

**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, Study FX2014-05**

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Foamix Pharmaceuticals, Inc

**Protocol No. FX2014-05
Novella Clinical No. CT9901715**

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 3, 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 12 weeks of treatment was 20% 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) |
|-------------------|-------------------------------|--------------------------------|
| CCI | CCI | CCI |
| CCI | CCI | CCI |
| CCI | CCI | CCI |

Assuming 12% dropout rate, CCI subjects on active, and CCI 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 CCI in the minocycline 4% foam versus CCI in the vehicle group. The standard deviation in change from baseline was approximately 9.2. The 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) |
|--|--|--------------------------------|
| CCI | CCI | CCI |
| CCI | CCI | CCI |
| C | CCI | CCI |

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, CCI subjects on active, and CCI on vehicle will provide > 90% power for a 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 15% 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 45%. With a 15% non-inferiority margin, there will be approximately 90% power to show non-inferiority with sample sizes of CCI and 150 in the Minocycline 4% foam and vehicle groups respectively. The margin of 15% 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 [REDACTED] subjects completing week 12, which reported an SD of [REDACTED]

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 **cc** 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 $\alpha=0.05$ 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 Tertiary Efficacy Endpoints

The tertiary efficacy endpoints will include the following:

- The percent change from Baseline in the inflammatory lesion count at Weeks 3, 6, 9 and 12
- The absolute change from Baseline in the inflammatory and noninflammatory lesions, and the IGA Treatment Success at Week 3
- The absolute change from Baseline in the noninflammatory lesion count at Weeks 3, 6, 9 and 12
- The percent change from Baseline in the noninflammatory lesion count at Weeks 3, 6, 9 and 12

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 15% of the noninflammatory lesion percent reduction in the vehicle group at Week 12. A lower 97.5% confidence limit will be calculated for $\mu_a - 0.85 \times \mu_v$, where μ_a and μ_v 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 $p \leq 0.025$) 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 Clinical 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. FX2014-05
Novella Clinical No. CT991715**

STATISTICAL ANALYSIS PLAN FOR OPEN-LABEL PHASE

**A RANDOMIZED, DOUBLE-BLIND STUDY TO COMPARE THE
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MODERATE-TO-SEVERE ACNE VULGARIS**

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October 19, 2017

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Tables – Open-Label Phase

| | |
|--------------|---|
| 14.1 | Summary of Disposition, Demographic, and Baseline Data Summary Tables |
| 14.1.1.1.1 | Summary of Subject Enrollment and Disposition, All Subjects Entering Open-Label Phase |
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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-Vehicle 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-Vehicle 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-Vehicle 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 prior to the first dose of study drug during the double-blind phase.

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Table 14.1.3.1.1: Summary of Concomitant Medications
 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-Vehicle 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

Concomitant = ongoing or with stop dates on or after first day 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)

| Visit | N | DB-FMX-101, 4% (N=XXX) | | | N | DB-Vehicle Foam (N=XXX) | | |
|------------------------------|-----|------------------------|--------|-----------|-----|-------------------------|--------|-----------|
| | | Mean (SD) | Median | Min, Max | | 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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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) 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

| | Overall (N=XXX) |
|---|----------------------------|
| Q1: How satisfied are you with this product in treating your acne? | |
| N | XXX |
| 1-Very Satisfied | XXX (XX.X) |
| 2- Satisfied | XXX (XX.X) |
| 3-Somewhat Satisfied | XXX (XX.X) |
| 4-Dissatisfied | XXX (XX.X) |
| 5-Very Dissatisfied | 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 |
| 1-Very Likely | XXX (XX.X) |
| 2- Likely | XXX (XX.X) |
| 3-Somewha Likely | XXX (XX.X) |
| 4-Unliklely | XXX (XX.X) |
| 5-Very Unlikely | XXX (XX.X) |

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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

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

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 starting 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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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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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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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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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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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.

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.

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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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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

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[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

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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.

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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.

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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.

