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Oyster Point Pharma, Inc.

Clinical Protocol: OPP-005:

A Single-Center, Randomized, Controlled, Masked Clinical Trial to Evaluate the Efficacy of OC-01 Nasal Spray on Goblet Cell and Meibomian Gland Stimulation (The IMPERIAL Study)

Statistical Analysis Plan for Safety Data
Version 1.0

Prepared [redacted]
Date: July 1, 2020

[redacted]

[redacted]

Revision History

[redacted]

[redacted]

[redacted]

Prepared by:

[redacted]

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Contents

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1 Synopsis

Protocol Title:	A Single-Center, Randomized, Controlled, Masked Clinical Trial to Evaluate the Efficacy of OC-01 Nasal Spray on Goblet Cell and Meibomian Gland Stimulation (The IMPERIAL Study)
Protocol Number:	OPP-005
Investigational Product:	OC-01 (varenicline) Nasal Spray: • 1.2 mg/mL
Study Objective:	The objective of this study is to evaluate the safety and effectiveness of OC-01 Nasal Spray as compared to placebo in simulating Goblet Cell and Meibomian Gland function in adult subjects with DED.
Treatment Assignment	45 subjects will be randomized in a 2:1 ratio to the two treatment groups. • 1.2 mg/mL • Placebo (vehicle) Subjects who passed screening at Visit 1 will be randomized and administered study drug in office at Visit 2.
Sample Size and Power	The sample size for this study is not based on statistical power considerations.
Safety Endpoint	Safety Endpoint: • Adverse Events
Analysis Populations	The safety population will include all randomized subjects who received study drug. Analysis on the safety population will group subjects according to the treatment actually received.

[redacted]

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2 Abbreviations

AE	adverse event
CRF	case report form
DED	dry eye disease
FDA	Food and Drug Administration
HIPAA	Health Information Portability and Accountability Act
IB	Investigator's Brochure
ICF	informed consent form
IRB	institutional review board
mg	Milligram
mL	Milliliter
SAE	serious adverse event
SAP	Statistical Analysis Plan
SD	Standard deviation
TEAE	treatment-emergent adverse event

[redacted]

[redacted]

3 Introduction

This statistical analysis plan (SAP) contains the detailed technical specifications for the safety data only described in the OPP-005 protocol Amendment #4 (26 March 2019).

The reviewer can refer to the study protocol and the case report form (CRF) for details of study design, conduct and data collection. Specifications of tables and data listings are contained in a separate document.

The objective of this SAP is to evaluate the safety of OC-01 (varenicline) Nasal Spray as compared to placebo on incidence of treatment-emergent adverse event (TEAE) in adult participants with dry eye disease (DED).

If the analyses described in the protocols differ from those in this SAP, the methods of the SAP prevail.

4 Study Objective

The objective of this study is to evaluate the safety and effectiveness of OC-01 Nasal Spray as compared to placebo in simulating Goblet Cell and Meibomian Gland function in adult subjects with DED.

5 Study Design

Protocol OPP-005 is a Phase 2, single-center, randomized, masked, placebo-controlled study designed to evaluate the safety of OC-01 Nasal Spray as compared to in adult participants with DED. Approximately 45 subjects at least 18 years of age with a physicians' diagnosis of dry eye disease and meeting all other study eligibility criteria will be randomized to receive an application of OC-01 or placebo at a single visit.

Appendix 1 describes the detailed study visits, measurements, and dosing information.

6 Sample Size Determination and Power Calculation

The sample size for this study is not based on statistical power considerations. The study will randomize approximately 45 subjects in a 2:1 ratio to the two treatment groups. It is expected that approximately 30 subjects will be enrolled in the investigational treatment arm and 15 subjects will be enrolled in the placebo arm. It is expected that all 45 subjects will be enrolled.

7 Statistical Analysis

[redacted]

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7.1 General Consideration

Descriptive and inferential statistics will be used to summarize results of Protocol OPP-005. Continuous variables will be summarized using the number of subjects (n), mean, SD, median, 25th and 75th percentiles, and minimum and maximum. Categorical variables will be summarized using frequency counts and percentages. Baseline measures will be defined as the last measure prior to the initiation of study treatment.

All summaries for safety data will be presented by treatment group. For the demographics and baseline characteristics, all summaries will be presented by treatment group. All collected data will be presented in listings which will be sorted by treatment, subject ID, and visit when it is appropriate. Summaries, data listings, and statistical analyses will be generated using SAS® Version 9.4 or higher.

