STATISTICAL ANALYSIS PLAN

For

STUDY AOB2016-01

A Randomized, Double Blinded, Phase IIb/III, Decentralized Study of B244 Delivered as a Topical Spray to Determine Safety and Efficacy in Participants with Mild to Moderate Acne Vulgaris

VERSION: 2.0

Prepared By:

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Ben Mitchell, PhD
Statistician
Analytics Insight, Inc.

Date

Approvals:

8/29/2017

Spiros Jamas, Sc.D.
Founding CEO/Head of Therapeutics
AOBiome, LLC

Date

29AUG2017

Noah Craft, MD, Ph.D.
CEO
Science 37, Inc.

Date

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1 LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Description
ADaM	analysis data model
AE	adverse event
BMI	body mass index
CDISC	Clinical Data Interchange Standards Consortium
CM	concomitant medication
CRF	case report form
ECG	electrocardiogram
FDA	Food and Drug Administration
HR	heart rate
ICH	International Conference on Harmonisation
ITT	intent-to-treat
MedDRA	Medical Dictionary for Regulatory Activities
PT	preferred term
SAP	statistical analysis plan
SD	standard deviation
SE	standard error
SOC	system organ class
TEAE	treatment-emergent adverse event
WHO	World Health Organization

2 REVISION HISTORY

Version	Date	Document Author	Revision Summary
Version 1.0	21July2017	Ben Mitchell	Original
Version 2.0	28Aug2017	Ben Mitchell	Add compliance table and listing. Add listing for Blood Pressure outliers. Clarify the handling of missing observations. Add appendix describing imputation of Adverse Events dates and Concomitant Medications.

3 RELEVANT DOCUMENTS: PROTOCOL, AMENDMENTS AND CASE REPORT FORMS

Protocol: AVB244-002

Case Report Form (CRF): Version 1.0 (21 July 2017)

4 COMMITMENT TO GOOD STATISTICAL PRACTICE

4.1 DEFINITION OF GOOD STATISTICAL PRACTICE

ICH Guidance on Statistical Principles for Clinical Trials (ICH E9) implicitly defines good statistical practice. Good statistical practice includes both appropriate statistical designs to minimize bias and maximize precision of analysis plus operational excellence to assure credibility of results. The scientific design associated with any clinical trial is found in the protocol and in a more detailed statistical analysis plan such as this one.

We interpret the operational side of good statistical practice as a transparent, reproducible, and validated approach to acquiring and analyzing clinical trial data. Reproducible research depends upon process transparency and also provides auditability of the statistical analysis. Analysis transparency requires that a navigable electronic process chain exist from defining the objective of the analysis to creating the results.

4.2 USE OF STANDARDS

Data standards are foundational for creating an environment where tools can be leveraged at different points in the analysis process. Data standards for clinical development of drugs have been defined and are maturing under various initiatives through the Clinical Data Interchange Standards Consortium (CDISC). Analytics Insight, Inc. uses Analysis Data Model (ADaM) statistical analysis files for producing analysis results. Other applicable standards include regulatory guidances from FDA and ICH:

- ICH Guidance on the Structure and Content of Clinical Study Reports (ICH E3)
- ICH Guidance for Good Clinical Practice (ICH E6)

5 STUDY OBJECTIVES AND ENDPOINTS

5.1 OBJECTIVES

5.1.1 Primary Objective

To evaluate the safety and tolerability of B244 in participants with acne vulgaris.

To assess the efficacy of B244 in participants with acne vulgaris from baseline to week 12 (end of treatment) by

- Reduction in inflammatory lesion count from baseline to week 12
- IGA success at week 12

5.1.2 Secondary Objectives

To evaluate the efficacy of B244 in comparison to placebo in participants with acne vulgaris from baseline to weeks 2, 4, 8, 12, and 16, with the exception of cases where week 12 is primary. Further details will be provided in the section on analyses.

