A Randomized, Double-Blind Study to Compare the Efficacy, Safety and Long-Term Safety of Topical Administration of FMX101 for 1 Year in the Treatment of Moderate-to-Severe Acne Vulgaris, Study FX2014-04

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16.1.9 Documentation of Statistical Methods

Statistical Analysis Plan, 14 Feb 2017

Statistical Analysis Plan, Open-Label Phase Amendment 1, 07 Dec 2017

Foamix Pharmaceuticals, Inc

Protocol No. FX2014-04
Novella Clinical No. CT9901615

STATISTICAL ANALYSIS PLAN

A RANDOMIZED, DOUBLE-BLIND STUDY TO COMPARE THE EFFICACY, SAFETY AND LONG-TERM SAFETY OF TOPICAL ADMINISTRATION OF FMX-101 FOR 1 YEAR IN THE TREATMENT OF MODERATE-TO-SEVERE ACNE VULGARIS

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February 14, 2017

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List of Abbreviations and Definitions of Terms

Abbreviation	Definition
AE	Adverse event
ANCOVA	Analysis of covariance
CFR	Code of Federal Regulations
eCRF	Electronic case report form
EOS	End of study
FDA	Food and Drug Administration
IGA	Investigator's global assessment
ITT	Intent-to-treat (population)
IWRS	Interactive web-based response (system)
MedDRA	Medical Dictionary for Regulatory Activities
PI	Principal investigator
PP	Per protocol (population)
SAE	Serious adverse event
SAP	Statistical Analysis Plan
TEAE	Treatment emergent adverse event
UPT	Urine pregnancy test
US	United States

1. INTRODUCTION

This Statistical Analysis Plan (SAP) is based on the study Protocol Version 4 dated October 14, 2016. This document provides additional details concerning the statistical analyses outlined in the protocol and reflects any changes to the protocol from any amendments. This plan will not repeat all the definitions given in the protocol but will provide further details of the summaries and analyses planned therein.

2. STUDY OBJECTIVES

The objectives of this study are:

- To evaluate the efficacy in the treatment of acne compared to vehicle of topical FMX-101, 4% administered daily for 12 weeks
- To evaluate the safety compared to vehicle of topical FMX-101, 4% administered daily for 12 weeks
- To evaluate the long-term safety of topical FMX-101, 4% administered daily for up to 40 additional weeks

3. STUDY DESIGN

The one-year study will have 2 parts. The first 12 weeks will be double-blind (DB) treatment with FMX-101, 4% or vehicle foam. The remaining 40 weeks will involve open-label (OL) treatment with FMX-101, 4% by any subjects who complete the first part of the study.

Part 1 – Double-blind

This is a randomized, multicenter, double-blind, vehicle-controlled, 2-arm study to evaluate the safety and efficacy over 12 weeks of FMX-101 minocycline foam, 4%, compared to vehicle, in the treatment of subjects with moderate to severe facial acne vulgaris.

Qualified subjects will be randomized to receive 1 of the following 2 treatments:

- FMX-101, 4% minocycline foam
- Vehicle foam

Subjects with qualifying lesion counts and Investigator's Global Assessments (IGA) of acne severity scores and will be assigned to 1 of 2 treatments according to the randomization schedule. Subjects will apply the assigned study drug topically once daily for 12 weeks as directed. Subjects will be advised to apply the study drug at approximately the same time each day, preferably in the evening before bedtime. Both the Investigator and subject will be blinded to the study drug identity.

Subjects will return for visits at Weeks 1, 3, 6, 9, and 12. Efficacy evaluations (acne lesion counts and IGAs will be performed at Weeks 3, 6, 9, and 12 during the study.

Part 2 – Open-label

At the Week 12 Visit, subjects may be invited to continue into the open-label part of this study for an additional 9 months of treatment. Subjects will be enrolled in this phase of the study until a total of approximately 400 subjects from Studies FX2014-04 and FX2014-05 have elected to continue in the open-label portion of their respective study. Subjects who elect to continue into the open-label part of this study will receive supplies of active FMX-101, 4% minocycline foam.

Treatment during this part of the study will be guided by each subject's clinical response. The Investigator may elect to suspend treatment of some or all areas if there is clinical improvement or resolution of the acne in those areas. Even if the treatment is partially or completely temporarily suspended, the subject will continue in the study and make all scheduled clinic visits. If at any time the acne recurs or worsens, treatment of the affected areas may be resumed.

Subjects may be discontinued from the study at any time if their disease becomes refractory or they become intolerant of the product.

4. HARDWARE AND SOFTWARE

Statistical analysis will be performed following Novella/TKL standard operating procedures and on the Novella/TKL computer network. All statistical analysis will be performed using SAS Version 9.2 with program code prepared specifically for the project by qualified Novella Clinical statisticians and SAS programmers.

The SAS programs will generate rich-text-formatted (RTF) output with the "RTF" extension using the SAS Output Delivery System (ODS). The summary tables and listings will be formatted using the Times New Roman 9-point font. The RTF output is included in report documents prepared with Microsoft Word and converted to PDF format without typographical change.

Datasets will be created and taken as input to validated SAS programs to generate the report-ready tables, listings, and figures. Each output display will show the names of the data sets and SAS program used to produce it.

5. DATABASE CLOSURE

The database closure will occur after the completion of each part of the study.

After completion of all data review procedures, validation of the project database, and approval of the data review document by the study sponsor, the clinical database will be closed. Any change to the clinical database after this time will require written authorization, with explanation, by the Sponsor and the Biostatistician.

6. SAMPLE SIZE DETERMINATION

In a phase 2 study, the proportion of subjects with an IGA score of 0 or 1 after [redacted] of treatment was [redacted] in the minocycline 4% foam group compared to 2% in the vehicle group. The following table provides a few alternate assumptions and corresponding sample sizes. Power was set to 90% and type-1 error to two-sided 0.05. Sample size was calculated based on Fisher's Exact test.

Vehicle IGA (0,1)	Minocycline 4% foam IGA (0,1)	Sample sizes (vehicle, active)
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Assuming [redacted] dropout rate, 300 subjects on active, and 150 subjects on vehicle will provide at least 90% power for a statistically significant difference on IGA 0 or 1. In the same phase 2 study, the change from baseline in inflammatory lesions was [redacted] in the minocycline 4% foam versus [redacted] in the vehicle group. The standard deviation in change from baseline was approximately [redacted] he following table shows alternate assumptions and corresponding sample sizes, for 90% power and a two-sided type 1 error of 0.05. The sample sizes were calculated using a t-test.

Vehicle mean inflammatory lesion reduction	Minocycline 4% foam mean inflammatory lesion reduction	Sample sizes (vehicle, active)
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

To summarize, using some conservative estimates of the effect on minocycline 4% foam versus the vehicle for both IGA and change in inflammatory lesions at week 12, 300 subjects on active, and 150 on vehicle will provide > 90% power for s statistically significant difference.

Another consideration for the sample size must be given to the secondary endpoint of noninflammatory lesions which will be compared to the vehicle for non-inferiority. The margin for non-inferiority will be [redacted] of the percent change from baseline to week 12. The standard deviation (SD) of percent change from baseline in noninflammatory lesions is projected to be approximately [redacted] With a [redacted] non-inferiority margin, there will be approximately 90% power to show non-inferiority with sample sizes of 300 and 150 in the Minocycline 4% foam and vehicle groups respectively. The margin of [redacted] appears to be reasonable given that the non-inflammatory lesions is a secondary endpoint. Any smaller margin will require a larger sample size for the secondary endpoint than for the primary endpoint.

The assumption for the SD of percentage change from baseline in non-inflammatory lesions was confirmed by a blinded review of CCI subjects completing week 12, which reported an SD of CCI%.

7. ANALYSIS POPULATIONS

The following populations will be defined for analysis:

- Intent-To-Treat (ITT) population: all randomized subjects.
- Per Protocol (PP) population: defined as the subset of the ITT population without any protocol deviations that may have an impact on the efficacy assessments. Subjects to be included in the PP population will be determined by the Sponsor/CRO prior to the unblinding of the study.

  Subjects may be excluded from the PP population if any of the following are met:

  - Failure to meet Inclusion/Exclusion criteria;
  - Have administered any interfering concomitant medications
  - Have not, in the opinion of the investigator, been compliant with the treatment regimen (e.g. reported frequent missed doses)
  - Randomization error

  Prior to breaking the blind, additional criteria for exclusion from the PP population may be included to accommodate for unforeseen events that occurred during the conduct of the study.
- Safety Population: all randomized subjects who take any study product. Subjects who have no post-Baseline assessments will be included in the Safety population unless all dispensed study drug is returned unused.

The ITT population will be the primary population for efficacy analysis. The PP population will be secondary for the co-primary endpoints only. The Safety population will be used for the analyses of safety endpoints.

All efficacy analyses will be conducted according to the randomized treatment assignment; all safety analyses will be conducted according to the treatment actually received.

8. HANDLING OF MISSING DATA

The primary population for all efficacy analyses will be the ITT population. For the analyses of the co-primary and secondary efficacy endpoints based on the ITT population, a variety of methods will be used to impute missing data, including multiple imputation (MI), last-observation-carried forward (LOCF), and baseline observation carried forward (BOCF). MI will be the primary imputation method. Sensitivity analyses using LOCF and BOCF will be

performed to assess the robustness of alternate imputation assumptions. All analyses using the PP population will use the Observed-Cases (OC) approach. i.e., there will be no imputation for missing data at any time point. No other imputations will be made unless otherwise specified.

The imputation procedures for post-baseline missing inflammatory lesion counts and missing IGA scores are described below.

- LOCF: The last observed value will be carried forward for any subsequent missing values. Baseline values will not be carried forward.
- BOCF: The baseline value will be used for any missing post-baseline values.
- MI: Multiple imputations is a simulation based approach where missing values are replaced by multiple Bayesian draws from the conditional distribution of missing data given the observed data and covariates, creating multiple completed data sets. These completed datasets can then be analyzed using standard analysis methods.

  MI procedures for *inflammatory lesion counts*:

  Intermittent missing values of inflammatory lesion counts will be imputed separately for each treatment group using the Markov Chain Monte Carlo (MCMC) method. 500 copies of the dataset with monotonic missing pattern will be generated.

  For each of the 500 datasets, missing values at scheduled visits (Weeks 3, 6, 9, and 12) will be imputed sequentially using an analysis of covariance (ANCOVA) model including treatment, baseline inflammatory lesion count, and inflammatory lesion counts at the previous scheduled visits. Specifically, missing values at Week 3 will be imputed based on the above mentioned model where the baseline value is included as a covariate. Missing values at Week 6 will be imputed where both the baseline value and Week 3 value, which might be imputed, are included as covariates. Missing values at each scheduled visit will be imputed in this manner until values at Week 12 are obtained. SAS Proc MI using the monotone regression method will be used.