7.2 Analysis Populations

7.2.1 Safety population

The safety population will include all randomized subjects who received study drug at Visit 2. Analysis of the safety population will group subjects according to the treatment actually received.

7.3 Definition of Study Day

Study Day = [Event date – Randomization date + 1] if after randomization
[Event date – Randomization date] if before randomization

Note that with the definition above, days of "0" will not be used.

For subjects whose reference date is missing, the study day will also be categorized as missing.

7.4 Missing and Partial Data

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

For all other cases, set date to date of first dose.

Adverse event end date
If year is present and month and day are missing or year and day are present and month is missing, set end month and day to December 31.

If month and year are present and day is missing, set the day to last day of the month.

If fatal event, date is set to minimum of imputed end date and death date.

For all other cases, set date to missing.

For summaries that present distribution of time expressed in weeks and months, weeks will be defined as days divided by 7 and months as days divided by 30.4375.

7.5 Protocol Deviations

Important protocol deviations will be summarized by randomized treatment group.

7.6 Subject Disposition

The number and percentage of subjects randomized and included in analysis population will be summarized by treatment and overall.

The number of all subjects who completed the study and reasons for discontinuation will be summarized by treatment group and overall. The Case Report Form (CRF) lists the following reasons why subjects may discontinue study:

- Non-fatal adverse event (AE)

[redacted]

[redacted]

- Protocol violation
- Lost to follow-up
- Pregnancy
- Physician decision
- Subject non-compliance
- Death
- Study terminated by sponsor
- Withdrawal by subject
- Other reasons

7.7 Demographics and Baseline Characteristics

Demographic and baseline characteristics for safety population will be summarized using descriptive statistics by treatment group.

Continuous demographic and baseline variable includes age; categorical variables include gender, ethnicity, and race.

7.8 Medical, Ocular and Dry Eye History

Medical history terms and ocular history terms will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 22.0 and the number and percent of subjects with medical history will be summarized by (SOC) and Preferred Term (PT) for each treatment group based on the safety population.

7.9 Treatment Exposure

All exposure data will be listed by treatment, subject ID for safety population.

8 Intranasal Examination

Intranasal assessments collected at Screening (Visit 1) will be summarized by treatment group and laterality with counts and percentages.

9 Safety Analysis

The safety population will be used for all safety analyses. All recorded safety parameters will be listed by treatment, subject ID and date.

9.1 Adverse Events

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The investigator will promptly review each Adverse Event (AE) for accuracy and completeness, and classify each AE according to its intensity, its relationship to study drug or administration procedure, and its seriousness. AEs will be coded using version 22.0 of the MedDRA dictionary. AEs will be monitored throughout the study and documented on the appropriate AE form. AEs will be categorized as ocular and non-ocular events as well as by system organ class (SOC) and preferred term (PT), seriousness, severity, and relation to study medications.

All treatment-emergent adverse events (TEAEs) will be summarized. A TEAE is defined as an AE that is new or worsened in severity compared to the first dose of study drug. All AEs will be presented in data listing with a flag indicating the event is a TEAE.

TEAEs will be summarized by subject. In addition, the number of TEAE episodes that occurred during the study will be provided in the overall summary of AE table.

The following presentations of TEAEs will be generated:

- Overall adverse events summary;
- Serious adverse events (SAE) by SOC and PT;
- TEAEs by Severity;
- TEAEs by Relationship;
- Ocular TEAEs by SOC and PT;
- Non-ocular TEAEs by SOC and PT;
- TEAEs leading to study discontinuation.

