unity will mean the odds of response are greater for voclosporin than for placebo and therefore indicate a benefit of the voclosporin treatment arm. The p-value of the treatment effect will also be reported.

The following SAS program will be used for the primary efficacy analysis:

```
proc logistic data = data;
class treatment_arm mmf_use biopsy_class region / param=glm;
model response = treatment_arm mmf_use biopsy_class baseline_upcr region;
run;
```

Listing of renal responders and non-responders will also be provided.

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6.11.2.2 Proportion of subjects in partial renal response defined as a 50% reduction from baseline in UPCR

Change from baseline in UPCR will be calculated as the post baseline measurement minus the AURORA 1 baseline measurement. Percent change from baseline will be calculated as:

$$\text{Percent change from baseline (UPCR\_pc)} = \left(\frac{Change\ from\ baseline}{Baseline}\right) \text{x } 100$$

A 50% reduction in UPCR will be indicated by UPCR_pc <= -50. Subjects with missing UPCR values will be considered non-responders. This endpoint will be analyzed at Months 6, 12, 18, 24, 30 and 36, and presented similarly to the primary efficacy endpoint as described above. A listing of subjects considered partial responders will be provided.

This analysis will also be performed using the alternative baseline definition of the lowest UPCR value pre-dosing.

6.11.2.3 Renal flare and Extra-renal flare as adjudicated by the Clinical Endpoints Committee (CEC)

The proportion of subjects with renal and extra-renal flares (as adjudicated by the CEC) will be analyzed in a similar fashion to the proportion of subjects achieving response.

The ability for an individual subject to experience a flare depends on first achieving a given response. This response is a post randomization event and subsequent analysis and results can, therefore, be difficult to interpret. While the numbers of subjects with flares will be summarized, the main analysis will, in essence, be an analysis of 'positive outcome' vs 'negative outcome' including all subjects. A positive outcome will be defined as a subject with an initial response without a subsequent flare, while a negative outcome will be the absence of an initial response or a flare following initial response.

Both Renal flares and Extra-Renal flares will be summarized as described for Response Rate. Additionally, the frequency and percentage of both Renal flares and Extra-Renal flares will be summarized by year.

6.11.2.4 Change from Baseline Endpoints

The following endpoints are included in change from baseline endpoints:

- Change in SELENA-SLEDAI scores from AURORA 1 baseline at Months 6, 12, 18, 24 and 36. Change from baseline in SELENA-SLEDAI total score will be the response

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variable in the Mixed Effect Model Repeated Measures (MMRM) model. The scores of the individual SELENA-SLEDAI items and the total score of each subject will be listed.

- Change in UPCR, eGFR, urine protein, and serum creatinine from AURORA 1 baseline at Months 6, 12, 15, 18, 21, 24, 27, 30, 33 and 36.
- Changes in eGFR between last on-treatment value and last off-treatment values will also be summarized.
- Change in immunology parameters (C3, C4, and anti-dsDNA) from AURORA 1 baseline at Months 6, 12, 15, 18, 21, 24, 27, 30, 33 and 36.
- Change in HRQoL (SF-36) from AURORA 1 baseline at Months 6, 12, 18, 24, 30, and 36. Only the scales (Physical functioning, Role limitations due to physical health, Role limitations due to emotional problems, Energy/fatigue, Emotional well-being, Social functioning, Pain, General health, Total Mean Score) will be summarized. MMRM will be performed only for Total Mean Score. The individual items and scales will be listed.

Change from baseline endpoints will be summarized using descriptive statistics for observed values and changes from baseline by treatment group. All data will be listed.

Change from baseline will be analyzed using a MMRM analysis with treatment arm, visit, treatment by visit interaction, biopsy class, MMF use at baseline, region and baseline value included as a covariates in the model. Results will be expressed as differences between treatment arms (along with the associated 95% CI). The observed and change from baseline values will be summarized by treatment visit and treatment arms. The Least Squares (LS) means and their corresponding 95% CI of the change from baseline values will also be presented for each visit and for the overall change. The model will be fitted using an unstructured (UN) covariance matrix. Should the UN covariance matrix not converge, then an autoregressive (AR(1)) covariance matrix will be used. The covariance matrix used will be indicated in the footnotes. The Kenward-Roger degree of freedom adjustment will be applied. LS mean plots of mean change from baseline versus visit will be presented for UPCR and eGFR.

