[redacted]

STATISTICAL ANALYSIS PLAN

A Phase 2, randomized, prospective, double-masked, vehicle-controlled study to assess the efficacy and safety of Nexagon® (NEXAGON) applied topically in subjects with corneal persistent epithelial defects (PED) resulting from severe ocular chemical and/or thermal injuries.

Sponsor: [redacted]

Protocol Number: NEX-PED-005

Author: [redacted]

Date: 10FEB2022

Version: 1.0

[redacted]

A Phase 2, randomized, prospective, double-masked, vehicle-controlled study to assess the efficacy and safety of Nexagon® (NEXAGON) applied topically in subjects with corneal persistent epithelial defects (PED) resulting from severe ocular chemical and/or thermal injuries.

Protocol Number: **NEX-PED-005**

SAP Version: **1.0**

SAP Date: **10FEB2022**

Statistical Analysis Plan Approval (Approval pg. 1 of 2)

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Statistical Analysis Plan Approval (Approval pg. 2 of 2)

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4CA42E3D4C18477AB532E224446F3B78

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Date

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Table of Contents

[redacted]

List of Abbreviations

ADaM	Analysis Data Model
AE	Adverse Event
ANCOVA	Analysis of Covariance
ATC	Anatomical Therapeutic Chemical
[redacted]	[redacted]
BCVA	Best Corrected Visual Acuity
CF	Counting Fingers
CI	Confidence Interval
COVID-19	Coronavirus (COVID-19) pandemic
CP	Conditional Power
CRA	Clinical Research Associate
CRO	Contract Research Organization
CS	Clinically Significant
DTA	Data Transfer Agreement
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
EOS	End of Study
ETDRS	Early Treatment Diabetic Retinopathy Study
FAS	Full Analysis Set
FAS-IA	Full Analysis Set for the IA
FUP	Follow-up
HM	Hand Movements
IAP1	Interim Analysis Primary Endpoint 1
IAP2	Interim Analysis Primary Endpoint 2
IAS1	Interim Analysis Secondary Endpoint 1
IAS2	Interim Analysis Secondary Endpoint 2
ICH	International Conference on Harmonisation
IOP	Intraocular Pressure
LOCF	Last Observation Carried Forward
logMAR	Logarithm of the Minimum Angle of Resolution
LS	Lease Squares
IP	Investigational Product
MedDRA	Medical Dictionary for Regulatory Activities
NCS	Not Clinically Significant
NPL	No Perception of Light
OL	Open-Label
PCI	Potentially Clinically Important
PDF	Portable Document Format
PED	Persistent Epithelial Defect
PL	Perception of Light
PP	Per Protocol
PT	Preferred Term
re-epi	re-epithelialization

RTF	Rich Text Format
SaaS	Software-as-a-Service
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SDC	Statistics & Data Corporation
SDTM	Study Data Tabulation Model
SOC	System Organ Class
SOP	Standard Operating Procedure
TEAE	Treatment-Emergent Adverse Event
VA	Visual Acuity
WHODrug	World Health Organization Drug Dictionary

1. Introduction

The purpose of this statistical analysis plan (SAP) is to describe the planned analyses and reporting for protocol NEX-PED-005,

This SAP is being written with due consideration of the recommendations outlined in the most recent International Conference on Harmonisation (ICH) E9 Guideline entitled Guidance for Industry: Statistical Principles for Clinical Trials and the most recent ICH E3 Guideline, entitled Guidance for Industry: Structure and Content of Clinical Study Reports.

This SAP describes the data that will be analyzed and the subject characteristics, efficacy, and safety assessments that will be evaluated. This SAP provides details of the specific statistical methods that will be used. The statistical analysis methods presented in this document will supersede the statistical analysis methods described in the clinical protocol, and any changes to the protocol stated analyses will be detailed in Section 17. If additional analyses are required to supplement the planned analyses described in this SAP, they may be completed and will be identified in the clinical study report.

2. Study Objectives

The objective of this study is to assess the efficacy and safety of two topical ocular dose concentrations of Nexagon® (NEXAGON) as a treatment for non-healing corneal persistent epithelial defects (PEDs) resulting from severe chemical and/or thermal ocular injuries.

2.1 Primary Endpoint

The primary efficacy endpoint is corneal epithelial recovery, defined as a cornea that re-epithelializes by of treatment and remains re-epithelialized for after initial re-epithelialization was first recorded, as assessed by the Investigator.