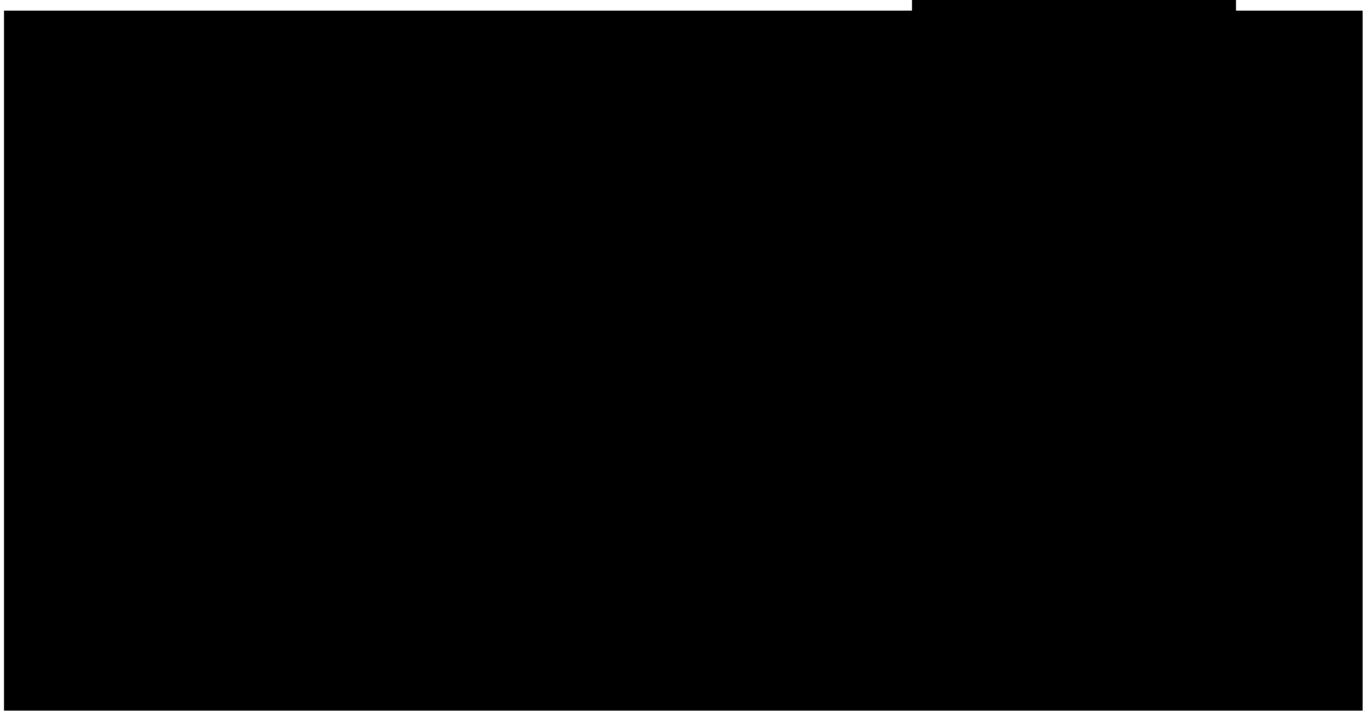
9.2 Prior and Concomitant Medications

Prior and concomitant medications will be coded using the World Health Organization Drug Dictionary (WHO DD version B3, March 2019) and summarized for each treatment group in the safety population. A prior medication is defined as any medication taken within 60 days before dosing on Day 1 in the study. Any medication taken from the day of first dose of the study treatment up to the day of last date of the study will be considered as a concomitant medication for analysis.

Table 1 describes the classification of prior and concomitant medications.

[redacted]

[redacted]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Appendix 1 Schedule of Visits and Measurements

Procedure	Screening (Visit 1)	Treatment and Imaging (Visit 2)	
		Pre-Treatment	Post-Treatment
Informed consent/HIPAA	X		
Demographics	X		
Medical history, prior medication(s), ocular history and updates	X		
Eligibility criteria	X		
Urine pregnancy test[1]	X_1		
OSDI© questionnaire	X		
Eye Dryness Score (EDS)	X		
Imaging of Goblet Cells with Heidelberg Retinal Tomograph 3®		X	X
Imaging of Meibomian Glands with Oculus Keratograph 5M®		X	X
Slit lamp biomicroscopy	X	X	
Corneal fluorescein staining	X		
Schirmer's test	X		
Schirmer's test with cotton swab stimulation	X		
Intranasal examination	X		
Randomization		X	
Dispense investigational drug / placebo		X	
Administer investigational drug / placebo			X
Concomitant medication	X	X	
AE Query	X	X	X
1- If applicable for women of childbearing potential			

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Appendix 2 Table of Contents

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[redacted]

Listing 16.2.8 Intranasal Examination (Safety Population)
Listing 16.2.9 Treatment-Emergent Adverse Events (Safety Population)

[redacted]

[redacted]

Appendix 3 Tableshell

Table 14.1.1 Subjects Screened and Screen Failures (All Subjects)