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The SAS code anticipated to be used for analysis of the change from baseline endpoints is as follows:

```
proc mixed data=dataset;
class subject treatment visit biopsy class mmf use region;
model response = treatment visit treatment*visit biopsy_class mmf_use region
baseline / ddfm=kr
repeated visit / subject=subject type=un r corr;
lsmeans visit*treatment / pdiff cl e;
run;
```

6.11.3 Healthcare Resource Utilization (HRU)

Information on healthcare resource utilization will be collected and documented in the EDC system. This information will be collected via interview of the subject by the study staff and entered into the EDC system. General information collected may include:

- Number of visits to ANY health care professionals (HCP), other than study doctor
- Types of HCP visited (specialists versus primary care)
- Diagnostic tests performed (Yes/No)

Healthcare Resource Utilization is collected at Months 12, 15, 18, 21, 24, 27, 30, 33, and 36. Key aspects will be summarized by visit and changes over time will be explored. All the items will also be listed at subject level.

6.11.4 Sensitivity Analysis

Not applicable.

6.11.5 Exploratory Analysis

Not applicable.

6.11.6 Key Secondary Endpoints

Not applicable.

6.11.7 Other Secondary Endpoints

Not applicable.

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6.11.8 [redacted]

[redacted]

6.11.9 Multiplicity

All secondary endpoints and the supportive analyses will be considered as descriptive evidence of efficacy and will be analyzed without any procedures to account for multiple comparisons.

6.12 Safety Analyses

The safety analyses will be presented by the treatment received for the safety population. The primary safety endpoints are the AE profile and routine biochemical and hematological assessments at Month 36. The safety analyses will be presented by treatment group for the safety population. The following safety endpoints will be summarized:

- Biochemical (including liver function tests) and hematological laboratory tests
- AE profile and routine biochemical and hematological safety parameters
- Vital signs (blood pressure, heart rate, temperature) at specific time points and change from baseline
- Standard 12-lead ECG change from baseline.

6.12.1 Adverse Events

A treatment-emergent adverse event (TEAE) is defined as:

Any AE that has an onset on or after the first dose of AURORA 1 study drug and on or before the last dose of study drug in AURORA 2 + 30 days.

Most adverse event displays will restrict TEAEs to those starting after the first dose of AURORA 2 study drug.

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A treatment-related TEAE is defined as a TEAE that is assessed by the Investigator or Sponsor as being related to study drug. If a TEAE has a missing relationship to study drug it is assumed to be related to the study drug for analysis purposes.

A disease-related TEAE is defined as a TEAE that is assessed by the Investigator or Sponsor as being related to the disease under study. If a TEAE has a missing relationship to the disease under study it is assumed to be related to the disease under study for analysis purposes.

Missing severity assessments will be summarised as severe.

Adverse event tables will comprise tables summarizing AURORA 2 TEAEs as well as some tables summarizing all TEAEs from month 0 to month 36.

The following tables will be presented for AURORA 2 TEAEs:

- Summary table of overall incidence, the number of events, relative risk and 95% CI (voclosporin:placebo) including the following top line summaries:
  - Any AE
  - Any TEAE
  - Any Treatment-Related TEAE
  - Any Serious TEAE
  - Any Treatment-Related Serious TEAE
  - Any TEAE Leading to Voclosporin/Placebo Modification
  - Any TEAE Leading to Voclosporin/Placebo Discontinuation
  - Any TEAE Resulting to Death
  - Disease-Related TEAE
  - Disease-Related Serious TEAE
- TEAEs by System Organ Class and Preferred term
- TEAEs by System Organ Class, Preferred term and severity
- Treatment-Related TEAE by System Organ Class and Preferred Term
- Treatment-Related TEAE by System Organ Class, Preferred Term and Severity
- TEAE by System Organ Class and Preferred Term Leading to Dose Modification
- TEAE by System Organ Class and Preferred Term Leading to Voclosporin/Placebo Discontinuation
- TEAE by System Organ Class and Preferred Term Resulting in Death
- Disease-Related TEAE by System Organ Class and Preferred Term
- Serious TEAE by System Organ Class and Preferred Term