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Data Listing 16.1.1: All Ongoing Concomitant Medications at the End of Double-Blind Phase
 All Subjects

| Site/ Subject | Double-Blind Phase Treatment Group | WHO Preferred Term (Verbatim Term) / ATC Classification | Indication | Dose/ Dose Unit | Frequency/ Route | Start Date (Day)/ Stop Date (Day) [1] | Ongoing? |
|------------------|---------------------------------------|---|------------|--------------------|---------------------|--|----------|
| XX/XX X | FMX-101,4% | xxxxxxxxx(xxxxxxx) / xxxxxxxxxxxxxx | xxxxxxx | xxxxx/xxx | xxx/xxxxx | ddMMMyyyy (XX)/ ddMMMyyyy (XX) | Y |

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

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Data Listing 16.1.2.: All Adverse Events Ongoing at the End of Double-Blind Phase
 All Subjects

| Site/ Subject | Double-Blind Phase Treatment Group | 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/XX X | FMX-101,4% | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Inside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXXX / XXXXXXXXXX / XXXXXXXXXX | XXXXXXXXXX / XXXXXXXXXX / Yes: XXXX |
| | | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Outside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXXX / XXXXXXXXXX / XXXXXXXXXX | XXXXXXXXXX / XXXXXXXXXX / No |
| XX/XX X | FMX-101,4% | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Inside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXXX / XXXXXXXXXX / XXXXXXXXXX | XXXXXXXXXX / XXXXXXXXXX / XXX |

[1] TEAEs of double-blind phase are defined as AEs starting on or after the date of first application of study medication of the double-blind phase, but before the date of the first application of the open-label phase.

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

Data Listing 16.2.1.2.1: Subject Disposition
 Safety Population Entering Open-Label Phase

| Site/Subject | DB Treatment Group | 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 | FMX-101,4% | ddMMMyyyy | ddMMMyyyy | ddMMMyyyy (XX) | ddMMMyyyy (XX) | ddMMMyyyy (XX) | Completed |
| XX/XXX | FMX-101,4% | ddMMMyyyy | ddMMMyyyy | ddMMMyyyy (XX) | ddMMMyyyy (XX) | ddMMMyyyy (XX) | Lost to Follow-up |
| XX/XXX | Vehicle Foam | ddMMMyyyy | ddMMMyyyy | ddMMMyyyy (XX) | ddMMMyyyy (XX) | ddMMMyyyy (XX) | XXXXXXXX |
| XX/XXX | Vehicle Foam | ddMMMyyyy | ddMMMyyyy | ddMMMyyyy (XX) | ddMMMyyyy (XX) | ddMMMyyyy (XX) | XXXXXXXX |

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 Subjects with Deviations in the Open-Label phase

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

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Data Listing 16.2.4.4.1: Concomitant Medications starting in the Open-Label Phase
 All Subject Entering Open-Label Phase

| Site/ Subject | Double Blind Treatment Group | WHO Preferred Term (Verbatim Term) / ATC Classification | Indication | Dose/ Dose Unit | Frequency/ Route | Start Date (Day)/ Stop Date (Day) [1] | Ongoing? |
|------------------|------------------------------------|--|-------------------------------|--------------------|---------------------|--|----------|
| XX/XXX | FMX-101,4% | XXXXXXXXXX(XXXXXXXX) / XXXXXXXXXXXXXXXX | XXXXXXXXXXXXXXXXXXXX XXXXX | XXXXX/XXX | XXX/XXXXX | ddMMMyyyy (XX)/ ddMMMyyyy (XX) | Y |

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..

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Data Listing 16.2.5.1.1: Study Medication Exposure and Usage
 All Subjects Entering Open-Label phase

| Site/Subject | Double-Blind Treatment Group | Date of First Dose in DB | Date (Day) of Last Dose in OL [1] | Total Days of Exposure [2] | Visit | # Canisters Dispensed | # Canisters Returned | Kit Number Dispensed | Regions Beyond the Face where Study Drug was Applied |
|--------------|------------------------------|--------------------------|-----------------------------------|----------------------------|------------------|-----------------------|----------------------|----------------------|--|
| 01/002 | FMX-101,4% | ddMMMyyy(XX) | ddMMMyyy(XX) | 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 Subjects Entering Open-Label Phase

| Site/ Subject | Double Blind Treatment Group | Kit Number Dispensed | Number of Canisters Returned in Kit | Amount Returned (g) | Amount Applied (g) [1] |
|------------------|------------------------------------|----------------------------|---|---------------------------|------------------------------|
| XX/XXX | FMX-101,4% | 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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<< Display for only unique kit numbers >>