- Change in inflammatory lesion count
- Change in non-inflammatory lesion count

- Change in Total Lesion Count (sum of inflammatory and non-inflammatory)
- Change in IGA and IGA Success
- Improvement in patient reported quality of life score using the Skindex-16 questionnaire in participants with acne vulgaris

5.1.3 Exploratory Objectives

- To evaluate blood pressure collected by the home blood pressure monitor - at baseline and weeks 2, 4, 8, 12 and 16 in B244-treated participants compared to placebo.
- To evaluate facial skin microbiota in participants with acne vulgaris at baseline and weeks 2, 4, 8, 12 and 16 in B244-treated participants compared to placebo.

5.2 ENDPOINTS

5.2.1 Safety and Tolerability

- Safety and tolerability endpoints will consist of all adverse events reported during the study.

Efficacy and Exploratory endpoints will consist of observations at baseline and weeks 2, 4, 8, 12, and 16 unless otherwise stated.

5.2.2 Efficacy

- Number of Inflammatory Lesions
- Number of Non-Inflammatory Lesions
- Total Lesion Count (sum of inflammatory and non-inflammatory)
- Investigator Global Assessment (IGA)
- Skindex-16

5.2.3 Exploratory

- Systolic and Diastolic blood pressure from the home blood pressure monitor
- Microbial content, microbiota composition, and B244 presence

6 OVERALL STUDY DESIGN AND METHODS

Phase IIb/III, randomized, double blinded, decentralized clinical trial evaluating the safety, tolerability, and efficacy of B244 compared to placebo in the treatment of acne vulgaris

7 PRIMARY, SECONDARY, EXPLORATORY AND SAFETY VARIABLES

7.1 PRIMARY VARIABLES

- Reduction in inflammatory lesion count from baseline to week 12
- IGA success from baseline to week 12

7.2 SECONDARY VARIABLES

- Change in inflammatory lesion count from baseline to weeks 2, 4, 8 and 16
- Change in non-inflammatory lesion count from baseline to all visits: weeks 2, 4, 8, 12, and 16
- Change in Total Lesion Count (sum of inflammatory and non-inflammatory) from baseline to weeks 2, 4, 8, 12 and 16
- IGA success from baseline to weeks 2, 4, 8 and 16
- Mean change in IGA from baseline to weeks 2, 4, 8, 12 and 16
- Improvement in patient reported quality of life score using the Skindex-16 questionnaire in participants with acne vulgaris from baseline to weeks 2, 4, 8, 12, and 16.

7.3 EXPLORATORY VARIABLES

- Systolic and Diastolic blood pressure from the home blood pressure monitor - at baseline and weeks 2, 4, 8, 12 and 16
- Facial skin microbiota in participants with acne vulgaris at baseline and weeks 2, 4, 8, 12, and 16 in B244-treated participants compared to placebo. This will be an ad hoc analyzes.

7.4 SAFETY VARIABLES

The safety variables are:

- Incidence and severity of adverse events

8 SAMPLE SIZE AND STATISTICAL POWER CONSIDERATIONS

Primary efficacy power calculations assume a >25% difference between B244 treatment and placebo and a 15% dropout. As per FDA statistical guidance for co-primary endpoints, each of the endpoints comprising the co-primary endpoint will be tested at an alpha level of $p<0.05$. In order to achieve 90% power with a 5% Type I error rate, a total of 372 participants is required.

8.1 ASSESSMENT OF MULTIPLE PRIMARY EFFICACY VARIABLES

No adjustment will be made to alpha since it is required that all primary efficacy analyses be significant.

9 ANALYSIS SETS

9.1 EFFICACY ANALYSIS SET (INTENT TO TREAT SET)

All subjects who were randomized into the study and received at least 1 study drug application.

9.2 SAFETY ANALSYIS SET (INTENT TO TREAT SET)

All subjects who were randomized into the study and received at least 1 study drug application.