2.2 Secondary Endpoints

2.3 Exploratory Endpoints

[redacted]

2.4 Safety Variables

The safety variables include the incidence of treatment-emergent adverse events (TEAEs).

2.5 Statistical Hypotheses

The null and alternative hypotheses, based on the primary endpoint, are as follows:

[redacted]

[redacted]

3. Study Design and Procedures

3.1 General Study Design

This phase 2 multi-center trial is a randomized, prospective, double-masked, vehicle-controlled study to assess the efficacy and safety of NEXAGON applied topically in subjects with corneal PED resulting from severe ocular chemical and/or thermal injuries.

A subject's participation is to start with screening (Eligibility Assessment Visit) to determine eligibility for enrollment into the study prior to Day 1. If the subject is considered eligible for the study, the subject will be randomized to receive either NEXAGON [redacted] or NEXAGON [redacted] or Vehicle [redacted], respectively on Day 1.

[redacted]

For all subjects, the first investigational product application will occur following randomization [redacted] with investigational product (NEXAGON [redacted] or NEXAGON

[redacted]

[redacted]or Vehicle)[redacted]. Following investigational product application, [redacted]

The study will comprise of 2 periods, a Treatment Period and Post-healing Follow-up Period:

Treatment Period (Masked):

During the Treatment Period, masked investigational product will be administered on [redacted]

- If re-epithelialization of the defect has NOT occurred [redacted] another single application of masked investigational product will be administered [redacted]
- If re-epithelialization occurs at any time during the masked Treatment Period, subjects will enter a [redacted] Post-healing Follow-up Period to assess durability of the corneal epithelium.
- [redacted]

Post-healing Follow-up Period (Masked)

During the [redacted] Post-healing Follow-up Period subjects will be assessed [redacted] following initial re-epithelialization to confirm durability of the epithelium.

- If the healed epithelium is sustained within the Post-healing Follow Period (durable), the subject will then exit the study having completed all visits.
- [redacted]

Open-Label Section

In the open-label section of the study subjects will receive a salvage dose of NEXAGON [redacted].

- If re-epithelialization has not been achieved [redacted] dose of NEXAGON [redacted] will be applied [redacted] A final assessment of healing for these subjects will be conducted [redacted]
- [redacted]

[redacted]

- If re-epithelialization has not occurred [redacted], the subject will exit the study.

The maximum duration for study participation for a subject [redacted]

At each study visit, following randomization until the end of the study, the subject will undergo assessments as detailed in Table 2 (Schedule of Assessments). Assessments will be performed by a designee at the study site who is masked to the allocated investigational product and include [redacted] The occurrence of any Treatment Emergent Adverse Events will also be assessed at each study visit, and up to [redacted] following the final application of investigational product.

3.2 Study Visit Windowing

Study day will be referred to in all tables and listings. Table 1a shows the planned study visits and the acceptable visit window for each visit for subjects who are in the study for the maximum duration. Table 1b shows the planned study visits and acceptable visit window by study period. Visits that are not able to be completed within the windows specified in the protocol must be recorded as protocol deviations.

Note: Day 1 corresponds to the day of randomization, there is no Day 0.

[redacted]

Table 1a. Study Visit Windows [redacted]

[redacted]

[redacted]

Table 1b. Study Visit Windows [redacted]

[redacted]

[redacted]

3.3 Dose Regimen, Study Flow Diagram, and Schedule of Visits and Assessments

The dosing regimen is provided in Figure 1, the study flow diagram (visit schedule and dosing days) is provided in Figure 2 and the schedule of visits and assessments is provided in Table 2.

[redacted]

[redacted]

Figure 2. Study Flow Diagram – [redacted]

[redacted]

Table 2. Schedule of Visits and Assessments

[redacted]

[redacted]

4. Study Treatments

4.1 Method of Assigning Subjects to Treatment Groups

A subject who meets all the inclusion criteria and none of the exclusion criteria is eligible for randomization [redacted] Subjects are to be randomized to one of three treatment group:

- GROUP A – NEXAGON [redacted]
- GROUP B – NEXAGON [redacted]
- GROUP C – Vehicle (0%)

A statistician not directly involved in the analysis of the study results will prepare the randomization schedule using block randomization to maintain balance between treatment groups. Randomization is to be done [redacted]

When a subject is confirmed to be eligible for randomization [redacted] treatment assignment for that subject will be determined by [redacted]

4.2 Masking and Unmasking

All subjects, investigators, and study personnel involved with the conduct of the study will be masked with regard to treatment assignments.