  MI procedures for *IGA Treatment Success*:

  The imputation of post-baseline IGA scores will be performed following a similar approach as described above for inflammatory lesion counts. Intermittent missing IGA scores will be imputed separately for each treatment group where 500 copies of the dataset with monotonic missing pattern will be generated. For each of the 500 datasets, missing values at scheduled visits (Weeks 3, 6, 9, and 12) will be imputed sequentially using an ANCOVA model including treatment, baseline IGA score, and IGA scores at the previous scheduled visits. The logistic regression method for monotone data will be used for the imputation. IGA Treatment Success status (Yes/No) will then be derived based on the imputed dataset.

  A pre-specified seed number of CCI [redacted] will be used in all imputation procedures as described above.

9. DATA CONVENTIONS FOR ANALYSIS

9.1 General Statistical Principles

All statistical processing will be performed using the SAS system (Version 9.2 or higher).

All observed and derived variables (e.g., change from baseline, percentage change from baseline, Treatment Success) used in the summaries of analyses will be presented in by-subject listings. Descriptive statistics will be used to provide an overview of the efficacy and safety results. For categorical parameters, the number and percentage of subjects in each category will be presented. Missing responses will be enumerated, but the calculation of percentages will exclude missing responses. For quantitative variables (e.g., age), descriptive statistics will include number of subjects with non-missing data, mean, standard deviation (SD), median, minimum value and maximum value.

All efficacy analyses will be conducted according to the subject's randomized treatment; all safety analyses will be conducted according to the actual treatment received.

All hypothesis testing will be conducted using two-sided tests with α=0.05 level of significance unless otherwise specified. No adjustments for multiple comparisons are planned.

9.2 Study Day

Day 1 is defined as the date of first study drug administration. Study day is calculated relative to the date of Day 1.

9.3 Baseline and Change from Baseline

Baseline value is defined as the last non-missing value prior to the first dose of study drug. Changes from Baseline in lesion count will be calculated as the Baseline value minus the post-Baseline value. Thus, a positive change will reflect a reduction in lesion count. The percent change from Baseline lesion count will be calculated as the Baseline value minus the post-Baseline value divided by the Baseline value, expressed as a percentage. Thus, a positive percent change will reflect a reduction in lesion count.

9.4 Analysis Visit Window

Efficacy endpoints will be analyzed according to their windowed visits defined by actual study day. If more than one visit occurs within a single visit window, then the analysis will take the one closest to the target day. The following analysis visit windows will apply:

Visit	Week	Target Day	Efficacy Assessment Window
Double-Blind Phase			
2	1	7	Post-dose ─ Day 14
3	3	21	15 ─ 31
4	6	42	32 ─ 52
5	9	63	53 ─ 73
6	12	84	74 ─ 94
Open-Label Phase			
7	16	112	95 ─ 133
8	22	154	134 ─ 175
9	28	196	176 ─ 217
10	34	238	218 ─ 259
11	40	280	260 ─ 301
12	46	322	302 ─ 343
13	52	364	344 ─ 384

10. STATISTICAL EVALUATION

10.1 Interim Analysis

No interim analysis is planned.

10.2 Subject Disposition

The number and percentage of subjects who are screened, randomized, included in each analysis population, who complete the study, withdraw from the study (overall and by reason for withdrawal), and who are excluded from the PP population (overall and by reason for exclusion) will be summarized, overall, by treatment group and by sites.

A by-subject enrollment and disposition listing will be presented for all randomized subjects. Subjects who are screen failures and subjects who are not randomized will also be presented in a separate listing.

10.3 Protocol Deviation

Protocol deviations will be presented in a by-subject listing.

10.4 Demographic and Baseline Characteristics

Demographics and baseline characteristics will be summarized overall and by treatment for the ITT, PP and Safety populations. The following demographic and baseline variables will be included:

- Age (years)
- Age group (9-<13 years , ≥13-<18 years, ≥18 years)
- Sex
- Race
- Ethnicity
- Baseline lesion count (inflammatory, noninflammatory, total)
- Baseline IGA score (moderate=3, severe=4)

10.5 Study Medication Exposure and Compliance

The following parameters of study medication exposure will be summarized by treatment group and study period for the ITT and PP populations:

- Total number of days of exposure to study drug, defined as the date of last dose of study drug minus date of first dose of study drug plus 1;
- Amount of drug dispensed
- Amount of drug used
- Amount of drug per day

Amount of drug used is defined as the difference in weight between the returned and dispensed canisters, where weight of dispensed canisters will be calculated as the product of total number of dispense canister and the unit weight per canister.

Investigator's assessment of subject's compliance (Yes, No) with the treatment regimen at each visit will be summarized by treatment using frequency counts and percentages.

10.6 Prior and Concomitant Medications

Prior (with stop dates prior to Day 1) and concomitant medications (ongoing or with stop dates on or after Day 1) for all randomized subjects will be provided in a by-subject listing.

10.7 Medical/Surgical History

Past and current medical conditions for all randomized subjects will be provided in a by-subject listing. Surgical history will also be provided in a by-subject listing.

10.8 Efficacy Analyses

10.8.1 Primary Efficacy Endpoints

The co-primary efficacy endpoints are:

- The absolute change from Baseline in the inflammatory lesion count at Week 12
- Treatment Success (dichotomized as Yes/No) at Week 12, where success is defined as an IGA score of 0 or 1, and at least a 2-grade improvement (decrease) from Baseline

10.8.2 Secondary Efficacy Endpoints

The secondary efficacy endpoints will include the following:

- The percent change from Baseline in the noninflammatory lesion count at Week 12
- The absolute change from Baseline in the inflammatory lesion count and IGA Treatment Success at the interim visit at Week 9
- The absolute change from Baseline in the inflammatory lesion count and IGA Treatment Success at the interim visit at Week 6

10.8.3 CCI

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10.9 Efficacy Analyses

10.9.1 Primary Efficacy Analyses

In order to attain the primary efficacy goal of FMX-101 4% to be considered superior to vehicle, both co-primary efficacy endpoints must be significant (i.e., attaining significance at the two-sided 0.05 level without adjustment for multiplicity). The null hypotheses of the equality of FMX-101 4% and vehicle are:

- H_{01}: the absolute changes from Baseline in inflammatory lesion count at Week 12 in the two treatment groups are equal

- H_{02}: the IGA success rates at Week 12 in the two treatment groups are equal

The primary efficacy analyses will be based on the ITT population using MI and are as follows:

- Absolute change from baseline in inflammatory lesion count:

  For each of the multiple imputed datasets, change from baseline in inflammatory lesion count will be analyzed using an ANCOVA model, with treatment as a main effect, baseline inflammatory lesion count as a covariate, and investigational site a blocking factor. The difference in the mean change from baseline between FMX-101 4% and vehicle, along with its estimated standard error (SE) will be reported. These results will be combined in Proc MIANALYZE using Rubin's formula and the resulting p-value will be used for inference at the 0.05 level of significance. The combined estimated mean difference in change from baseline (FMX-101 4% minus vehicle) and the associated 95% confidence interval (CI) will be reported.

- Dichotomized IGA Success Rate:

  For each of the multiple imputed datasets, the dichotomized IGA (Yes/No) will be analyzed using a Cochran-Mantel-Haenszel (CMH) test, stratified by investigational site. The Mantel-Haenszel risk ratio, along with its estimated SE, 95% CI and the associated p-value will be reported.

  These results will be combined in Proc MIANALYZE and the resulting p value will be used for inference at the 0.05 level. The combined estimated log of the risk ratio (FMX-101 4% / vehicle) and associated 95% confidence limits will be back-transformed.

  If the overall IGA Treatment Success rate is less than 10%, the simple proportion of responders in each treatment group, the proportion difference, along with the estimated SE will be reported and combined in Proc MIANALYZE. The resulting p-value, proportions, proportion difference and their 95% CIs will be presented.

Sensitivity analyses of the co-primary efficacy endpoints will be performed using the same method as described above for each MI dataset. Sensitivity analyses will include:

- ITT population (OC, LOCF, and BOCF)
- PP population (OC)

Homogeneity among investigational sites will be assessed by including an investigational site by treatment interaction in the ANCOVA model of the ITT OC analysis of the absolute change from baseline in inflammatory lesion counts. Investigational site by treatment interaction will be tested at 0.1 level, and if significant, it will further be explored.

10.9.2 Secondary Efficacy Analyses

Secondary efficacy endpoints will be analyzed similar to the appropriate co-primary efficacy parameter.

Secondary efficacy endpoints will be tested sequentially at 0.05 level of significance, only if both co-primary efficacy endpoints are significant in the primary analyses.

The first secondary endpoint of noninflammatory lesions at Week 12 will be tested initially as a non-inferiority comparison of FMX-101, 4% to vehicle. The non-inferiority margin is defined as CCI of the noninflammatory lesion percent reduction in the vehicle group at Week 12. A lower 97.5% confidence limit will be calculated for μa-0..85×μv, where μa and μv are the mean percent reduction of noninflammatory lesions of FMX-101, 4% and vehicle respectively. If the confidence limit is above 0, non-inferiority will be concluded. If non-inferiority is concluded, the superiority of FMX-101, 4% to vehicle for noninflammatory lesions at Week 12 will be tested.

The sequential testing will proceed according to the order in Section 10.8.2. Testing of secondary efficacy endpoints at an earlier timepoint for each type of lesion and IGA Treatment Success will be performed only if superiority (one-sided p<=0.025) is seen at the later timepoint.

Absolute change from baseline in inflammatory lesion count and noninflammatory lesion count, and the IGA assessments will be summarized for each study period. No statistical testing will be performed for the open label efficacy data.

10.9.3 Subject Satisfaction Questionnaire

Answers to subject satisfaction questionnaire (Q1-Q8) will be summarized using frequency counts and percentages at Visit 6, Week 12 and Visit 13, Week 52.

10.10 Safety Analysis

All safety analyses will be based on the Safety Population according to the treatment received. No statistical tests will be performed for any of the safety assessments.

10.10.1 Adverse Events

AE terms will be coded using MedDRA dictionary. AEs that occur after informed consent but before administration of the study product will be recorded as medical history. A treatment-emergent AE (TEAE) is defined as an AE that merges during treatment having been absent pre-treatment, or worsen relative to the pre-treatment state. In particular, for subjects entering the OL phase, all AEs starting on or after the date of the first application of study medication of the DB phase, but before the date of the first application of the OL phase will be considered as TEAEs of the DB phase. All AEs starting on or after the first application of the OL phase will be considered as TEAEs of the OL phase. If relationship to treatment is missing, the event will be conservatively summarized as being related to study drug. If severity is missing, a separate category of missing severity will be included in the summary table, and no imputation of severity will be performed. Through the data cleaning process, all attempts will be made to avoid missing values for relationship and severity.