Table 14.1.1 Subjects Screened and Screen Failures All Subjects	
Category	All Subjects N=xx n (%)
Number of subjects screened	xx
Number of subjects with screen failure	xx (xx.x)
Screen failure reason	
Non-Fatal Adverse Event	xx (xx.x)
Protocol Violation	xx (xx.x)
Lost to Followup	xx (xx.x)
Pregnancy	xx (xx.x)
Physician Decision	xx (xx.x)
Subject non-compliance	xx (xx.x)
Death	xx (xx.x)
Study Terminated by Sponsor	xx (xx.x)
Withdraw by Subject	xx (xx.x)
Other	xx (xx.x)

Source: Listings 16…. O:\projects\ Oyster Point Pharma\OPP-005\tables\xxx.sas (ddmmmyyyy hh:mm)

[redacted]

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[redacted]

Table 14.1.2 Subject Disposition (All Subjects)

Table 14.1.2 Subject Disposition All Subjects			
Category	OC-01 1.2 mg/mL N=xx n (%)	Placebo N=xx n (%)	Total N=xx n (%)
Randomized	xx	xx	xx
Safety population [1]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects completed study	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects discontinued from study (for reasons other than study completion)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-Fatal Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol Violation	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to Followup	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pregnancy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Physician Decision	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subject non-compliance	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study Terminated by Sponsor	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdraw by Subject	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)

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Percentages are calculated based on all randomized subjects.
[1] The safety population will include all randomized subjects who received study drug at Visit 2.

[redacted]

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Table 14.1.3 Demographics (Safety Population)

Table 14.1.3 Demographics Safety Population			
Category	OC-01 1.2 mg/mL N=xx	Placebo N=xx	Total N=xx
Age (Year)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Range (min, max)	xx, xx	xx, xx	xx, xx
Quartiles (25th, median, 75th)	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Sex, n (%)			
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity, n (%)			
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)
Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Reported	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race, n (%)			
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)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)

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SD: Standard Deviation.

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Table 14.1.4 Important Protocol Deviation (Safety Population)

Table 14.1.4 Important Protocol Deviation Safety Population			
	OC-01 1.2 mg/mL N=xx n (%)	Placebo N=xx n (%)	Total N=xx n (%)
No. of subjects with at least one major protocol deviation	xx (xx,x)	xx (xx,x)	xx (xx,x)
<Major Deviation 1>	xx (xx,x)	xx (xx,x)	xx (xx,x)
<Major Deviation 2>	xx (xx,x)	xx (xx,x)	xx (xx,x)

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Percentages are based on the total number of subjects in the Safety Analysis Set. Some subjects may have multiple major protocol deviations.

[redacted]

[redacted]

Table 14.1.5.1 Ocular Medical History (Safety Population)

Table 14.1.5.1 Ocular Medical History Safety Population			
MedDRA System Organ Class Preferred term	OC-01 1.2 mg/mL N=xx n (%)	Placebo N=xx n (%)	Total N=xx n (%)
Subjects with any Ocular Medical History	xx (xx,x)	xx (xx,x)	xx (xx,x)
System Organ Class 1	xx (xx,x)	xx (xx,x)	xx (xx,x)
Preferred Term 1	xx (xx,x)	xx (xx,x)	xx (xx,x)
Preferred Term 2	xx (xx,x)	xx (xx,x)	xx (xx,x)
……			
System Organ Class xx	xx (xx,x)	xx (xx,x)	xx (xx,x)
Preferred Term 1	xx (xx,x)	xx (xx,x)	xx (xx,x)
Preferred Term 2	xx (xx,x)	xx (xx,x)	xx (xx,x)
……			

Source: Listings 16…. O:\projects\ Oyster Point Pharma\OPP-005\tables\xxx.sas (ddmmmyyyy hh:mm)

Note: Ocular medical history was coded using the Medical Dictionary for Regulatory Activities (MedDRA) Version 22.0. Only medical histories collected on the CRF form of Ocular History are included for the summary.
Each subject could only contribute once to each of the incidence rates, regardless of the number of occurrences.