The Investigator may unmask a subject's treatment assignment only in the case of an emergency when knowledge of the investigational product is essential for the clinical management or welfare of the subject. [redacted]

If a drug-related serious adverse event (SAE) is reported, the Medical Monitor may unmask the treatment assignment for the individual subject.

5. Sample Size and Power Considerations

Assuming the true rate of corneal epithelialization in each of the NEXAGON arms of [redacted]

Assuming a discontinuation rate [redacted] Enrollment will continue until [redacted]

6. Data Preparation

6.1 Input Data

Electronic case report forms (eCRFs) will be developed
Data from source documents will be entered into the eCRF by site personnel.

The electronic clinical study database will be

After data are entered into the clinical study database, electronic edit checks and data review will be performed. All data validation specifications and procedures are detailed in the
When the database has been declared to be complete and accurate, the database will be locked. Any changes to the database after data have been locked can only be made with the approval of

All analyses outlined in this document will be carried out after the following have occurred:

- All data requirements are met according
- Protocol deviations have been identified and status defined (major/minor deviations).
- Analysis populations have been determined.
- Randomized treatment codes have been unmasked.

In addition, the laboratory data will be included in the statistical analysis.

6.2 Output Data

Data from the electronic clinical study database and external data will be transferred to and incorporated into standard formats following the Study Data Tabulation Model (SDTM). Data will then be mapped to analysis datasets using the Analysis Data Model (ADaM). Both SDTM- and ADaM-formatted data will be used to create the subject listings, while all tables and figures will be based on the ADaM-formatted data.

SDTM will follow the and will be implemented using the SDTM Implementation Guide and the SDTM Controlled Terminology
ADaM data will follow the ADaM model and will be implemented using the ADaM Implementation Guide and the ADAM Controlled terminology . Both SDTM and ADaM will be validated Any discrepancies in the validation will be noted in reviewer's guides accompanying the final data transfers.

Define.xml will be created for SDTM and ADaM

7. Analysis Populations

[redacted]

8. General Statistical Considerations

8.1 Unit of Analysis

The study eye will be defined as [redacted]

8.2 Missing or Inconclusive Data Handling

[redacted]

[redacted]

8.3 Definition of Baseline and Final On-Treatment Visit

Baseline will be defined as the last measurement prior to the first dose of study medication. Change from baseline will be calculated as follow-up visit value minus baseline value.

[redacted]

The final on-treatment visit is defined as the day of initial corneal re-epithelialization, treatment [redacted] or day of discontinuation during treatment.

[redacted]

8.4 Data Analysis Conventions

All data analysis will be performed by [redacted] after the study is completed and the database has been locked and released for unmasking. Statistical programming and analyses will be performed using [redacted] Output will be provided in rich text format (RTF) for tables and portable document format (PDF) for tables, listings, and figures using landscape orientation. All study data will be listed by subject, treatment, and visit (as applicable) based on all randomized subjects unless otherwise specified.

Summaries for continuous and ordinal variables will include the number of observations (n), arithmetic mean, standard deviation (SD), median, minimum, and maximum. Minima and maxima will be reported with the same precision as the raw values; means and medians will be presented to one additional decimal place than reported in the raw values. Standard deviations will be presented to two additional decimal places than reported in the raw values. Summaries for discrete variables will include counts and percentages. All percentages will be rounded to one decimal place (i.e., XX.X%). Differences between active treatment groups and placebo will be calculated as active minus placebo and change from baseline will be calculated as follow-up visit minus baseline.

[redacted]

Unless otherwise specified, summaries will be presented by treatment group and, where appropriate, visit. Listings will be sorted by treatment group, subject number, visit/time point, and parameter as applicable.

8.5 Adjustments for Multiplicity

[redacted]

[redacted]

9. Disposition of Subjects

Subject enrollment, inclusion in analysis populations, and study completion/withdrawal from the study for the main study as well as the open-label section of the study will be summarized and listed in terms of the numbers and percentages of subjects who were randomized, completed the study, and discontinued from the study. Subjects who are not discontinued from the study will be considered study completers. Disposition will be summarized by treatment group and for all subjects.