In this situation it is the same as the Efficacy Analysis Set.

9.3 PER PROTOCOL ANALYSIS SET

The cumulative amount of study drug exposure will be estimated by calculating the difference between the starting weight of the (4) bottles of drug at the time the drug was dispensed and the final weight of the (4) bottles at the last visit. The amount of product used per day will be estimated by dividing the change by the number of days the subject was on treatment. These weights will be compared to the weight of the product that would be used if the subject was compliant with the protocol and used the spray 2 times per day for 3 months.

Percent compliance will be summarized for each subject from date of first dose through the treatment period based on the net weight of the product administered. Net weight is calculated as the weight collected at a given visit week or if the subject stopped using the study drug at the visit minus the weight at Day 1. Based on information provided by AOBiome, the expected amount of study drug used per week is approximately 7.91 g/week for 4 sprays/application.

Percent Compliance = 100 × Net weight of study drug / Expected Net weight for 28 days of use

The Per-protocol analysis set will include subjects who were in the Efficacy analysis set, completed their Week 12 visit and had Percent Compliance ≥ 50%.

10 GENERAL CONSIDERATIONS FOR STATISTICAL ANALYSES

10.1 DATA PRESENTATIONS

10.1.1 Continuous Data Presentations

Unless otherwise specified, descriptive statistics for continuous data will be presented using the number of subjects with data to be summarized (n), mean, standard deviation (SD), median, minimum and maximum.

The same number of decimal places as in the raw data will be presented when reporting minimum and maximum; 1 more decimal place than in the raw data will be presented when reporting mean, LS mean, and median; and 2 more decimal places than in the raw data will be presented when reporting SD and SE.

In general, statistical analysis on continuous data will consist of observed values at baseline and post-baseline visits. Change from baseline and percent change from baseline will also be provided. In such instance where hypothesis testing will performed, active vs. control, ANCOVA will be used for Site and Baseline values.

10.1.2 Categorical Data Presentations

All categorical/qualitative data will be presented using frequency counts and percentages. In general, the total number of subjects (n) will be used as the denominator for percentage calculations, unless otherwise stated. For AE summaries, the percentages will be based on the number of subjects who received the study treatment.

Categorical data will be summarized based on reduced denominators (i.e., only subjects with available data will be included in the denominators), where individual variable values are missing. The number of subjects with data and number of subjects with missing category will be summarized, when missing values exist.

All percentages will be presented to 1 decimal place, unless otherwise specified. Percentages equal to 100 will be presented as 100%; percentages will not be presented for zero frequencies.

10.1.3 Tests of Hypothesis and Significance Levels

The statistical tests used for the analysis of baseline variables and efficacy parameters will be performed at $\alpha = 0.10$ significance level. All tests will be two-sided.

10.1.4 Multiple Records at a Time Point

For analysis purposes, mean values of multiple measurements collected for individual subjects at a given time point (or visit) will be used in analysis for that time point. All collected measurements and the mean values will be listed.

10.1.5 Listing Presentations

Subject listings of analysis data that support summary tables and figures along with their source data will be provided. Measurements from subjects excluded from the pre-defined analysis sets or extra measurements (such as unscheduled or repeat assessments) will not be included in summary tables unless specified otherwise, but will be included in the subject listings. In general, subject listings will be sorted by subject number, and assessment date and time, if applicable.

All analyses and summaries will be produced using SAS® version 9.4.

10.2 DEFINITIONS AND DERIVED VARIABLES

10.2.1 Baseline Value

Baseline values are defined as the last non-missing assessment prior to the first dose of study drug, unless otherwise specified. If multiple measurements were made at the last visit prior to the first dose of study drug, then the baseline value will be the mean of all non-missing results from the last visit prior to the first dose of study drug.

10.2.2 Last Available Value

The last available value is defined as the assessment or measurement collected at the "final visit" while on study drug (collected ≤ 1 day after the last study drug dose).