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- Serious TEAE by System Organ Class, Preferred Term and Severity
- Treatment-Related, Serious TEAE by System Organ Class and Preferred Term
- Treatment-Related, Serious TEAE by System Organ Class, Preferred Term and Severity
- Serious TEAE by System Organ Class and Preferred Term Leading to Dose Modification
- Serious TEAE by System Organ Class and Preferred Term Leading to Voclosporin/Placebo Discontinuation
- Disease-Related, Serious TEAE by System Organ Class and Preferred Term

The following displays of AURORA 2 TEAEs will also be presented:

- Treatment-Emergent Adverse Events by Descending Frequency of Preferred Term
- Non-Serious Treatment-Emergent Adverse Events Occurring at an Incidence of >2% by Descending Frequency, System Organ Class and Preferred Term
- Treatment-Emergent Adverse Events by Descending Difference of Preferred Term between Treatment Group
- Listing of Serious TEAE
- Listing of TEAE Resulting in Death
- Listing of Post-Treatment Adverse Events Resulting in Death

The following displays will include all TEAEs from the start of AURORA 1:

- TEAE by System Organ Class and Preferred Term by Year of Onset
- Treatment-Related TEAE by System Organ Class, Preferred Term and Year of Onset
- TEAE by System Organ Class and Preferred Term Leading to Dose Modification by year of onset
- Serious TEAE by System Organ Class and Preferred Term by Year of Onset
- Treatment-Related, Serious TEAE by System Organ Class and Preferred Term and Year of onset
- Serious TEAE by System Organ Class and Preferred Term Leading to Dose Modification by year of onset

The following displays will be presented for all randomized subjects from Aurora 1?

- TEAE by System Organ Class and Preferred Term
- Serious TEAE by System Organ Class and Preferred Term

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In counting the number of AEs reported, a continuous event (i.e., reported more than once and which did not cease), will be counted only once for a subject; a non-continuous AE reported several times by the same subject will be counted as multiple events.

6.12.1.1 Exposure-Adjusted Incidence Rates

Tables showing the overall incidence rate, total number of subjects with a given event and total events per 100 years exposure will be produced. These tables will incorporate all events from AURORA 1 and AURORA 2.

All AEs will be listed.

6.12.2 Laboratory Data

Descriptive statistics, including 95% confidence intervals, of the observed values and change from baseline (continuous data) will be presented by treatment group and visit for each hematology, urinalysis and serum chemistry continuous parameter. Each measurement will be classed as below, within, or above normal range, based on ranges supplied by the laboratory used. Shift tables in relation to the normal range from baseline to each follow-up visit will be presented.

Analysis of all samples for hematology, chemistry, hepatic function, lipid profiles, and urinalysis will be performed at a central laboratory using standard validated methods (see the laboratory manual). All study data analyses involving laboratory values will be based on results from the central laboratory.

The table below shows the tests, parameters, and time points that will be summarized by treatment arm. For the screening time points, only the last non-missing measurements will be included in the summary.

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Table 2.5 Laboratory Parameters

Test Type	Test Parameters	Collection at Visits
Hematology	Complete blood count (CBC)	All visits
	Hematocrit	
	Hemoglobin	
	Mean corpuscular hemoglobin (MCH)	
	Mean corpuscular hemoglobin concentration (MCHC)	
	Mean corpuscular volume (MCV)	
	Platelet count	
	Red blood cells (RBC)	
	Red blood cell morphology	
	White blood cells (WBC)	
	Differential (absolute and %)	All visits
	Bands	
	Basophils	
	Eosinophils	
	Lymphocytes	
	Monocytes	
	Neutrophils	

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Test Type	Test Parameters	Collection at Visits
Blood Chemistry	Alanine aminotransferase (ALT)	All visits
	Albumin	All visits
	Alkaline phosphatase (ALP)	All visits
	Aspartate aminotransferase (AST)	All visits
	Bicarbonate	All visits
	Bilirubin (direct and total)	All visits
	Blood urea nitrogen (BUN)	All visits
	Calcium	All visits
	Chloride	All visits
	Cholesterol (total, HDL,and LDL)	Month 24 and Month 36
	Creatine kinase	Every 6 months
	Creatinine	All visits
	Gamma-glutamyl transferase (GGT)	All visits
	Glucose	All visits
	Glycosolated hemoglobin (HbA1c)	Annually
	Lactic dehydrogenase (LDH)	All visits
	Magnesium	All visits
	Phosphorous, inorganic	All visits
	Potassium	All visits
	Protein, total	All visits
	Sodium	All visits
	Triglycerides	Annually
	C-reactive Protein	All visits