[redacted]

The number and percentage of subjects prematurely discontinued from the study and the reasons for study discontinuation will be summarized by treatment group for all subjects who discontinued the study. The reasons for study discontinuation that will be summarized include AE, lost to follow-up, physician decision, protocol violation, screen failure, study terminated by sponsor, withdrawal by subject, and other. [redacted]

The number and percentage of subjects with major protocol deviations will be summarized by treatment group for all randomized subjects. [redacted]

[redacted]

10. Demographic and Pretreatment Variables

10.1 Demographic Variables

The demographic variables collected in this study include age, gender at birth, race, and ethnicity. Demographic variables will be summarized for all randomized subjects [redacted]

A subject listing that includes all demographic variables will be provided.

10.2 Pretreatment Variables

Baseline disease characteristics will be summarized separately for all randomized subjects [redacted]

Summaries will be presented for the study eye. For subjects with a bilateral ocular injury, the assessments detailed above will also be listed for the fellow eye (in addition to the study eye).

[redacted]

11. Medical History and Concomitant Medications

11.1 Medical History

General ocular history, and non-ocular medical history will be coded using the Medical Dictionary for Regulatory Activities (MedDRA)[redacted] Medical history, including details of any ongoing medical conditions, will be recorded prior to Day 1 and before eligibility is confirmed.

[redacted]

SOCs will be listed in alphabetical order and PTs within an SOC will be listed in order of descending frequency across all subjects.

Listings of medical history will be generated separately for both ocular data and non-ocular data.

11.2 PED History

A detailed ocular examination and history will be conducted prior to the Day 1 visit and assessed against the inclusion and exclusion criteria of the protocol.

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

11.3 Prior and Concomitant Medications

[redacted]

[redacted]

Prior and concomitant medications will be listed for all randomized subjects. [redacted]

11.4 Concomitant Procedures

Concomitant procedures will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) [redacted] and summarized by SOC and PT.

Concomitant procedures will be listed using all randomized [redacted]

12. Treatment Exposure

Treatment exposure will be defined in two ways, as the extent of treatment exposure and the number of treatment doses. The number of treatment doses is the number of actual applications of NEXAGON or Vehicle.

[redacted]

13. Efficacy Analyses – Masked Portion of Study

13.1 Primary Efficacy Outcome Analysis

The primary efficacy outcome will be the comparison of each dose of NEXAGON to Vehicle for the proportion of subjects with corneal epithelial recovery, defined as a cornea that re-epithelializes [redacted] of treatment and remains re-epithelialized [redacted] after initial re-epithelialization was first recorded (during the masked treatment portion of the study and assessed by the

Investigator). Subjects who discontinue the study early, or who have missing data resulting in the inability to conclude corneal epithelial recovery, will be considered as not having corneal epithelial recovery (missing data imputed as failure).

The number and proportion of subjects with corneal epithelial recovery will be summarized by treatment group and tested between treatment groups

[redacted]

13.1.1 Sensitivity Analyses

[redacted]

13.2 Secondary Efficacy Outcome Analyses

The secondary efficacy outcomes will be analyzed using the [redacted] with reference to the masked treatment period. [redacted]

The following secondary efficacy endpoints, [redacted]

- [redacted]
- [redacted]
- [redacted]

13.2.1 [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

14. Exploratory Analyses

The exploratory efficacy outcomes will be [redacted]

- [redacted]
- [redacted]
- [redacted]

- Primary, secondary, and exploratory endpoints will also be assessed (as applicable) for the open-label section of the study.
-

14.1

14.4

[redacted]

15. Safety Analyses

All safety analyses will be conducted using the safety population. Summaries of safety measures during the masked treatment and follow-up periods [redacted] will be completed similarly.

15.1 Adverse Events

An Adverse Event (AE) is defined as any untoward medical occurrence in a subject or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporarily associated with the use of an investigational product whether or not related to the investigational product. AEs will be recorded from the time of first application of the investigational product and until the final visit.

Treatment-emergent adverse events (TEAEs), defined as AEs that occur after the first dose of study medication, are undesirable events not present prior to investigational product treatment, or an already present event that worsens either in intensity or frequency following treatment.

Serious Adverse Events (SAE) any untoward medical occurrence that at any dose results in death, is life-threatening and/or sight threatening, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect. SAEs are undesirable events (experiences) or reaction not present prior to investigational product treatment, or an already present event that worsens in magnitude to be classified as an SAE, either in intensity or frequency following treatment.