All AEs will be presented in a by-treatment and by-subject listing, detailing the verbatim term given by the investigator, the preferred term (PT), system organ class (SOC), onset date and time, end date and time, severity, outcome, relationship to study drug, action taken with study

drug, other action taken, seriousness and criteria for seriousness. Serious AEs (SAEs) and TEAEs leading to study discontinuation will also be presented in a separate listing.

An overall summary of AEs will be presented by treatment and overall for each Study Period. The summary will include the total number of events, frequency counts and percentages with:

- Any AE
- Any TEAE
- Any serious TEAE
- Any treatment-related TEAE
- Any TEAE leading to study discontinuation

For each Study Period, summaries of the incidence of TEAEs, SAEs, and TEAEs leading to study discontinuation will be displayed by treatment according to the following:

- All TEAEs by PT in descending order of frequency (the combined frequency of both treatments)
- All TEAEs by SOC, PT, and maximum severity (mild, moderate, or severe)
- All TEAEs by SOC, PT, and maximum causality (not related, related) to the study drug

At each level of summarization, a subject will be counted once if he/she reported one or more events. The severity of TEAEs and relationship to study drug will be summarized in a similar manner. For summaries of relationship to study drug, a subject will be classified according to the closest relationship. For summaries of TEAE severity, a subject will be classified according to the highest severity.

10.10.2 Vital Signs

Vital sign parameters will be summarized using descriptive statistics at Baseline and at each post-baseline time point. Changes from Baseline will also be summarized.

10.10.3 Physical Examinations

Physical examinations will be summarized using descriptive statistics at Baseline and at each post-baseline time point. Shifts from Baseline will also be summarized. Abnormal physical examination findings will be displayed in a by-subject listing.

10.10.4 Clinical Laboratory Results

Absolute values and changes from baseline will be summarized for clinical laboratory (chemistry, hematology) results using descriptive statistics. Shift tables for each clinical laboratory test will cross-tabulate the number of subjects with values below the laboratory reference range (low), values within the laboratory reference range (normal) or above the

laboratory range (high) at baseline with the number of subjects with low, normal or high values at each post-baseline time point. Normal ranges and values outside the normal ranges will be identified by the central laboratory. A separate listing of out of normal range laboratory results will be provided.

A listing of subjects with pre-treatment and treatment-emergent clinically significant abnormal laboratory values will be presented for each treatment group. Clinical significance is based on the Investigator's judgment.

Urine pregnancy test will be presented in a by-subject listing.

10.10.5 Tolerability

Erythema, dryness, hyperpigmentation and skin peeling at the sites of study drug application will be assessed at each study visit on a scale of 0 to 3 (0=none; 1=mild; 2=moderate; 3=severe). Itching will be assessed using the same scale based on the subjects' subjective assessment. The intensity and location of each finding will be recorded.

Erythema, dryness, hyperpigmentation, skin peeling, and itching will be summarized using frequency counts and percentages by location (facial, non-facial) at each visit.

11. CHANGES FROM THE PROTOCOL AND PLANNED ANALYSES

Not applicable.

12. HEADINGS

Each page of the analysis will show the sponsor's name, the investigational product, and the protocol number. Report tables will be embedded in the MS Word report document from SAS program output without change. The footer of each table will show the name of the SAS program module which generated it, the names of all data sets providing input data in the program and the date and time the table was generated.

13. ARCHIVING AND RETENTION OF DOCUMENTS

After finalization of the analysis, the following will be archived at Novella Clincial and/or with the study sponsor:

- SAP and any amendments
- All SAS code used in the project for statistical analysis, report tables generation, and analysis data set creation
- Tables, listings and figures as included in the clinical study report
- SAS study data tabulation model (SDTM) and analysis dataset model (ADaM) datasets

14. REFERENCES

Rubin, D.B. (1987). Multiple Imputation for Nonresponse in Surveys. New York: Wiley.

Foamix Pharmaceuticals, Inc

Protocol No. FX2014-04
Novella Clinical No. CT991615

STATISTICAL ANALYSIS PLAN FOR OPEN-LABEL PHASE
Amendment 1.0

A RANDOMIZED, DOUBLE-BLIND STUDY TO COMPARE THE EFFICACY, SAFETY AND LONG-TERM SAFETY OF TOPICAL ADMINISTRATION OF FMX-101 FOR 1 YEAR IN THE TREATMENT OF MODERATE-TO-SEVERE ACNE VULGARIS

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December 7, 2017

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Table 14.1.1.1.1: Summary of Subject Enrollment and Disposition
All Subjects Entering Open-Label Phase

	DB-FMX-101, 4%	**DB-Vechicle Foam**	**Overall**
Number of Subjects Entering Open-Label	XXX	XXX	XXX
Number of Subjects in Safety Population, n (%)	XXX (100)	XXX (100)	XXX (100)
Number of Subjects Completing the Open-Label Phase, n (%)[1]	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Number of Subjects Discontinued from the Open-Label Phase, n (%)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Reason for Discontinuation, n (%)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Adverse Event (including a clinically significant abnormal lab result)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Lost to Follow-up	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Subject Request	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Poor Protocol Adherence	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Administrative, Other	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Other	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

Note: DB=Double-Blind phase.
[1] Subject are identified as completing the open-label phase if they rolled into the open-label phase and did not discontinue.

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Table 14.1.2.1.1: Summary of Subject Demographics and Baseline Characteristics
Safety Population Entering Open-Label Phase

	DB-FMX-101, 4% (N=XXX)	**DB-Vechicle Foam (N=XXX)**	**Overall (N=XXX)**
Age (years)			
N	XXX	XXX	XXX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX
Age Group, n (%)			
9─ < 13 years	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
≥13-<18 years	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
≥ 18 years	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Sex, n (%)			
Female	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Male	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Race, n (%)			
White	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Black or African American	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Asian	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
American Indian or Alaska Native	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Native Hawaiian or Other Pacific Islander	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Multiple Races Reported	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Ethnicity, n (%)			
Hispanic or Latino	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Not Hispanic or Latino	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

DB=Double-Blind Phase; IGA=Investigator's Global Assessment; SD=Standard deviation.
Note: Baseline value is defined as the last non-missing value prior to the first dose of study drug during the double-blind phase.

Table 14.1.2.1.1: Summary of Subject Demographics and Baseline Characteristics (Continued)
Safety Population Entering Open-Label Phase

	DB-FMX-101, 4% (N=XXX)	**DB-Vechicle Foam (N=XXX)**	**Overall (N=XXX)**
Baseline Inflammatory Lesion Counts			
N	XXX	XXX	XXX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX
Baseline Noninflammatory Lesion Counts			
N	XXX	XXX	XXX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX
Baseline Total Lesion Counts			
N	XXX	XXX	XXX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX
Baseline IGA Score, n (%)			
2 – Moderate	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
3 – Severe	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

DB=Double-Blind Phase; IGA=Investigator's Global Assessment; SD=Standard deviation.
Note: Baseline value is defined as the last non-missing value on or prior to the day of the first dose of study drug during the double-blind phase.

Table 14.1.3.1.1: Summary of Concomitant Medications starting in Open-Label Phase
by Anatomical Therapeutic Chemical Class (ATC) and Preferred Term
Safety Population Entering Open-Label Phase

Anatomical Therapeutic Chemical Class **Preferred Term**	**DB-FMX-101, 4%** **(N=XXX)**	**DB-Vechicle Foam** **(N=XXX)**	**Overall** **(N=XXX)**
Subjects with any Concomitant Medication, n (%)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<< Anatomical Therapeutic Chemical Class >>	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<< Concomitant Medication Preferred Term >>	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<< Concomitant Medication Preferred Term >>	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<< Concomitant Medication Preferred Term >>	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<< Anatomical Therapeutic Chemical Class >>	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<< Concomitant Medication Preferred Term >>	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<< Concomitant Medication Preferred Term >>	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<< Concomitant Medication Preferred Term >>	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

DB=Double-Blind

[1] Concomitant medications starting on or after the first dose in the Open-Label Phase . Counts reflect number of subjects in each treatment group reporting one or more concomitant medication that map to the WHO Drug anatomical therapeutic chemical or preferred term. A subject may be counted once only in each row of the table.

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14.2.4.1.1: Summary of Inflammatory Lesion Counts
Safety Population Entering Open-Label Phase (Observed-Cases)

Analysis Visit	DB-FMX-101, 4% (N=XXX)				DB-Vehicle Foam (N=XXX)			
	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
Baseline/Visit								
Absolute Value	XXX	XX.X (XX.X)	XX.X	XX,XX	XXX	XX.X (XX.X)	XX.X	XX,XX
Visit 3/Week 3								
Absolute Value	XXX	XX.X (XX.X)	XX.X	XX,XX	XXX	XX.X (XX.X)	XX.X	XX,XX
Change from Baseline	XXX	XX.X (XX.X)	XX.X	XX,XX	XXX	XX.X (XX.X)	XX.X	XX,XX
Percent Change from Baseline	XXX	XX.X (XX.X)	XX.X	XX.X,XX.X	XXX	XX.X (XX.X)	XX.X	XX.X,XX.X
Visit 4/Week 6								
Absolute Value	XXX	XX.X (XX.X)	XX.X	XX,XX	XXX	XX.X (XX.X)	XX.X	XX,XX
Change from Baseline	XXX	XX.X (XX.X)	XX.X	XX,XX	XXX	XX.X (XX.X)	XX.X	XX,XX
Percent Change from Baseline	XXX	XX.X (XX.X)	XX.X	XX.X,XX.X	XXX	XX.X (XX.X)	XX.X	XX.X,XX.X
Visit 5/Week 9								
Absolute Value	XXX	XX.X (XX.X)	XX.X	XX,XX	XXX	XX.X (XX.X)	XX.X	XX,XX
Change from Baseline	XXX	XX.X (XX.X)	XX.X	XX,XX	XXX	XX.X (XX.X)	XX.X	XX,XX
Percent Change from Baseline	XXX	XX.X (XX.X)	XX.X	XX.X,XX.X	XXX	XX.X (XX.X)	XX.X	XX.X,XX.X
<<<< **Visit 6/Week 12, Visit 7/Week 16, Visit 8/Week 22, Visit 9/Week 28, Visit 10/Week 34, Visit 11/Week 40, Visit 12/Week 46, Visit 13/Week 52**>>>								

DB=Double-Blind phase; SD=Standard deviation.
Note: Baseline value is defined as the last non-missing value prior to the first dose of study drug during the double-blind phase.
Change from baseline is calculated as baseline value minus post-baseline value. Percent change from baseline is calculated as the baseline value minus the post-baseline value divided by the baseline value, expressed as a percentage

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14.2.5.1.1: Summary of Non-Inflammatory Lesion Count
Safety Population Entering Open-Label Phase (Observed-Cases)