Table 14.1.5.2 Non-Ocular Medical History (Safety Population)

Programming note: same format as Table 14.1.5.1

[redacted]

[redacted]

Table 14.1.6.1 Ocular Prior Medications (Safety Population)

Table 14.1.6.1 Ocular Prior Medications Safety Population			
WHO Drug ATC2 WHO Drug ATC4	OC-01 1.2 mg/mL N=xx n (%)	Placebo N=xx n (%)	Total N=xx n (%)
Subjects with Any Ocular Prior Medications	xx (xx,x)	xx (xx,x)	xx (xx,x)
ATC2 1	xx (xx,x)	xx (xx,x)	xx (xx,x)
ATC4 1	xx (xx,x)	xx (xx,x)	xx (xx,x)
ATC4 2	xx (xx,x)	xx (xx,x)	xx (xx,x)
……			
ATC2 xx	xx (xx,x)	xx (xx,x)	xx (xx,x)
ATC4 1	xx (xx,x)	xx (xx,x)	xx (xx,x)
ATC4 2	xx (xx,x)	xx (xx,x)	xx (xx,x)
……			

Source: Listings 16.… O:\projects\ Oyster Point Pharma\OPP-005\tables\xxx.sas (ddmmmyyyy hh:mm)

Note: World Health Organization Drug Dictionary (WHO-DD) version WHODRUG GLOBAL B3 March 1, 2019 was used for medication coding.
A prior medication is defined as any medication taken within 60 days before dosing on Day 1. Each subject could only contribute once to each of the incidence rates, regardless of the number of occurrences.

[redacted]

[redacted]

Table 14.1.6.2 Non-Ocular Prior Medications (Safety Population)

Programming note: same format as Table 14.1.6.1.

Table 14.1.6.3 Ocular Concomitant Medications (Safety Population)

Programming note: same format as Table 14.1.6.1.

Footnote:

World Health Organization Drug Dictionary (WHO-DD) version WHODRUG GLOBAL B3 March 1, 2019 was used for medication coding. Concomitant medications are all medications taken from the day of first dose of the study treatment up to the day of last date of the study.

Table 14.1.6.4 Non-Ocular Concomitant Medications (Safety Population)

Programming note: same format as Table 14.1.6.1.

Footnote:

World Health Organization Drug Dictionary (WHO-DD) version WHODRUG GLOBAL B3 March 1, 2019 was used for medication coding. Concomitant medications are all medications taken from the day of first dose of the study treatment up to the day of last date of the study.

[redacted]

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Table 14.3.1 Overall Summary of Treatment-Emergent Adverse Events (Safety Population)

Table 14.3.1 Overall Summary of Treatment-Emergent Adverse Events Safety Population			
Category	OC-01 1.2 mg/mL N=xx n (%)	Placebo N=xx n (%)	Total N=xx n (%)
Subjects with any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with any ocular TEAEs	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with any resolved ocular TEAEs	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with any non-ocular TEAEs	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with any treatment-emergent SAEs	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with any treatment-related treatment emergent SAEs	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with any TEAE by maximum severity [1]			
Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)
Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with any TEAEs related to study drug	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with any TEAEs related to study discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with any TEAEs leading to death	xx (xx.x)	xx (xx.x)	xx (xx.x)

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[1] Subjects reporting more than one event are counted only once at the maximum severity reported.

[redacted]

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[redacted]

Table 14.3.2.1 Ocular Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

Table 14.3.2.1 Ocular Treatment-Emergent Adverse Events by System Organ Class and Preferred Term Safety Population			
System Organ Class (SOC) Preferred Term (PT)	OC-01 1.2 mg/mL N=xx n (%)	Placebo N=xx n (%)	Total N=xx n (%)
Any Ocular TEAEs	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
…….			
System Organ Class xx	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listings 16…. O:\projects\ Oyster Point Pharma\OPP-005\tables\xxx.sas (ddmmmyyyy hh:mm)

n (%) = number (percent) of subjects with events.
Note: A TEAE is defined as AE that is new or worsened in severity compared to the first dose of study drug. TEAEs were coded using MedDRA version 22.0.

Table 14.3.2.2 Non-Ocular Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

Programming note: same format as Table 14.3.2.1.

[redacted]

[redacted]

Table 14.3.3.1 Treatment-Emergent Adverse Events by Severity (Safety Population)

Table 14.3.3.1 Treatment-Emergent Adverse Events by Severity Safety Population				
System Organ Class Preferred Term	Severity	OC-01 1.2 mg/mL N=xx n (%)	Placebo N=xx n (%)	Total N=xx n (%)
Any TEAEs	Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1	Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listings 16…. O:\projects\ Oyster Point Pharma\OPP-005\tables\xxx.sas (ddmmmyyyy hh:mm)

n (%) = number (percent) of subjects with events.
Note**:** A TEAE is defined as AE that is new or worsened in severity compared to the first dose of study drug. TEAEs were coded using MedDRA version 22.0.
[1] Subjects reporting more than one event are counted only once at the maximum severity reported.