10.2.3 Study Day

Study Day follows the CDISC SDTM standard and is defined as (Assessment date – First date of study drug dosing) + 1, where the assessment date is on or after the first date of dosing; (Assessment date – First date of study drug dosing), where the assessment date is before the first date of dosing.

The SDTM Study Day may be defined differently from the Protocol specified Visit Day. In this document, "Day x" refers to the protocol specified Day x. "Study Day y" refers to the number of days from first dosing date that is defined in this section. There will be no Study Day 0.

10.2.4 Age

Age (years) will be calculated as the number of years between date of birth and date of informed consent, expressed as an integer. E.g., a subject will be considered 14 until the day of his 15th birthday.

10.2.5 Efficacy Variables

Efficacy variables for: inflammatory lesions, Non-Inflammatory lesions, and Total Lesion Count are:

- Number of Lesions
- Change from Baseline of Number of Lesions
- Percent Change from Baseline of Number of Lesions

Number of Lesions will be assessed for baseline and post-baseline visits (Week 2, 4, 8, 12 and 16). Change from Baseline and Percent Change from Baseline will be assessed at post-baseline visits (Week 2, 4, 8, 12 and 16).

IGA will be categorized by both score and Success.

Success is defined as a post baseline score of either 0 or 1. Score will be categorized for baseline and post-baseline visits (Week 2, 4, 8, 12 and 16). Success will be categorized for post-baseline visits (Week 2, 4, 8, 12 and 16).

IGA will further be analyzed by

- Score
- Change from Baseline of Score
- Percent Change from Baseline of Score

Score will be assessed for baseline and post-baseline visits (Week 2, 4, 8, 12 and 16). Change from Baseline and Percent Change from Baseline will be assessed at post-baseline visits (Week 2, 4, 8, 12 and 16).

Skindex-16 Quality of Life Sub scores

- Total Skindex-16 score: Mean all responses for Skindex-16 questionnaire
- Symptom Subscale: Mean of questions 1–4
- Emotional Subscale: Mean of questions 5–11
- Functional Subscale: Mean of questions 12–16.

Efficacy variables for each of the above four Skindex-16 Quality of Life Sub scores will be:

- Mean of Scores
- Change from Baseline of Mean of Scores
- Percent Change from Baseline of Mean of Scores

Mean of Scores will be assessed for baseline and post-baseline visits (Week 2, 4, 8, 12 and 16). Change from Baseline and Percent Change from Baseline will be assessed at post-baseline visits (Week 2, 4, 8, 12 and 16).

To amplify the meaning of "Mean Score." E.g., if there are 14 non-missing values and the sum of those 14 values is 42, then the score is 42/14 = 3. The same rule will apply to the sub scores.
using the Skindex-16 and Common Terminology Criteria for Adverse Events to assess rash symptoms: results of a pooled-analysis (N0993)
Pamela J. Atherton, Charles L. Loprinzi, Michelle A. Neben Wittich, Robert C. Miller, Aminah Jatoi, and Jeff A. Sloan

10.2.6 Primary Efficacy Variables:

1. Reduction in inflammatory lesion count at week 12
2. IGA Success at week 12

10.2.7 Safety Variables

10.2.7.1 Study Drug Exposure, Compliance, and Average Daily Dose

Section 9.3 describes how to derive compliance and average daily dose.

10.2.7.2 Treatment-Emergent Adverse Events

Treatment-emergent adverse events (TEAEs) are defined as all AEs that begin on or after date/time of first dose of study drug.

10.2.7.3 Concomitant Medications

Prior medications are those medications that were taken prior to the first date of study drug dosing. Concomitant medications are those medications taken during the treatment period. A prior medication can also be a concomitant medication if it continued into the treatment period of the study. Specifically, concomitant medications are medications

- that are continued from screening and continued after start of study drug dosing,
- with start dates or stop dates within the treatment period, or
- that are taken after first study drug dosing or continued after treatment period.