	DB-FMX-101, 4% (N=XXX)				DB-Vehicle Foam (N=XXX)			
Visit	**N**	**Mean (SD)**	**Median**	**Min, Max**	**N**	**Mean (SD)**	**Median**	**Min, Max**
Baseline/Visit 1								
Absolute Value	XXX	XX.X (XX.X)	XX.X	XX,XX	XXX	XX.X (XX.X)	XX.X	XX,XX
Visit 3/Week 3								
Absolute Value	XXX	XX.X (XX.X)	XX.X	XX,XX	XXX	XX.X (XX.X)	XX.X	XX,XX
Change from Baseline	XXX	XX.X (XX.X)	XX.X	XX,XX	XXX	XX.X (XX.X)	XX.X	XX,XX
Percent Change from Baseline	XXX	XX.X (XX.X)	XX.X	XX.X,XX.X	XXX	XX.X (XX.X)	XX.X	XX.X,XX.X
Visit 4/Week 6								
Absolute Value	XXX	XX.X (XX.X)	XX.X	XX,XX	XXX	XX.X (XX.X)	XX.X	XX,XX
Change from Baseline	XXX	XX.X (XX.X)	XX.X	XX,XX	XXX	XX.X (XX.X)	XX.X	XX,XX
Percent Change from Baseline	XXX	XX.X (XX.X)	XX.X	XX.X,XX.X	XXX	XX.X (XX.X)	XX.X	XX.X,XX.X
Visit 5/Week 9								
Absolute Value	XXX	XX.X (XX.X)	XX.X	XX,XX	XXX	XX.X (XX.X)	XX.X	XX,XX
Change from Baseline	XXX	XX.X (XX.X)	XX.X	XX,XX	XXX	XX.X (XX.X)	XX.X	XX,XX
Percent Change from Baseline	XXX	XX.X (XX.X)	XX.X	XX.X,XX.X	XXX	XX.X (XX.X)	XX.X	XX.X,XX.X

<<<< **Visit 6/Week 12, Visit 7/Week 16, Visit 8/Week 22, Visit 9/Week 28, Visit 10/Week 34, Visit 11/Week 40, Visit 12/Week 46, Visit 13/Week 52**>>>

DB=Double-Blind phase; SD=Standard deviation.
Note: Baseline value is defined as the last non-missing value prior to the first dose of study drug during the double-blind phase.
Change from baseline is calculated as baseline value minus post-baseline value. Percent change from baseline is calculated as the baseline value minus the post-baseline value divided by the baseline value, expressed as a percentage

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Foamix Pharmaceuticals, Inc.
Protocol No. FX2014-04, Open-Label Phase

14.2.6.1.1: Summary of Investigator's Global Assessment (IGA)
Safety Population Entering Open-Label Phase (Observed-Cases)

	DB-FMX-101, 4% (N=XXX)	**DB-Vehicle Foam (N=XXX)**
Baseline/Visit 1, n (%)		
N	XXX	XXX
3-Moderate	XXX (XX.X)	XXX (XX.X)
4-Severe	XXX (XX.X)	XXX (XX.X)
Visit 3/Week 3, n (%)		
N	XXX	XXX
0-Clear	XXX (XX.X)	XXX (XX.X)
1-Almost Clear	XXX (XX.X)	XXX (XX.X)
2-Mild	XXX (XX.X)	XXX (XX.X)
3-Moderate	XXX (XX.X)	XXX (XX.X)
4-Severe	XXX (XX.X)	XXX (XX.X)
5-Very Severe	XXX (XX.X)	XXX (XX.X)
IGA Treatment Success	XXX (XX.X)	XXX (XX.X)
<Continue for Visit 4/Week 6, Visit 5/Week 9, Visit 6/Week 12, Visit 7/Week 16, Visit 8/Week 22, Visit 9/Week 28, Visit 10/Week 34, Visit 11/Week 40, Visit 12/Week 46 and Visit 13/Week 52>		

DB=Double-Blind phase.
Note: IGA treatment success is a score of 'clear' (0) or "almost clear" (1) and at least 2 grade decrease from Baseline.

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14.2.7.1: Summary of Subject Satisfaction Questionnaire at Week 52
Safety Population Entering Open-Label Phase

	DB-FMX-101, 4% (N= XXX)	DB-Vehicle (N=XXX)	Overall (N=XXX)
Q1: How satisfied are you with this product in treating your acne?			
N	XXX	XXX	XXX
1-Very Satisfied	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
2- Satisfied	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
3-Somewhat Satisfied	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
4-Dissatisfied	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
5-Very Dissatisfied	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

<Continue for :>

Q2: How satisfied are you with how easy this product is to use?

Q3: How satisfied are you with this product compared to other products you have previously used for acne, such as gels and creams?

Q4: How satisfied are you with how this product feels on your skin after treatment?

Q5: How satisfied are you with the odor of this product after treatment?

Q6: How satisfied are you with the color of this product after treatment?

Q7: Overall, how satisfied are you with this product?

Q8: Overall, how likely are you to recommend this product to a friend?			
N	XXX		XXX
1-Very Likely	XXX (XX.X)		XXX (XX.X)
2- Likely	XXX (XX.X)		XXX (XX.X)
3-Somewha Likely	XXX (XX.X)		XXX (XX.X)
4-Unliklely	XXX (XX.X)		XXX (XX.X)
5-Very Unlikely	XXX (XX.X)		XXX (XX.X)

DB= Double-Blind

Table 14.3.1.1.1: Overall Summary of Adverse Events
Safety Population who entered Open-Label Phase
All AEs Starting in Open-Label Phase

	DB-FMX-101, 4% **(N =XXX)**	**DB-Vehicle** **(N =XXX)**	**Overall** **(N =XXX)**
Subjects with any treatment-emergent AE (TEAE), n (%) [1]	XX (XX.X)	XX (XX.X)	XX (XX.X)
Number of treatment-emergent AEs	XXX	XXX	XXX
Subjects with any serious TEAE (SAE), n (%)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Number of serious TEAEs (SAE)	XXX	XXX	XXX
Subjects with any treatment-related TEAE, n (%)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Number of treatment-related TEAEs	XXX	XXX	XXX
Subjects with any TEAE leading to study discontinuation, n (%)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Number of TEAEs leading to study discontinuation	XXX	XXX	XXX

DB=Double-Blind

Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA. A subject may be counted once only in each row of the table.

[1] All AEs staring on or after the first application of the Open-Label phase will be considered as TEAEs of the Open-Label phase.

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Foamix Pharmaceuticals, Inc.
Protocol No. FX2014-04, Open-Label Phase

Table 14.3.1.2.1.1: Summary of Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term in Descending Frequency
Safety Population Entering Open-Label Phase

System Organ Class **Preferred Term**	**Overall** **(N=XXXX)**
Subjects with any TEAE, n (%)	XXX (XX.X)
<< Adverse Event System Organ Class >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event System Organ Class >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)

Note: Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA system organ class or preferred term. A subject may be counted once only in each row of the table. TEAEs of the Open-Label phase are defined as AEs starting on or after the first application of the Open-Label phase.

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Foamix Pharmaceuticals, Inc.
Protocol No. FX2014-04, Open-Label Phase

Table 14.3.1.2.2.1: Summary of Treatment-Emergent Adverse Events
by Preferred Term in Descending Frequency
Safety Population Entering Open-label Phase

System Organ Class **Preferred Term**	**Overall** **(N=XXX)**
Subjects with any TEAE, n (%)	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)

Note: Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA preferred term. A subject may be counted once only in each row of the table. TEAEs of the Open-Label phase are defined as AEs starting on or after the first application of the Open-Label phase.

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Table 14.3.1.2.3.1: Summary of Treatment-emergent Adverse Events
by System Organ Class, Preferred Term, and Maximum Severity
Safety Population Entering Open-Label Phase

System Organ Class **Preferred Term**	**Severity**	**Overall** **(N=XXX)**
Subjects with any TEAE, n (%)	Total	XXX (XX.X)
	Mild	XXX (XX.X)
	Moderate	XXX (XX.X)
	Severe	XXX (XX.X)
<< Adverse Event System Organ Class >>	Total	XXX (XX.X)
	Mild	XXX (XX.X)
	Moderate	XXX (XX.X)
	Severe	XXX (XX.X)
<< Adverse Event Preferred Term >>	Total	XXX (XX.X)
	Mild	XXX (XX.X)
	Moderate	XXX (XX.X)
	Severe	XXX (XX.X)

Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA system organ class or preferred term. A subject may be counted only once at the highest severity. TEAEs of the Open-Label phase are defined as AEs starting on or after the first application of the Open-Label phase.

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Table 14.3.1.2.4.1: Summary of Treatment-emergent Adverse Events
by System Organ Class, Preferred Term, and Maximum Causality
Safety Population Entering Open-Label Phase

System Organ Class **Preferred Term**	**Severity**	**Overall** **(N=XXX)**
Subjects with any TEAE, n (%)	Total	XXX (XX.X)
	Related	XXX (XX.X)
	Not Related	XXX (XX.X)
<< Adverse Event System Organ Class >>	Total	XXX (XX.X)
	Related	XXX (XX.X)
	Not Related	XXX (XX.X)
<< Adverse Event Preferred Term >>	Total	XXX (XX.X)
	Related	XXX (XX.X)
	Not Related	XXX (XX.X)

Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA system organ class or preferred term. A subject may be counted only once at the highest causality. TEAEs of the Open-Label phase are defined as AEs starting on or after the first application of the Open-Label phase.

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Foamix Pharmaceuticals, Inc.
Protocol No. FX2014-04, Open-Label Phase

Table 14.3.1.3.1.1: Summary of Serious Adverse Events
by System Organ Class and Preferred Term in Descending Frequency
Safety Population who entered Open-Label Phase
All SAEs Starting in Open-Label Phase

System Organ Class **Preferred Term**	**Overall** **(N=XXX)**
Subjects with any SAE, n (%)	XXX (XX.X)
<< Adverse Event System Organ Class >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event System Organ Class >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)

Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA system organ class or preferred term. A subject may be counted once only in each row of the table.

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Foamix Pharmaceuticals, Inc.
Protocol No. FX2014-04, Open-Label Phase

Table 14.3.1.3.2.1: Summary of Serious Adverse Events
by System Organ Class, Preferred Term, and Maximum Severity
Safety Population Entering Open-Label Phase
All SAEs Starting in Open-Label Phase

System Organ Class **Preferred Term**	**Severity**	**Overall** **(N = XXX)**
Subjects with any SAE, n (%) [1]	Total	XXX (XX.X)
	Mild	XXX (XX.X)
	Moderate	XXX (XX.X)
	Severe	XXX (XX.X)
<< Adverse Event System Organ Class >>	Total	XXX (XX.X)
	Mild	XXX (XX.X)
	Moderate	XXX (XX.X)
	Severe	XXX (XX.X)
<< Adverse Event Preferred Term >>	Total	XXX (XX.X)
	Mild	XXX (XX.X)
	Moderate	XXX (XX.X)
	Severe	XXX (XX.X)

Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA system organ class or preferred term. A subject may be counted only once at the highest severity.