Test Type	Test Parameters	Collection at Visits
Urinalysis	Complete urinalysis (to include urine protein, creatinine, blood, urine microscopy).	All visits

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Test Type	Test Parameters	Collection at Visits
Proteinuria	FMV will be performed to analyze UPCR. A 24-hour urine may be substituted for FMV if required.	All visits
	FMV	All visits
	24-hour urine	Every 6 months

Test Type	Test Parameters	Collection at Visits
Pregnancy Test	A serum pregnancy test will be performed for females of childbearing potential. Urine pregnancy tests will be done using a dipstick.	Month 12, Month 24, and Month 36 (Serum) Month 12, Month 15, Month 18, Month 21, Month 27, Month 30, Month 33 (Urine)

Test Type	Test Parameters	Collection at Visits
Lupus Markers	Anti-double-stranded DNA (anti-dsDNA) antibodies	All visits
	Serum Complement 3 Complement 4	All visits
Special Tests	Estimated glomerular filtration rate (eGFR)	All visits

Additional eGFR tables will summarize changes from last on treatment value to last off treatment value. The slope of eGFR over time will also be summarized. eGFR slope will be assessed from AURORA 1 baseline to Week 4 and then from Week 4 through to the end of AURORA 2.

A listing of all laboratory measurements recorded throughout the study will be presented.

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6.12.3 Vital Signs

Descriptive statistics for observed values and changes from baseline in the following vital signs will be presented by treatment group and visit:

- Systolic blood pressure (mmHg)
- Diastolic blood pressure (mmHg)
- Pulse rate (bpm)
- Body temperature (degrees Celsius).

Mean values for systolic and diastolic blood pressure will be used in the summary tables. Where the mean value is unavailable, an individual measure at the visit in question will be used. Listings of all vital sign measurements will be provided.

6.12.4 Electrocardiogram Data

Descriptive statistics for observed values and changes from baseline as recorded in the AURORA 1 database for subjects that did not participate in AURORA 2, and as recorded in the AURORA 2 database for subjects that did participate in AURORA 2 in the following ECG variables at Months 6, 12, 18, 24, and 36, will be tabulated at each follow-up:

- Heart rate (bpm)
- PR interval (ms)
- QRS complex (ms)
- QT interval (ms)
- QTc interval (ms)
- QTcF interval (ms)

Shift tables in relation to the overall interpretation (Normal, Abnormal NCS, and Abnormal CS) from baseline to each follow-up visit will be presented. Listings of all ECG measurements will be provided.

6.12.5 Physical Examination

Physical examination will be summarized for the safety population at timepoints: Month 12 and 36. The following parameters will be summarized: Height (as part of demography at screening only) and Weight.

Physical examination results with clinically significant abnormalities (Yes/No) will be listed.

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7 INTERIM ANALYSIS

The study will be ongoing during regulatory interaction and as such, regular reporting events will be required to ensure authorities are provided the most up to date information available.

These reporting events will incorporate both safety and efficacy analyses.

Timing of the interim analyses will range from 3 months post the final subject final visit of the AURORA 1 study (i.e., when the last subject reaches Month 15 of the AURORA 2 continuation study) up to 6 months prior to the end of AURORA 2 (i.e., when the last subject reaches Month 30 of the AURORA 2 continuation study).

8 DATA SAFETY MONITORING BOARD ANALYSIS

Data presentations for the Data and Safety Monitoring Board (DSMB) deliverables are provided in a separate SAP.

9 CHANGES TO PLANNED PROTOCOL ANALYSIS

Additional analyses will be performed to compare subjects who did not participate in AURORA 2 with those who participated.

Protocol stated: "Subjects who receive treatment from more than 1 arm will be assigned to the Orelvo arm." And this was updated to "Subjects who receive voclosporin treatment for more than 14 days will be assigned to the voclosporin arm irrespective of the arm they were randomized to".

Protocol did not mention covariates for MMRM analysis. In addition to baseline covariate the following covariates will be included in the model: biopsy class, MMF use at baseline, region.

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10 REFERENCES

1. SAS Institute Inc. The SAS System, Version 9.4. Cary, NC, SAS Institute Inc. 2013.

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