10.3 GENERAL METHOD FOR HANDLING MISSING DATA AND DROPOUTS

In general, missing data will not be imputed.

10.4 SAFETY DATA HANDLING

10.4.1 Adverse Events

All AEs will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) Dictionary.

Adverse events with incomplete start dates will be considered TEAEs, if:

- Day and month are missing and the AE start year is equal to or after the year of the first date of study drug dosing and full or partial AE end date is on or after the year of the first date of study drug;
- Day is missing and the AE year and month are equal to or after the year and month of the first date of study drug dosing;
- AE start year is missing and full or partial AE end date is on or after the first date of study drug.

If severity or relationship of an AE to study drug is not recorded, the severity or relationship will be imputed as “severe” or relationship as “related.”, for analysis purposes.

10.4.2 Concomitant Medications

All medications will be mapped according to the World Health Organization (WHO) Drug Dictionary.

In principle, missing medication start dates and stop dates will not be imputed. For the display of individual concomitant medications, listings will contain partial date information.

10.5 USE OF A "SUBSET" OF SUBJECTS

No Subset analysis of subjects will be performed.

11 STUDY SUBJECTS

11.1 ENROLLMENT AND DISPOSITION

Number of subjects screened and the reasons for screen failures will be documented in the CSR. Enrollment and disposition will be summarized for all screened subjects. The subject disposition summary will include:

- Subjects who were screened
- Subjects who failed screening
- Subjects who were in the Efficacy Analysis Set
- Subjects who were in the Per-protocol Analysis Set
- Subjects who were in the Safety Analysis Set
- Subjects who completed study
- Subjects who terminated study prematurely
- The primary reason for premature termination

A subject disposition listing will be provided for all enrolled subjects.

12 SUBJECT CHARACTERISTICS

12.1 DEMOGRAPHICS

Demographics will be summarized by treatment group for the Safety Population. Demographic characteristics will include age, age category, sex, race and ethnicity. Demographics information will be listed.

12.2 BASELINE CHARACTERISTICS

Baseline characteristics will be summarized by treatment group for the Safety Population.

Baseline characteristics include female reproductive status and baseline pregnancy test results.

All of the above information will be provided in a subject data listing.

13 EFFICACY ANALYSIS

In this study, efficacy data analyses will be based on subjects who are in the Efficacy Analysis Set. Analysis results will be presented by treatment group.

13.1 PRIMARY ENDPOINT ANALYSIS

For primary efficacy variables (all at week 12) Reduction in inflammatory lesion count and IGA Success will be analyzed using ANCOVA controlling for Site and Baseline.

13.2 SECONDARY AND EXPLORATORY ENDPOINTS ANALYSES

13.2.1 Analysis of Secondary Endpoints

For efficacy variables Reduction in inflammatory lesion count, Reduction in non-inflammatory lesion count, IGA Success at Weeks 2, 4, 8 and 16 and Reduction in total (sum of inflammatory

and non-inflammatory) lesion count at Weeks 2, 4, 8, 12 and 16, the Cochran-Mantel-Haenszel test with investigator sites as stratum will be used. For the Skindex-16 variables, the difference from Weeks 2, 4, 8, 12, and 16 to baseline for each visit will use a two-sample t-test.

Secondary Endpoint values will be included in a Listing.

13.2.2 Analysis of Exploratory Endpoints

Systolic and Diastolic blood pressure from the home blood pressure monitor at baseline and weeks 2, 4, 8, 12 and 16 will be summarized by treatment group and included in a Listing.

Facial skin microbiota results will appear in an ad hoc analysis.

13.2.3 Dosing Summaries

Summary of Dosing and compliance will be presented. Listings of Dosing and Compliance will be included

14 SAFETY ANALYSES

Safety will be evaluated from safety variables of special interest: concomitant medications; TEAEs; and serious adverse events (SAEs). Summaries of safety information will be presented for the Safety Population. Listings will be provided for Concomitant medications, Adverse Events and Blood Pressure findings.