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Table 14.3.1.3.3.1: Summary of Serious Adverse Events
by System Organ Class, Preferred Term, and Maximum Causality
Safety Population Entering Open-Label Phase
All SAEs Starting in Open-Label Phase

System Organ Class **Preferred Term**	**Severity**	**Overall** **(N=XXX)**
Subjects with any SAE, n (%)	**Total**	XXX (XX.X)
	Related	XXX (XX.X)
	Not Related	XXX (XX.X)
<< Adverse Event System Organ Class >>	**Total**	XXX (XX.X)
	Related	XXX (XX.X)
	Not Related	XXX (XX.X)
<< Adverse Event Preferred Term >>	Total	XXX (XX.X)
	Related	XXX (XX.X)
	Not Related	XXX (XX.X)

Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA system organ class or preferred term. A subject may be counted only once at the highest causality.

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Foamix Pharmaceuticals, Inc.
Protocol No. FX2014-04, Open-Label Phase

Table 14.3.1.4.1.1: Summary of Treatment-emergent Adverse Events Leading to Study Discontinuation
by System Organ Class and Preferred Term in Descending Frequency
Safety Population Entering Open-Label Phase

System Organ Class **Preferred Term**	**Overall** **(N=XXX)**
Subjects with any TEAE, n (%)	XXX (XX.X)
<< Adverse Event System Organ Class >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event System Organ Class >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)
<< Adverse Event Preferred Term >>	XXX (XX.X)

Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA system organ class or preferred term. A subject may be counted once only in each row of the table. TEAEs of the Open-Label phase are defined as AEs starting on or after the first application of the Open-Label phase.

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Table 14.3.1.4.2.1: Summary of Treatment-emergent Adverse Events Leading to Study Discontinuation
by System Organ Class, Preferred Term, and Maximum Severity
Safety Population Entering Open-Label Phase

System Organ Class **Preferred Term**	**Severity**	**Overall** **(N=XXX)**
Subjects with any TEAE, n (%)	Total	XXX (XX.X)
	Mild	XXX (XX.X)
	Moderate	XXX (XX.X)
	Severe	XXX (XX.X)
<< Adverse Event System Organ Class >>	Total	XXX (XX.X)
	Mild	XXX (XX.X)
	Moderate	XXX (XX.X)
	Severe	XXX (XX.X)
<< Adverse Event Preferred Term >>	Total	XXX (XX.X)
	Mild	XXX (XX.X)
	Moderate	XXX (XX.X)
	Severe	XXX (XX.X)

Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA system organ class or preferred term. A subject may be counted only once at the highest severity. TEAEs of the Open-Label phase are defined as AEs starting on or after the first application of the Open-Label phase.

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Table 14.3.1.4.3.1: Summary of Treatment-emergent Adverse Events Leading to Study Discontinuation
by System Organ Class, Preferred Term, and Maximum Causality
Safety Population Entering Open-Label Phase

System Organ Class **Preferred Term**	**Severity**	**Overall** **(N=XXX)**
Subjects with any TEAE, n (%)	Total	XXX (XX.X)
	Related	XXX (XX.X)
	Not Related	XXX (XX.X)
<< Adverse Event System Organ Class >>	Total	XXX (XX.X)
	Related	XXX (XX.X)
	Not Related	XXX (XX.X)
<< Adverse Event Preferred Term >>	Total	XXX (XX.X)
	Related	XXX (XX.X)
	Not Related	XXX (XX.X)

Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA system organ class or preferred term. A subject may be counted only once at the highest causality. TEAEs of the Open-Label phase are defined as AEs starting on or after the first application of the Open-Label phase.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX / Reference: Data Listings XXXX

Table 14.3.2.1.X.1: Summary of Clinical Laboratory Results by Visit
[Hematology] [Chemistry]
Safety Population Entering Open-Label Phase

	DB-FMX-101, 4% (N=XXX)		DB-Vehicle Foam (N=XXX)	
	Observed Values	**Change from Baseline**	**Observed Values**	**Change from Baseline**
Parameter 1 (units)				
Baseline/Visit 1				
N	XXX	--	XXX	--
Mean (SD)	XX.X (XX.X)	--	XX.X (XX.X)	--
Median	XX.X	--	XX.X	--
Min, Max	XX.X, XX.X	--	XX.X, XX.X	--
Visit 3/Week3				
N	XXX	XXX	XXX	XXX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X	XX.X
Min, Max	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Visit 6/Week12				
N	XXX	XXX	XXX	XXX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X	XX.X
Min, Max	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X

<Continue for Visit 9/Week 28, Visit 13/Week 52 and for Parameter 2, 3, ….>

Note: DB=Double-Blind phase. Baseline value is defined as the last non-missing value prior to the first dose of study drug during the double-blind phase.
Change from baseline is calculated as baseline value minus post-baseline value.

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Foamix Pharmaceuticals, Inc.
Protocol No. FX2014-04, Open-Label Phase

Table 14.3.3.1.1: Summary of Vital Signs by Visit
Safety Population Entering Open-Label Phase

	DB-FMX-101, 4% (N=XXX)		DB-Vehicle Foam (N=XXX)	
	Observed Values	**Change from Baseline**	**Observed Values**	**Change from Baseline**
Weight (kg)				
Baseline/Visit 1				
N	XXX	-	XXX	-
Mean (SD)	XX.X (XX.X)	-	XX.X (XX.X)	-
Median	XX.X	-	XX.X	-
Min, Max	XX.X, XX.X	-	XX.X, XX.X	-
Visit 6/Week 12				
N	XXX	XXX	XXX	XXX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X	XX.X
Min, Max	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Visit 13/Week 52				
N	XXX	XXX	XXX	XXX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X	XX.X
Min, Max	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X

Note: DB=Double Blind phase. Baseline value is defined as the last non-missing value prior to the first dose of study drug during the double-blind phase.
Change from baseline is calculated as baseline value minus post-baseline value

Generated on XX/XX/X XX:XX by XXXX / Uses: XXXX, XXXX, XXXX / Reference: Data Listing XXXXXXXXXX

[Programming note: add page break between Weight and Blood pressure]

Table 14.3.3.1.1: Summary of Vital Signs by Visit (Continued)
Safety Population Entering Open-Label Phase

	DB-FMX-101, 4% (N=XXX)		DB-Vehicle Foam (N=XXX)	
	Observed Values	**Change from Baseline**	**Observed Values**	**Change from Baseline**
Systolic Blood Pressure (mmHg)				
Baseline/Visit 1 [1]				
N	XXX	--	XXX	--
Mean (SD)	XX.X (XX.X)	--	XX.X (XX.X)	--
Median	XX.X	--	XX.X	--
Min, Max	XX.X, XX.X	--	XX.X, XX.X	--
Visit 3/Week 3				
N	XXX	XXX	XXX	XXX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X	XX.X
Min, Max	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Visit 4/Week 6				
N	XXX	XXX	XXX	XXX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X	XX.X
Min, Max	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X

<Continue for **Visit 6/Week 12, Visit 7/Week 16, Visit 8/Week 22, Visit 9/Week 28, Visit 10/Week 34, Visit 11/Week 40, Visit 12/Week 46, Visit 13/Week 52>**
<Continue for **Diastolic Blood Pressure (mmHg), Pulse Rate (beats/minute)>**

Note: DB=Double-Blind phase. Baseline value is defined as the last non-missing value prior to the first dose of study drug in the double-blind phase.
Change from baseline is calculated as baseline value minus post-baseline value

Generated on XX/XX/X XX:XX by XXXX / Uses: XXXX, XXXX, XXXX / Reference: Data Listing XXXXXXXXXX

Table 14.3.3.2.1.1: Summary of Physical Exam by Study Visit
Safety Population Entering Open-Label Phase
with Abnormal Findings

	DB-FMX-101, 4% (N=XXX)			**DB-Vehicle Foam (N=XXX)**		
	Baseline/Visit 1 (N=XXX)	**Visit 6/Week 12 (N=XXX)**	**Visit 13/Week 52 (N=XXX)**	**Baseline/Visit 1 (N=XXX)**	**Visit 6/Week 12 (N=XXX)**	**Visit 13/Week 52 (N=XXX)**
Abnormal, n/N (%)						
General Appearance Assessment	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Dermatology Assessment	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
HEENT Results	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Lymphatic Results	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Respiratory Results	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Cardiovascular Results	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Abdominal Results	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Musculoskeletal Results	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Neurological Results	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

Note: DB=Double-Blind phase.

Generated on XX/XX/X XX:XX by XXXX / Uses: XXXX, XXXX, XXXX / Reference: Data Listing XXXXXXXXXX

Table 14.3.3.2.2.1: Shifts in Physical Exam Result from Baseline to Week 12 and Week 52
Safety Population Entering Open-Label

		DB-FMX-101, 4% (N=XXX)	DB-Vehicle Foam (N=XXX)
Any Body System			
	Visit 6/Week 12		
	N [1]	XXX	XXX
	Abnormal to Normal, n (%)	XXX (XX.X)	XXX (XX.X)
	Normal to Abnormal, n (%)	XXX (XX.X)	XXX (XX.X)
	Visit 13/ Week 52		
	N [2]	XXX	XXX
	Abnormal to Normal, n (%)	XXX (XX.X)	XXX (XX.X)
	Normal to Abnormal, n (%)	XXX (XX.X)	XXX (XX.X)

<Continue for General Appearance, Dermatology, HEENT, Lymphatic, Respiratory, Cardiovascular, Abdominal, Musculoskeletal and Neurological Assessment >

Note: DB=Double-Blind phase. Baseline value is defined as the last non-missing value prior to the first dose of study drug during the double-blind phase
[1] Number of subjects in the safety population with physical exam for both baseline and week 12 within treatment group.
[2] Number of subjects in the safety population with physical exam for both baseline and week 52 within treatment group.