[redacted]

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[redacted]

Table 14.3.3.2 Treatment-Emergent Adverse Events by Relationship (Safety Population)

Programming note: same format as Table 14.3.3.1. Please change Severity to Relationship. The category of relationship includes Related, and Not Related.

Table 14.3.4 Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

Programming note: same format as Table 14.3.2.1.

Table 14.3.5 Serious Treatment-Emergent Adverse Events Related to Study Drug (Safety Population)

Programming note: same format as Table 14.3.2.1.

Table 14.3.6 Treatment-Emergent Adverse Events Leading to Study Discontinuation (Safety Population)

Programming note: same format as Table 14.3.2.1.

[redacted]

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[redacted]

Table 14.4.1 Intranasal Examination Results (Safety Population)

Table 14.4.1 Intranasal Examination Results Safety Population				
	OC-01 1.2 mg/mL N=xx n/N1 (%)		Placebo N=xx n/N1 (%)	
Visit/Result	Left Nostril	Right Nostril	Left Nostril	Right Nostril
Visit 1 [1]				
Normal	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)
Abnormal	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)	xx/xx (xx.x)

Source: Listings 16.... O:\projects\ Oyster Point Pharma\OPP-005\tables\xxx.sas (ddmmmyyyy hh:mm)
Column header counts are the number of treated subjects.
N1 are the number of treated subjects with non-missing data at given visit.
[1] Screening visit

[redacted]

Oyster Point Pharma, Inc.

Clinical Protocol: OPP-005:

A Single-Center, Randomized, Controlled, Masked Clinical Trial to Evaluate the Efficacy of OC-01 Nasal Spray on Goblet Cell and Meibomian Gland Stimulation (The IMPERIAL Study)

Abbreviated Statistical Analysis Plan
Version 1.0

Prepared by [redacted]
Date: February 14, 2020

Prepared by:

[redacted]

Date: February 14, 2020

Author: [redacted]

Study OPP-005: A Single-Center, Randomized, Controlled, Masked Clinical Trial to Evaluate the Efficacy of OC-01 Nasal Spray on Goblet Cell and Meibomian Gland Stimulation (The IMPERIAL Study)

Brief Summary of Analysis:

The sample size for the study is not based on statistical power calculation and sample size at the end of the study is relatively small. For this reason, [redacted]

Meibography Analysis:

1. A change from Pre-treatment analysis will be performed, [redacted] Descriptive statistics consisting of the number of subjects (n), mean, standard deviation, median ,25th and 75th percentiles, and minimum and maximum will be used to summarize each time point (Pre-Treatment, Post Treatment) as well as the Change from Pre-treatment. Pre-treatment and post-treatment in area and perimeter [redacted]

2. A summary analysis [redacted] will also utilize descriptive statistics consisting of the number of subjects (n), mean, standard deviation, 25th and 75th percentiles, and minimum and maximum. [redacted]

3. A by subject listing for both area and perimeter will be provided containing each subjects meibography [redacted] number of meibography reads (n), mean, standard deviation, 25 and 75th percentiles, and minimum and maximum. These statistics will summarize the change from pre-treatment meibography read results for each subject by eye laterality and lid discretion.

Goblet Cell Analysis:

1. A change from Pre-treatment analysis will be performed, maintaining intrasubject, eye laterality independence for both the active 0.2% OC-01 treatment group as well as placebo. Descriptive statistics consisting of the number of subjects (n), mean, standard deviation, median ,25th and 75th percentiles, and minimum and maximum will be used to summarize each time point (Pre-Treatment, Post Treatment) as well as the overall Change from Pre-treatment. [redacted]

2. A summary analysis of Goblet Cell [redacted] utilize descriptive statistics consisting of the number of subjects (n), mean, standard deviation, 25th and 75th percentiles, and minimum and maximum, [redacted]

3. A by subject listing for both area and perimeter will be provided containing each subjects Goblet Cell measurement results detailing the eye laterality for each time point. [redacted] number of Goblet Cell measurements (n), mean, standard deviation, 25 and 75 percentiles, and minimum and maximum. These statistics will summarize the change from pre-treatment Goblet Cell measurement results for each subject by eye laterality.