14.1 CONCOMITANT MEDICATIONS

14.1.1 Prior and Concomitant Medications

All reported medications (prior and concomitant) will be summarized. If a subject took a medication prior to and after first study drug dosing, the subject will be counted in both summaries of prior and concomitant medication. Subjects receiving multiple medications within

a given anatomical therapeutic chemical (ATC) classification level will be counted only once for the ATC classification level. Subjects receiving multiple medications within a standardized medication name will be counted only once for the standardized medication name. ATC classification level and standardized medication names will be presented alphabetically. All medications will be listed.

14.2 ADVERSE EVENTS

The Treatment-emergent adverse event (TEAE) summary table will be subject based and be presented by the number and percentages of subjects reporting events. TEAEs will be summarized by system organ class (SOC) and preferred term (PT) using Medical Dictionary for Regulatory Activities (MedDRA. Listings will be provided for all AEs, TEAEs, and SAEs.

Given that roughly 186 subjects will receive active treatment, there is about an 85% chance that an Adverse Event with a 1% chance of occurring will be observed in that population, and near certainty (100%) chance that an Adverse Event with a 5% chance of occurring will be observed

14.3 BLOOD PRESSURE FINDINGS

Descriptive statistics for systolic blood pressure, diastolic blood pressure will be provided for each treatment group and each visit. All blood pressure parameters will be included in a listing.

15 DEVIATION FROM PROTOCOL

An alpha=10% for significance will be used rather than the 5% as indicated in the protocol.

16 APPENDIX

16.1 IMPUTATION OF AE AND CONCOMITANT MEDICATION DATES

Adverse Event

If onset date is completely missing, onset date is set to date of first dose.

If (year is present and month and day are missing) or (year and day are present and month is missing):

If year = year of first dose, then set month and day to month and day of first dose

If year < year of first dose, then set month and day to December 31st.

If year > year of first dose, then set month and day to January 1st.

If month and year are present and day is missing:

If year=year of first dose and

if month = month of first dose then set day to day of first dose date

if month < month of first dose then set day to last day of month

if month > month of first dose then set day to 1st day of month

if year < year of first dose then set day to last day of month

if year > year of first dose then set day to 1st day of month

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

Concomitant Medications

If start date is completely missing:

start date will not be imputed.

If (year is present and month and day are missing) or (year and day are present and month is missing):

set month and day to January 1.

If year and month are present and day is missing:

set day to 1st day of month.

If end date is completely missing:

end date will not be imputed.

If (year is present and month and day are missing) or (year and day are present and month is missing):

set month and day to December 31.

If year and month are present and day is missing:

set day to last day of the month.

16.2 TIME OF EVENTS TABLE

Visit name (Day)	Screening (Day 0)	Baseline (Day 1)	Week 2 (Day 14)	Week 4 (Day 28)	Week 8 (Day 56)	Week 12 (Day 84)	Week 16 (Day 112)	Unscheduled Visit
Visit Window, in Days	-28 to -8	-7 to 1	+/-3	+/-3	+/-3	+/-3	+/-3	
Informed Consent[1]	X							
Inclusion/Exclusion Criteria	X	X						
Demographics	X	X						
Medical History / Current Medical Conditions	X	X						X
Microbiota swabs		X		X	X	X	X	X
Skindex-16		X	X	X	X	X	X	X[2]
Investigational Product Administration		X	X	X	X	X		
Photography		X	X	X	X	X	X	X[2]
IGA		X	X	X	X	X	X	X[2]
Lesion Count		X	X	X	X	X	X	X[2]
Blood Pressure		X	X	X	X	X	X	X[2]
Concomitant Medications[3]	As required							
Adverse Events / Serious Adverse Events	As required							

1: Informed consent must be provided by all patients before any screening procedures are performed.