Generated on XX/XX/X XX:XX by XXXX / Uses: XXXX, XXXX, XXXX / Reference: Data Listing XXXXXXXXXX

Table 14.3.4.1: Summary of Tolerability Assessment
Safety Population Entering Open-Label

	DB-FMX-101, 4% (N=XXX)				DB-Vehicle Foam (N=XXX)			
	0=None	**1=Mild**	**2=Moderate**	**3=Severe**	**0=None**	**1=Mild**	**2=Moderate**	**3=Severe**
Visit 2/ Week 1								
Face, n (%)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Erythema	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Dryness	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Hyperpigmentation	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Skin Peeling	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Itching	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Non-facial Sites, n (%)								
Erythema	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Dryness	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Hyperpigmentation	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Skin Peeling	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Itching	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

< Continue for Visit 3/Week 3, Visit 4/Week 6, Visit 5/Week 9, and Visit 6/Week 12, Visit 7/Week 16, Visit 8/Week 22, Visit 9/Week 28, Visit 10/Week 34, Visit 11/Week 40, Visit 12/Week 46 and Visit 13/Week 52>

Note: DB=Double Blind phase. If more than one non-face area is affected (neck, chest, back, right shoulder, right arm, left shoulder, left arm and other), the region affected maximally is reported and the maximum intensity is reported

Generated on XX/XX/X XX:XX by XXXX / Uses: XXXX, XXXX, XXXX / Reference: Data Listing XXXXXXXXXX

Data Listing 16.2.1.2.1: Subject Disposition
All Randomized Subjects
Randomized Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/Subject	Date of First Dose in DB [1]	Date (Day) of First Dose in OL [2]	Date (Day) of Last Dose in OL [3]	Date (Day) of Last Visit	Date (Day) of Last Contact	Completion Status / With drawl Reason
XX/XXX	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy (XX)	ddMMMyyyy (XX)	ddMMMyyyy (XX)	Completed
XX/XXX	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy (XX)	ddMMMyyyy (XX)	ddMMMyyyy (XX)	Lost to Follow-up
XX/XXX	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy (XX)	ddMMMyyyy (XX)	ddMMMyyyy (XX)	XXXXXXX
XX/XXX	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy (XX)	ddMMMyyyy (XX)	ddMMMyyyy (XX)	XXXXXXX

DB= Double- Blind. OL=Open-Label
Note: Study day is calculated relative to the date of Day 1, the date of first study drug administration during the double-blind phase.
[1] First dose administration (Day 1)
[2] First report of drug administration after rolling into the open-label phase
[3] Last report of drug administrated during the open-label phase

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Data Listing 16.2.2.1: Protocol Deviations
All Randomized Subjects with Protocol Deviations
Randomized Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/ Subject	Type	Description	Action Taken
XX/XXX	Study product use	XXXXXXXXX	Retrained on protocol
XX/XXX	Missed Visit	XXXXXXXXX	Other: XXXX

Data Listing 16.2.4.4.1: Concomitant Medications used at Any Time During the Study
All Randomized Subject
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/Subject	WHO Preferred Term (Verbatim Term) / ATC Classification	Indication	Dose/ Dose Unit	Frequency/ Route	Start Date (Day)/ Stop Date (Day) [1]
XX/XXX	xxxxxxxxx(xxxxxxx)/ xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxx	xxxxx/xxx	xxx/xxxxx	ddMMMyyyy (XX)/ ddMMMyyyy (XX)
XX/XXX	xxxxxxxxx(xxxxxxx)/ xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxx	xxxxx/xxx	xxx/xxxxx	ddMMMyyyy (XX)/ ddMMMyyyy (XX)

Note: Concomitant = ongoing or with stop dates on or after Day 1.
[1] Study day is calculated relative to the date of Day 1, the date of first study drug administration during the double-blind phase.
Generated on XX/XX/XX:XXXX by XXXX / Uses: XXXX

Data Listing 16.2.4.4.2: Concomitant Medications used during Double-Blind Phase
All Randomized Subject
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/Subject	WHO Preferred Term (Verbatim Term) / ATC Classification	Indication	Dose/ Dose Unit	Frequency/ Route	Start Date (Day)/ Stop Date (Day) [1]	Ongoing at end of Double-Blind Phase?
XX/XXX	xxxxxxxxx(xxxxxxx)/ xxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxx	xxxxx/xxx	xxx/xxxxx	ddMMMyyyy (XX)/ --	Y
XX/XXX	xxxxxxxxx(xxxxxxx)/ xxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxx	xxxxx/xxx	xxx/xxxxx	ddMMMyyyy (XX)/ ddMMMyyyy (XX)	N

Note: Includes concomitant medications ongoing or with stop dates on or after Day 1 but start date prior to first dose in Open-Label Phase.
[1] Study day is calculated relative to the date of Day 1, the date of first study drug administration during the double-blind phase. If end date is missing the concomitant medication is ongoing.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XXXX

<<<<Programmer note: if stop date is not provided include a "/" after the start date to clarify >>>>

Data Listing 16.2.4.4.3: Concomitant Medications starting in the Open-Label Phase
All Randomized Subject
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/Subject	WHO Preferred Term (Verbatim Term) / ATC Classification	Indication	Dose/ Dose Unit	Frequency/ Route	Start Date (Day)/ Stop Date (Day) [1]
XX/XXX	xxxxxxxxx(xxxxxxx)/ xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxx	xxxxx/xxx	xxx/xxxxx	ddMMMyyyy (XX)/ --
XX/XXX	xxxxxxxxx(xxxxxxx)/ xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxx	xxxxx/xxx	xxx/xxxxx	ddMMMyyyy (XX)/ ddMMMyyyy (XX)

Note: Includes concomitant medications starting on or after the first dose in the Open-Label Phase.
[1] Study day is calculated relative to the date of Day 1, the date of first study drug administration during the double-blind phase.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XXXX

<<<<Programmer note: if no stop date is provided include a "/" after the start date to clarify >>>>

Data Listing 16.2.5.1.1: Study Medication Exposure and Usage
All Randomized Subjects
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/Subject	Date of First Dose in DB	Date (Day) of Last Dose [1]	Phase of Last Dose	Total Days of Exposure [2]	Visit	# Canisters Dispensed	# Canisters Returned	Kit Number Dispensed	Regions Beyond the Face where Study Drug was Applied
XX/XXX	ddMMMyyy(XX)	ddMMMyyy(XX)	Double-Blind	92	Baseline/Visit 1	2		19197	NONE
					Visit 2/Week 1	2	2	19197	NONE
					Visit 3/Week 3	2	0	13345	NONE
					Visit 4/Week 6	2	2	19818	NONE
					Visit 5/Week 9	2	2	14092	NONE
					Visit 6/Week 12	2	2	90047	NONE
					Visit 6/Week 12	2	2	90048	NONE

<< Continue for Visit 7/Week 16, Visit 8/Week 22, Visit 9/Week 28, Visit 10/Week 34, Visit 11/Week 40, Visit 12/Week 46, Visit 13/Week 52>>

DB= Double-Blind; OL= Open-Label
[1] Study day is calculated relative to the date of Day 1, the date of first study drug administration during the double-blind phase.
[1]Total number of days to exposure to study drug is defined as the date of last dose of the study drug minus the first dose of study drug plus 1.

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Data Listing 16.2.5.2.1: Study Medication Accountability
All Randomized Subjects
Randomized Treatment: [DB-FMX-101, 4%][DB-Vehicle Foam]

Site/ Subject	Kit Number Dispensed	Number of Canisters Returned in Kit	Amount Returned (g)	Amount Applied (g) [1]
XX/XXX	XXXXX	X	XX.X	XX.X
	XXXXX	X	XX.X	XX.X
	XXXXX	X	XX.X	XX.X
	XXXXX	X	XX.X	XX.X
	XXXXX	X	XX.X	XX.X

[1] Weight of applied medication is defined as the difference in weight of returned and dispensed canisters. Sealed canisters will be assumed to be 0 g.

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Data Listing 16.2.6.1.1.1: Lesion Counts
All Randomized Subjects
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

			Inflammatory Lesions (IL)				Noninflammatory Lesions (NIL)				
Site/Subject	**Analysis Visit [1]**	**Date (Day) [2]**	**Papules**	**Pustules**	**Nodules**	**Total IL**	**Open Comedones**	**Closed Comedones**	**Total NIL**	**Total [3]**	**Non Facial Area [4]**
XX/XXX	Screening	ddMMMyyy (XX)	XX	XX	XX	XX	XX	XX	XX	XX	XX,XX
	Baseline/Visit 1	ddMMMyyy (XX)	XX	XX	XX	XX	XX	XX	XX	XX	-
	Visit 2/Week 1	ddMMMyyy (XX)	XX	XX	XX	XX	XX	XX	XX	XX	-
	Visit 3/Week 3	ddMMMyyy (XX)	XX	XX	XX	XX	XX	XX	XX	XX	-
	Visit 4/Week 6	ddMMMyyy (XX)	XX	XX	XX	XX	XX	XX	XX	XX	-
	Visit 5/Week 9	ddMMMyyy (XX)	XX	XX	XX	XX	XX	XX	XX	XX	-
	Visit 6/Week 12	ddMMMyyy (XX)	XX	XX	XX	XX	XX	XX	XX	XX	-

< Continue for Visit 7/Week 16, Visit 8/Week 22, Visit 9/Week 28, Visit 10/Week 34, Visit 11/Week 40, Visit 12/Week 46 and Visit 13/Week 52>

DB=Double-Blind

Note: If more than one visit occurs within a single analysis visit window, then the analysis will take the one closest to the target day. Values with * are not used in analysis.

[1] The 'unassigned' analysis visit indicates a visit that did not fall into an analysis window.

[2] Study day is calculated relative to the date of Day 1, the date of first study drug administration during the double-blind phase.

[3] Total includes inflammatory and noninflammatory.

[4] Regions beyond the face affected by acne.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XXXX

Data Listing 16.2.6.1.2.1: Total Inflammatory and Noninflammatory Lesion Counts
All Randomized Subjects
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/Subject	Analysis Visit [1]	Date (Day) [2]	Type	Total Inflammatory	Total Noninflammatory
XX/XXX	Screening	ddMMMyyyy (XX)	Absolute Value	XX	XX
	Baseline/Visit 1	ddMMMyyyy (XX)	Absolute Value	XX	XX
	Visit 2/Week 16	ddMMMyyyy (XX)	Absolute Value	XX	XX
			Change From Baseline	XX	XX
			Percent Change from Baseline	XX.X	XX.X
	Visit 3/Week 22	ddMMMyyyy (XX)	Absolute Value	XX	XX
			Change From Baseline	XX	XX
			Percent Change from Baseline	XX.X	XX.X
	Visit 4/Week 28	ddMMMyyyy (XX)	Absolute Value	XX	XX
			Change From Baseline	XX	XX
			Percent Change from Baseline	XX.X	XX.X

< Continue for Visit 6/Week 40, Visit 7/Week 16, Visit 8/Week 22, Visit 9/Week 28, Visit 10/Week 34, Visit 11/Week 40, Visit 12/Week 46 and Visit 13/Week 52>

Note: If more than one visit occurs within a single analysis visit window, then the analysis will take the one closest to the target day. Values with * are not used in analysis. Change from baseline is calculated as baseline value minus post-baseline value. Percent change from baseline is calculated as baseline value minus post-baseline value divided by the baseline value expressed as a percent.

[1] The “unassigned” analysis visit indicates a visit that did not fall into an analysis window.