Severity of an AE is defined as a qualitative assessment of the degree of intensity of an AE as determined by the Investigator or reported to him/her by the subject. The assessment of severity is made irrespective of relationship to study drug or seriousness of the event and should be evaluated according to the following scale:

- *Mild:* Event is noticeable to the subject but is easily tolerated and does not interfere with the subject's daily activities.
- *Moderate:* Event is bothersome, possibly requiring additional therapy, and may interfere with the subject's daily activities.
- *Severe*: Event is intolerable, necessitates additional therapy or alteration of therapy, and interferes with the subject's daily activities.

The relationship of each AE or SAE to the study drug should be determined by the Investigator using these explanations: definitely related, probably related, possibly related, unlikely to be related, and unrelated. Only definitely, probably, and possibly related TEAEs will be considered as treatment-related TEAEs. For TEAEs prior to rescue medication use, only those TEAEs with an onset date prior to the date that rescue medications were first used will be included.

Clinically significant abnormal laboratory findings or other abnormal assessments that are present at baseline and significantly worsen following the start of the study will be reported as AEs and SAEs. The Investigator will exercise his/her medical and scientific judgment in deciding whether an abnormal laboratory finding or other abnormal assessment is clinically significant.

Verbatim descriptions of AEs will be mapped to MedDRA [redacted] terms and presented in a data listing. Adverse events recorded in the eCRF which began prior to treatment will not be included in the summary tables but will be included in the AE data listings. All AEs, SAEs, and TEAEs will be presented separately in subject data listings. The TEAEs leading to study treatment discontinuation will also be listed separately.

An overall summary will be presented that includes the number of events and the number and percentage of subjects who experienced at least one TEAE, by treatment group and over all subjects. This summary will also include breakdowns of TEAEs further categorized as ocular (study eye and, for subjects with bilateral injury, fellow eye separately) or non-ocular, treatment-related TEAEs, TE-SAEs, TEAEs leading to treatment withdrawal, TEAEs leading to death, TEAEs by maximal severity, and TEAEs by relationship to study drug.

Treatment-emergent adverse events (TEAEs), those that occur after the first dose of study medication, will be summarized by treatment group using frequency and percentages for each SOC and PT within each SOC. Similar summaries will be presented for treatment related TEAEs, TEAEs by maximum severity, serious TEAEs, and TEAEs leading to test article discontinuation.

Separate summaries of TEAEs will be provided showing the number and percentage of subjects who experienced at least one TEAE by treatment group and over all subjects. Non-ocular TEAEs will be summarized using discrete summary statistics and presented by treatment group at the subject and event level by SOC and PT. Ocular TEAEs will be similarly summarized at the subject level for study and fellow eyes separately. If a subject reports the same PT multiple times within the same SOC, that PT will only be reported once within that SOC. As with the PT, if a subject reports multiple conditions within the same SOC, that SOC will only be reported once. In the summary, SOCs will be listed in ascending alphabetical order; PTs will be listed in order of descending frequency for all subjects within each SOC.

The number of subjects with any TEAEs (along with percentages) will be tabulated by SOC and PT within each SOC by treatment group. Summaries of TEAEs by maximal severity, strongest relationship to study drug, and strongest relationship to study drug and maximal severity will be presented for ocular AEs and non-ocular AEs separately. To count the number of subjects with any TEAEs, if a subject has multiple TEAEs coded to the same PT within the same SOC, the subject will be counted once under the maximum severity. TEAEs that led to test article discontinuation, defied as drug interruption or drug withdrawal as response to the AE, treatment related TEAEs, and TE-SAEs will also be summarized by SOC and PT.

15.2

[redacted]

[redacted]

15.3 Slit Lamp Examination

A slit lamp examination will be performed at each visit. [redacted]

[redacted]

15.4 PED Assessment [redacted]

The epithelial defect size will be assessed prior to Day 1 and randomization on Day 1 then at each follow-up visit. [redacted]

15.5 [redacted]

[redacted]

15.7 Clinical Laboratory Data

[redacted]

No specific laboratory results (other than a positive pregnancy test) will be used to exclude a subject from entry or continued participation in the study, unless in the Investigator's opinion the results indicate the subject has a concurrent condition that may affect the safety of the subject or potentially the outcome of the study.