2: If study participant has an unscheduled visit to end study participation, these study procedures will be conducted

3: A thorough review of any concomitant medications (including medication name, dose, unit, frequency, and route) should be performed at every visit.

16.3 LIST OF TABLES

No.	Description
1	Subject Disposition – Efficacy Analysis Set
2	Demographics– Efficacy Analysis Set
3	Medical History– Efficacy Analysis Set
4	Summary of Concomitant Medications – Efficacy Analysis Set
5	Study Drug Administration– Efficacy Analysis Set
6	Compliance
7	Reduction in Inflammatory Lesion Count at Week 12– Efficacy Analysis Set
8	IGA Success at Week 12– Efficacy Analysis Set
9	Change in Inflammatory Lesion Count at Week 12– Per Protocol Set
10	IGA Success at Week 12 – Per Protocol Set
11	Change in Inflammatory Lesion Count at Weeks 2, 4, 8 and 16 – Efficacy Analysis Set
12	Change in Non-inflammatory Lesion Count at Weeks 2, 4, 8, 12, and 16 – Efficacy Analysis Set
13	IGA Success at Weeks 2, 4, 8 and 16 – Efficacy Analysis Set
14	Change IGA at Weeks 2, 4, 8 and 16 – Efficacy Analysis Set
15	Reduction in Total Lesion Count (Sum of Inflammatory and Non-inflammatory) at Weeks 2, 4, 8, 12 and 16 – Efficacy Analysis Set
16	Quality of life score using the Skindex-16 Questionnaire at Weeks 2, 4, 8, 12, and 16 – Efficacy Analysis Set
17	Change in Inflammatory Lesion Count at Weeks 2, 4, 8 and 16 – Per Protocol Set
18	Change in Non-inflammatory Lesion Count at Weeks 2, 4, 8, 12, and 16 – Per Protocol Set
19	IGA Success at Weeks 2, 4, 8 and 16 – Per Protocol Set
20	Change IGA at Weeks 2, 4, 8 and 16 – Per Protocol Set
21	Change in Total Lesion Count (Sum of Inflammatory and Non-inflammatory) at Weeks 2, 4, 8, 12 and 16 – Per Protocol Set
22	Quality of Life Score using the Skindex-16 Questionnaire at Weeks 2, 4, 8, 12, and 16 – Per Protocol Set
23	Blood Pressure Summary by Visits – Efficacy Analysis Set
24	Blood Pressure Summary by Visits – Per Protocol Set
25	Adverse Events by Severity – Safety Analysis Set
26	Adverse Events Related to Study Treatment by Severity – Safety Analysis Set
27	Adverse Events leading to Discontinuation of Study Treatment by Severity – Safety Analysis Set
28	Serious Adverse Events – Safety Analysis Set
29	Serious Adverse Events Related to Study Treatment – Safety Analysis Set
30	Serious Adverse Events Leading to Discontinuation of Study Treatment – Safety Analysis Set

16.4 LIST OF LISTINGS

No.	Description
1	Disposition
2	Demographics
3	Baseline Characteristics
4	Medical History
5	Concomitant Medications
6	Previous Medications
7	Study Drug Administration
8	IGA and Lesion Count
9	Skindex-16 Questionnaire
10	Skin Swab Results
11	Adverse Events
12	Serious Adverse Events
13	Blood Pressure
14	Study Drug Medication Change
15	Protocol Deviations and Violations

16.5 LIST OF FIGURES

No.	Description
1	Change in Inflammatory lesion count at Weeks 2, 4, 8, 12, and 16 – Efficacy Analysis Set
2	Change in Non-inflammatory lesion count at Weeks 2, 4, 8, 12, and 16 – Efficacy Analysis Set
3	IGA Success at Weeks 2, 4, 8 and 16 – Efficacy Analysis Set
4	IGA Success at Weeks 2, 4, 8 and 16 – Efficacy Analysis Set