[2] Study day is calculated relative to the date of Day 1, the date of first study drug administration during the double-blind phase.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XXXX

Data Listing 16.2.6.2.1: Investigator's Global Assessment and Treatment Success
All Randomized Subjects
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/Subject	Analysis Visit [1]	Date (Day) [2]	IGA	Treatment Success
XX/XXX	Screening	ddMMMyyyy (XX)	3	-
	Baseline/Visit 1	ddMMMyyyy (XX)	3	-
	Visit 3/Week 3	ddMMMyyyy (XX)	3	No
	Visit 4/Week 6	ddMMMyyyy (XX)	3	No
	Visit 5/Week 9	ddMMMyyyy (XX)	1	Yes
	Visit 6/Week 12	ddMMMyyyy (XX)	1	Yes

<< Continue for Visit 7/Week 16, Visit 8/Week 22, Visit 9/Week 28, Visit 10/Week 34, Visit 11/Week 40, Visit 12/Week 46, Visit 13/Week 52>>

IGA= Investigator's Global Assessment

Note: If more than one visit occurs within a single analysis window, then the analysis will take the one closest to the target day. Value with * are not used in analysis

[1] The 'unassigned' analysis visit indicates a visit that did not fall into an analysis window.

[2] Study day is calculated relative to the date of Day 1, the date of first study drug administration during the double-blind phase.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XXXX

Data Listing 16.2.6.3.1: Subject Satisfaction Questionnaire
All Randomized Subjects
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/Subject	Analysis Visit [1]	Date (Day) [2]	Question	Response
XX/XXX	Visit 6/Week 12	ddMMMyyyy (XX)	Q1: How satisfied are you with this product in treating your acne?	1=Very Satisfied
			Q2: How satisfied are you with how easy this product is to use?	1=Very Satisfied
			Q3: How satisfied are you with this product compared to other products you have previously used for acne, such as gels and creams?	1=Very Satisfied
			Q4: How satisfied are you with how this product feels on you skin after treatment	1=Very Satisfied
			Q5: How satisfied are you with the odor of this product after treatment?	1=Very Satisfied
			Q6: How satisfied are you with the color of this product after treatment?	1=Very Satisfied
			Q7: Overall, how satisfied are you with this product?	1=Very Satisfied
			Q8: Overall, how likely are you to recommend this product to a friend?	1=Very Likely
XX/XXX	Visit 13/Week 52	ddMMMyyyy (XX)	Q1: How satisfied are you with this product in treating your acne?	1=Very Satisfied
			Q2: How satisfied are you with how easy this product is to use?	1=Very Satisfied
			Q3: How satisfied are you with this product compared to other products you have previously used for acne, such as gels and creams?	1=Very Satisfied
			Q4: How satisfied are you with how this product feels on you skin after treatment	1=Very Satisfied
			Q5: How satisfied are you with the odor of this product after treatment?	1=Very Satisfied
			Q6: How satisfied are you with the color of this product after treatment?	1=Very Satisfied
			Q7: Overall, how satisfied are you with this product?	1=Very Satisfied
			Q8: Overall, how likely are you to recommend this product to	1=Very Likely

[1] The 'unassigned' analysis visit indicates a visit that did not fall into an analysis window.
[2] Study day is calculated relative to the date of Day 1, the date of first study drug administration during the double-blind phase.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XXXX

Data Listing 16.2.7.1.1: Adverse Events at Any Time During the Study
All Randomized Subjects
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/ Subject	MedDRA SOC Term/ MedDRA Preferred Term / (Verbatim Term) /	Location of AE to Treatment Area	Treatment-emergent?[1]/ Onset Date (Day) – End Date (Day) [2]	Severity / Relationship / Outcome	Action Taken / Other Action Taken / SAE? SAE Criteria
XX/XXX	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Inside Treatment Area	Y / ddMMMyyyy (XX) – ddMMMyyyy (XX)	XXXXXXXX / XXXXXXXX / XXXXXXXX	XXXXXXXX / XXXXXXXX / Yes: XXXX
	XXXXXXXX / XXXXXXXX / (XXXXXXXX)	Outside Treatment Area	Y / ddMMMyyyy (XX) – ddMMMyyyy (XX)	XXXXXXXX / XXXXXXXX / XXXXXXXX	XXXXXXXX / XXXXXXXX / No
XX/XXX	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Inside Treatment Area	Y / ddMMMyyyy (XX) – ddMMMyyyy (XX)	XXXXXXXX / XXXXXXXX / XXXXXXXX	XXXXXXXX / XXXXXXXX / XXX

[1]TEAEs are defined as AEs starting on or after the date of the first application of study medication.
[2] Study day is calculated relative to the date of Day 1, the date of first study drug administration during double-blind phase.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XX

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Data Listing 16.2.7.1.2: Adverse Events Starting in the Double-Blind Phase
All Randomized Subjects
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/ Subject	MedDRA SOC Term/ MedDRA Preferred Term / (Verbatim Term) /	Location of AE to Treatment Area	Onset Date (Day) – End Date (Day) [1]	Severity / Relationship / Outcome	Action Taken / Other Action Taken / SAE? SAE Criteria
XX/XXX	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Inside Treatment Area	ddMMMyyyy (XX) – ddMMMyyyy (XX)	XXXXXXXX / XXXXXXXX / XXXXXXXX	XXXXXXXX / XXXXXXXX / Yes: XXXX
	XXXXXXXX / XXXXXXXX / (XXXXXXXX)	Outside Treatment Area	ddMMMyyyy (XX) – ddMMMyyyy (XX)	XXXXXXXX / XXXXXXXX / XXXXXXXX	XXXXXXXX / XXXXXXXX / No
XX/XXX	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Inside Treatment Area	ddMMMyyyy (XX) – ddMMMyyyy (XX)	XXXXXXXX / XXXXXXXX / XXXXXXXX	XXXXXXXX / XXXXXXXX / XXX

Note: Adverse Events starting in Double-Blind Phase are AEs with a start date on or after first dose in Double-Blind Phase but prior to first dose in Open-Label Phase.
[1]Study day is calculated relative to the date of Day 1, the date of first study drug administration. An AE with end date greater than Day 84 generally continued into the open-label phase.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XX

Data Listing 16.2.7.1.3:Adverse Events Starting in the Open-Label Phase
All Randomized Subjects Entering Open-Label Phase
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/ Subject	MedDRA SOC Term/ MedDRA Preferred Term / (Verbatim Term) /	Location of AE to Treatment Area	Onset Date (Day) – End Date (Day) [1]	Severity / Relationship / Outcome	Action Taken / Other Action Taken / SAE? SAE Criteria
XX/XXX	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Inside Treatment Area	ddMMMyyyy (XX) – ddMMMyyyy (XX)	XXXXXXXX / XXXXXXXX / XXXXXXXX	XXXXXXXX / XXXXXXXX / Yes: XXXX
	XXXXXXXX / XXXXXXXX / (XXXXXXXX)	Outside Treatment Area	ddMMMyyyy (XX) – ddMMMyyyy (XX)	XXXXXXXX / XXXXXXXX / XXXXXXXX	XXXXXXXX / XXXXXXXX / No
XX/XXX	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Inside Treatment Area	ddMMMyyyy (XX) – ddMMMyyyy (XX)	XXXXXXXX / XXXXXXXX / XXXXXXXX	XXXXXXXX / XXXXXXXX / XXX

Note: Adverse Events starting in Open-Label Phase are AEs with a start date on or after first dose in Open-Label Phase.
[1] Study day is calculated relative to the date of Day 1, the date of first study drug administration during double-blind phase.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XX

Data Listing 16.2.7.2.1: Serious Adverse Events Starting in Open-Label Phase Leading to Study Discontinuation
All Randomized Subjects Entering Open-Label Phase
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/ Subject	MedDRA SOC Term/ MedDRA Preferred Term / (Verbatim Term) /	Location of AE to Treatment Area	Onset Date (Day) – End Date (Day) [1]	Severity / Relationship / Outcome	Action Taken / Other Action Taken / SAE? SAE Criteria
XX/XXX	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Inside Treatment Area	Y / ddMMMyyyy (XX) – ddMMMyyyy (XX)	XXXXXXXX / XXXXXXXX / XXXXXXXX	XXXXXXXX / XXXXXXXX / Yes: XXXX
	XXXXXXXX / XXXXXXXX / (XXXXXXXX)	Outside Treatment Area	Y / ddMMMyyyy (XX) – ddMMMyyyy (XX)	XXXXXXXX / XXXXXXXX / XXXXXXXX	XXXXXXXX / XXXXXXXX / No
XX/XXX	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Inside Treatment Area	Y / ddMMMyyyy (XX) – ddMMMyyyy (XX)	XXXXXXXX / XXXXXXXX / XXXXXXXX	XXXXXXXX / XXXXXXXX / Yes: XXXX

Note: Adverse Events starting in Open-Label Phase are AEs with a start date on or after first dose in Open-Label Phase.
[1] Study day is calculated relative to the date of Day 1, the date of first study drug administration during double-blind phase.

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Data Listing 16.2.7.3.1: Treatment-Emergent Adverse Events Starting in Open-Label Phase Leading to Study Discontinuation
All Randomized Subjects Entering Open-Label Phase
Actual Treatment: [FMX-101,4%][Vehicle Foam]

Site/ Subject	MedDRA SOC Term/ MedDRA Preferred Term / (Verbatim Term) /	Location of AE to Treatment Area	Onset Date (Day) – End Date (Day) [1]	Severity / Relationship / Outcome	Action Taken / Other Action Taken / SAE? SAE Criteria
XX/XXX	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Inside Treatment Area	Y / ddMMMyyyy (XX) – ddMMMyyyy (XX)	XXXXXXXX / XXXXXXXX / XXXXXXXX	XXXXXXXX / XXXXXXXX / Yes: XXXX
	XXXXXXXX / XXXXXXXX / (XXXXXXXX)	Outside Treatment Area	Y / ddMMMyyyy (XX) – ddMMMyyyy (XX)	XXXXXXXX / XXXXXXXX / XXXXXXXX	XXXXXXXX / XXXXXXXX / No
XX/XXX	**XXXXXXXX /** XXXXXXXX / (XXXXXXXX)	Inside Treatment Area	Y / ddMMMyyyy (XX) – ddMMMyyyy (XX)	XXXXXXXX / XXXXXXXX / XXXXXXXX	XXXXXXXX / XXXXXXXX / Yes: XXXX

Note: Adverse Events starting in Open-Label Phase are AEs with a start date on or after first dose in Open-Label Phase.
[1] Study day is calculated relative to the date of Day 1, the date of first study drug administration during double-blind phase.