The same blood tests will be repeated when the subject completes the Treatment Period of the study. Refer to Table 2 (Schedule of Assessments).

Laboratory data will be presented in data listings. Clinical laboratory results will be summarized using continuous summaries, including continuous change from baseline. Qualitative laboratory values will be summarized with discrete statistics, including frequency and percent of subjects with normal, abnormal, high, and low values and using shift tables from baseline. A listing of potentially clinically important (PCI) laboratory findings will also be presented, where PCI is defined as any laboratory results that are abnormal, high or low.

16.

[redacted]

16.2 [redacted]

[redacted]

18. References

1. Brookmeyer R, Crowley J. A confidence interval for the median survival time. *Biometrics.* 1982;38:29-41.

2. Chan, I. S. F., and Zhang, Z. (1999). “Test-Based Exact Confidence Intervals for the Difference of Two Binomial Proportions.” Biometrics 55:1202–1209.

19. Revision History

Documentation of revision to the SAP will commence after approval of the final version 1.0.

20. Tables for Final Analysis

Tables that will be included in the topline delivery are shown in boldface font.

Table Number	Title	Population
14.1.1	Subject Disposition	All Randomized Subjects
14.1.2.1.1	Demographic Characteristics	All Randomized Subjects
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
14.1.3.1	Ocular Medical History	Safety Population
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
14.2.1.1	Corneal Epithelial Recovery [redacted]	Full Analysis Set
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
14.2.2.1	**Time to Corneal Epithelial Recovery**	**Full Analysis Set**
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
14.3.1	**Overall Summary of TEAEs by Treatment Group**	**Safety Population**
14.3.2.1	**Ocular TEAEs by System Organ Class and Preferred Term (Study Eye)**	**Safety Population**
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
14.3.6	TEAEs That Led to Premature Test Article Discontinuation	Safety Population

14.3.7	Treatment-Related TEAEs	Safety Population
14.3.8	Treatment-Emergent Serious Adverse Events	Safety Population
14.3.9.1	**Ocular Injury Questionnaire - Physician Assessment**	**Safety Population**
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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14.3.9.3	**PED Measurements** [redacted]	**Safety Population**
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
14.3.9.6	Exposure to Study Drug	Safety Population
14.3.10.1.1	Clinical Laboratory Measures - Hematology	Safety Population
14.3.10.1.2	Clinical Laboratory Measures – Shift in Hematology	Safety Population
14.3.10.2.1	Clinical Laboratory Measures - Chemistry	Safety Population
14.3.10.2.2	Clinical Laboratory Measures – Shift in Chemistry	Safety Population

21. Tables for Interim Analyses

Tables that will be included in Interim Analysis Stage I are shown in boldface font.

Table Number	Title	Population
1		

[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

22. Data Listings

Listing Number	Title	Population
16.1.7	Randomization Schedule	All Randomized Subjects
16.2.1.1	Subject Disposition	All Randomized Subjects
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

16.2.2.1	Protocol Deviations	All Randomized Subjects
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
16.2.4.1	Demographics	All Randomized Subjects
16.2.4.2.1	Ocular Medical History	All Randomized Subjects
16.2.4.2.2	Non-Ocular Medical History	All Randomized Subjects
16.2.4.3	PED History	All Randomized Subjects
16.2.4.4	Ocular Prior and Concomitant Medications	All Randomized Subjects
16.2.4.5	Non-Ocular Prior and Concomitant Medications	All Randomized Subjects
16.2.4.6	Concomitant Procedures	All Randomized Subjects
16.2.5	Investigational Product Administration	All Randomized Subjects
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
16.2.7.1	All Adverse Events	All Screened Subjects
16.2.7.2.1	Treatment-Emergent Adverse Events	All Screened Subjects
16.2.7.2.2	Treatment-Emergent Adverse Events Leading to Test Article Discontinuation	All Screened Subjects
16.2.7.2.3	Treatment-Related Treatment-Emergent Adverse Events	All Screened Subjects
16.2.7.3	Serious Adverse Events	All Screened Subjects
16.2.8.1.1	Clinical Laboratory Measurements – Hematology	All Randomized Subjects

16.2.8.2.1	Clinical Laboratory Measurements – Chemistry	All Randomized Subjects
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

23. Figures

Figure Number	Title	Population
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]