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Data Listing 16.2.8.1.1: Urine Pregnancy Test
All Randomized Subjects
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/ Subject	Childbearing Potential	Analysis Visit [1]	Date of Test (Day)[2]	Result
XX/XXX	XXXXXXX	Baseline/Visit 1	ddMMMyyyy (XX)	Negative
		Visit 2/Week 1	ddMMMyyyy (XX)	Negative
		Visit 3/Week 3	ddMMMyyyy (XX)	Negative
		Visit 4/Week 6	ddMMMyyyy (XX)	Negative
		Visit 5/Week 9	ddMMMyyyy (XX)	Negative
		Visit 6/Week 12	ddMMMyyyy (XX)	Negative
		Visit 13/Week 52	ddMMMyyyy (XX)	Negative
XX/XXX	Male	--	--	--

<<<<Include all available visits>>>>

[1] The 'unassigned' analysis visit indicates a visit that did not fall into an analysis window.
[2] Study day is calculated relative to the date of Day 1, the date of first study drug administration during the double-blind phase.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XX

Data Listing 16.2.8.1.2: Home Pregnancy Test
All Randomized Subjects
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/Subject	Childbearing Potential	Analysis Visit [1]	Date (Day) [2]	Was a Home Pregnancy Test dispensed?	Positive Pregnancy Test since last Visit?	Date of Positive Pregnancy Test
XX/XXX	XXXXX	Visit 6/ Week 12	ddMMMyyyy (XX)	XXX	-	-
		Visit 7/Week 16	ddMMMyyyy (XX)	XXX	XXX	-
		Visit 8/Week 22	ddMMMyyyy (XX)	XXX	XXX	-
		Visit 9/Week 28	ddMMMyyyy (XX)	XXX	XXX	-
		Visit 10/Week 34	ddMMMyyyy (XX)	XXX	XXX	-
		Visit 11/Week 40	ddMMMyyyy (XX)	XXX	XXX	-
		Visit 12/Week 46	ddMMMyyyy (XX)	XXX	XXX	-
		Visit 13/Week 52	ddMMMyyyy (XX)	XXX	XXX	-

[1] The 'unassigned' analysis visit indicates a visit that did not fall into an analysis window.
[2] Study day is calculated relative to the date of Day 1, the date of first study drug administration during the double-blind phase.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XX

Data Listing 16.2.8.2.1.X.1: Clinical Laboratory Tests
All Randomized Subjects
[Hematology][Chemistry][Urinalysis]
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/Subject	Analysis Visit [1]	Test Name	Test Date (Day)[2]	Result (Unit)	Abnormal?	Clinically Significant?	Reference Range
XX/XXX	Baseline/Visit 1	xxxx	ddMMMyyyy (XX)	xxxx (xxxx)	Normal		xxxx, xxxx
		xxxx	ddMMMyyyy (XX)	xxxx (xxxx)	Normal		xxxx, xxxx
		xxxx	ddMMMyyyy (XX)	xxxx (xxxx)	Low	No	xxxx, xxxx

<< Include for Visit 2/Week 1, Visit 3/Week 3, Visit 4/Week 6, Visit 5/Week 9, Visit 6/Week 12, Visit 1 Visit 7/Week 16, Visit 8/Week 22, Visit 9/Week 28, Visit 10/Week 34, Visit 11/Week 40, Visit 12/Week 46, Visit 13/Week 52>>>

[1] The "unassigned" analysis visit indicates a visit that did not fall into an analysis window.
[2] Study day is calculated relative to the date of Day 1, the date of first study drug administration.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XX

Data Listing 16.2.8.2.2.1: Clinically Significant Clinical Laboratory Tests for Hematology, Chemistry and Urinalysis
All Randomized Subjects
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/Subject	Analysis Visit [1]	Category of Laboratory Test	Test Name	Test Date (Day)[2]	Result (Unit)	Abnormal?	Reference Range
XX/XXX	Baseline/Visit 1	Chemistry	xxxx	ddMMMyyyy (XX)	xxxx (xxxx)	High	xxxx, xxxx
		Chemistry	xxxx	ddMMMyyyy (XX)	xxxx (xxxx)	High	xxxx, xxxx
		Chemistry	xxxx	ddMMMyyyy (XX)	xxxx (xxxx)	Low	xxxx, xxxx

<< Include for Visit 2/Week 1, Visit 3/Week 3, Visit 4/Week 6, Visit 5/Week 9, Visit 6/Week 12, Visit 1 Visit 7/Week 16, Visit 8/Week 22, Visit 9/Week 28, Visit 10/Week 34, Visit 11/Week 40, Visit 12/Week 46, Visit 13/Week 52>>>

[1] The “unassigned” analysis visit indicates a visit that did not fall into an analysis window.
[2] Study day is calculated relative to the date of Day 1, the date of first study drug administration.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XX

Data Listing 16.2.8.2.3.1: Out-of-Range (Abnormal) Clinical Laboratory Test Results for Hematology, Chemistry and Urinalysis
All Randomized Subjects
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/Subject	Analysis Visit [1]	Category of Laboratory Test	Test Name	Test Date (Day)[1]	Result (Unit)	Abnormal?	Clinically Significant
XX/XXX	Baseline/Visit1	Chemistry	xxxx	ddMMMyyyy (XX)	xxxx (xxxx)	High	No
		Chemistry	xxxx	ddMMMyyyy (XX)	xxxx (xxxx)	High	No
		Chemistry	xxxx	ddMMMyyyy (XX)	xxxx (xxxx)	Low	No

<< Include for Visit 2/Week 1, Visit 3/Week 3, Visit 4/Week 6, Visit 5/Week 9, Visit 6/Week 12, Visit 1 Visit 7/Week 16, Visit 8/Week 22, Visit 9/Week 28, Visit 10/Week 34, Visit 11/Week 40, Visit 12/Week 46, Visit 13/Week 52>>>

[1] The “unassigned” analysis visit indicates a visit that did not fall into an analysis window.
[2] Study day is calculated relative to the date of Day 1, the date of first study drug administration.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XX

Data Listing 16.2.8.3.1: Vital Signs
All Randomized Subjects
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/ Subject	Analysis Visit [1]	Date (Day) [2]	Height (cm)	Weight (kg)		Systolic Blood Pressure (mmHg)		Diastolic Blood Pressure (mmHg)		Pulse Rate (beats/minute)	
			Observed	Observed	CFBL	Observed	CFBL	Observed	CFBL	Observed	CFBL
XX/XXX	Baseline/Visit 1	ddMMMyyyy (XX)	xxx.x	xxx.x	--	xxx	--	xxx	--	xx	--
	Visit 2/Week 1	ddMMMyyyy (XX)	--	--	--	xxx	--	xxx	--	xx	--
	Visit 3/Week 3	ddMMMyyyy (XX)	--	--	--	xxx	xxx.x	xxx	xxx.x	xx	xx.x
	Visit 4/Week 6	ddMMMyyyy (XX)	--	--	--	xxx	xxx.x	xxx	xxx.x	xx	xx.x
	Visit 5/Week 9	ddMMMyyyy (XX)	--	--	--	xxx	xxx.x	xxx	xxx.x	xx	xx.x
	Visit 6/Week 12	ddMMMyyyy (XX)	--	xxx.x	xxx.x	xxx	xxx.x	xxx	xxx.x	xx	xx.x

< <<Continue for Visit 7/Week 16, Visit 8/Week 22, Visit 9/Week 28, Visit 10/Week 34, Visit 11/Week 40, Visit 12/Week 46 and Visit 13/Week 52>>>

CFBL=Change from baseline
Note: If more than one visit occurs within a single analysis visit window, then the analysis will take the one closest to the target day. Values with * are not used in analysis.
Baseline value is defined as the last non-missing value prior to the first dose of study drug. Change from baseline is calculated as baseline value minus post-baseline value.
[1] The “unassigned” analysis visit indicates a visit that did not fall into an analysis window.
[2] Study day is calculated relative to the date of Day 1, the date of first study drug administration.

Generated on XX/XX/XX:XXXX by LSTVS / Uses: XX

Data Listing 16.2.8.4.1: Physical Exam
All Randomized Subjects Abnormal Results
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/ Subject	Analysis Visit [1]	Date (Day) [2]	Body System	Result	Comment
XX/XXX	Baseline/Visit 1	ddMMMyyyy (XX)	General Appearance	Abnormal	XXXXXXXXX
	Visit 6/Week 12	ddMMMyyyy (XX)	Dermatological	Abnormal	XXXXXXXXX
	Visit 13/Week 52	ddMMMyyyy (XX)	Dermatological	Abnormal	XXXXXXXXX

[1] The "unassigned" analysis visit indicates a visit that did not fall into an analysis window.
[2] Study day is calculated relative to the date of Day 1, the date of first study drug administration.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XX

Data Listing 16.2.8.5.1: Tolerability Assessment for Face
All Randomized Subjects
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/ Subject	Analysis Visit [1]	Date (Day) [2]	Symptoms	Intensity	Comment
XX/XXX	Visit 2/Week1	ddMMMyyyy (XX)	Erythema	1=Mild	XXXXX
			Dryness	1=Mild	
			Hyper-Pigmentation	1=Mild	
			Skin Peeling	1=Mild	
			Itching	1=Mild	
	Visit 3/Week 3	ddMMMyyyy (XX)	Erythema	1=Mild	XXXXX
			Dryness	1=Mild	
			Hyper-Pigmentation	1=Mild	
			Skin Peeling	1=Mild	
			Itching	1=Mild	

<Continue for Visit 4/Week 6, Visit 5/Week 9, Visit 6/Week12, Visit 7/Week16, Visit 8/Week 22, Visit 9/Week 28, Visit 10/Week 34, Visit 11/Week 40, Visit 12/Week 46, Visit 13/Week 52>

Note: If more than one visit occurs within a single analysis visit window, then the analysis will take the one closest to the target day. Values with * are not used in analysis.
[1] The “unassigned” analysis visit indicates a visit that did not fall into an analysis window.
[2] Study day is calculated relative to the date of Day 1, the date of first study drug administration.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XX

Data Listing 16.2.8.5.2: Tolerability Assessment for Non-Facial Areas
All Randomized Subjects
Actual Treatment: [DB-FMX-101,4%][DB-Vehicle Foam]

Site/ Subject	Analysis Visit [1]	Date (Day) [2]	Symptoms	Affected Area [3]	Intensity [4]	Comment
XX/XXX	Visit 2/Week1	ddMMMyyyy (XX)	Erythema	Non-face: Neck	1=Mild	XXXXX
			Dryness		1=Mild	XXXXX
			Hyper-Pigmentation		1=Mild	
			Skin Peeling		1=Mild	
			Itching		1=Mild	
	Visit 3/Week 3	ddMMMyyyy (XX)	Erythema	Non-face: Neck	1=Mild	XXXXX
			Dryness		1=Mild	XXXXX
			Hyper-Pigmentation		1=Mild	
			Skin Peeling		1=Mild	
			Itching		1=Mild	

<Continue for Visit 4/Week 6, Visit 5/Week 9, Visit 6/Week12, Visit 7/Week16, Visit 8/Week 22, Visit 9/Week 28, Visit 10/Week 34, Visit 11/Week 40, Visit 12/Week 46, Visit 13/Week 52>

Note: If more than one visit occurs within a single analysis visit window, then the analysis will take the one closest to the target day. Values with * are not used in analysis.
[1] The “unassigned” analysis visit indicates a visit that did not fall into an analysis window.
[2] Study day is calculated relative to the date of Day 1, the date of first study drug administration.
[3] For non-face area, region affected maximally is reported
[4] For non-face area, maximum intensity is reported

Generated on XX/XX/XX:XXXX by XXXX / Uses: XX