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Data Listing 16.2.6.1.1.1: Lesion Counts
 All Subjects Entering Open-Label Phase

| Site/Subject | DB Treatment Group | Analysis Visit | Date (Day) [1] | Inflammatory Lesions (IL) | | | Noninflammatory Lesions (NIL) | | | Total [2] | Non Facial Area [3] | |
|--------------|--------------------|------------------|----------------|---------------------------|----------|---------|-------------------------------|----------------|------------------|-----------|---------------------|-----------|
| | | | | Papules | Pustules | Nodules | Total IL | Open Comedones | Closed Comedones | | | Total NIL |
| XX/XXX | FMX-101,4% | 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

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

[2] Total includes inflammatory and noninflammatory.

[3] Regions beyond the face affected by acne.

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

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 Protocol No. FX2014-05, Open- Label Phase

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Data Listing 16.2.6.1.2.1: Total Inflammatory and Noninflammatory Lesion
 Counts
 All Subjects Entering Open-Label Phase

| Site/Subject | Double-Blind Phase Treatment Group | Analysis Visit | Date (Day) [1] | Type | Total Inflammatory | Total Noninflammatory | | |
|--------------|---|-----------------|------------------|------------------------------|--------------------|------------------------------|------|------|
| XX/XXX | FMX-101,4% | 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 >

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

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Data Listing 16.2.6.2.1: Investigator's Global Assessment and Treatment Success
All Subjects Entering Open-Label Phase

| Site/Subject | Double-Blind Phase Treatment Group | Analysis Visit | Date (Day) [1] | IGA | Treatment Success |
|--------------|------------------------------------|------------------|----------------|-----|-------------------|
| XX/XXX | FMX-101,4% | 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

[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 16.2.6.3.1: Subject Satisfaction Questionnaire
 All Subjects Entering Open-Label Phase

| Site/Subject | Double-Blind Treatment Group | Visit | Date (Day) [1] | Question | Response |
|--------------|------------------------------|------------------|----------------|--|------------------|
| XX/XXX | FMX-101,4% | 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 | FMX-101,4% | 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] Study day is calculated relative to the date of Day 1, the date of first study drug administration during the double-blind phase.

Data Listing 16.2.7.1.1: All Adverse Events Started in Open-Label Phase
 All Subjects Entering Open-Label Phase

| Site/ Subject | Double- Blind Phase Treatment Group | 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 | FMX-101,4% | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Inside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXX / XXXXXXXXX / XXXXXXXXX | XXXXXXXXX / XXXXXXXXX / Yes: XXXX |
| | | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Outside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXX / XXXXXXXXX / XXXXXXXXX | XXXXXXXXX / XXXXXXXXX / No |
| XX/XXX | FMX-101,4% | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Inside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXX / XXXXXXXXX / XXXXXXXXX | XXXXXXXXX / XXXXXXXXX / XXX |

[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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 Protocol No. FX2014-05, Open-Label Phase

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Data Listing 16.2.7.2.1: Serious Adverse Events Leading to Study Discontinuation
 All Subjects who entered Open-Label Phase

| Site/ Subject | Double-Blind Phase Treatment Group | 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 | FMX-101,4% | 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 | FMX-101,4% | XXXXXXXX / XXXXXXXX / (XXXXXXXX) | Inside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXX / XXXXXXXX / XXXXXXXX | XXXXXXXX / XXXXXXXX / Yes: XXXX |

[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 16.2.7.3.1: Treatment-Emergent Adverse Events Leading to Study Discontinuation
 All Subjects who Entered Open-Label Phase

| Site/ Subject | Double-Blind Phase Treatment Group | 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 | FMX-101,4% | 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 | FMX-101,4% | XXXXXXXX / XXXXXXXX / (XXXXXXXX) | Inside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXX / XXXXXXXX / XXXXXXXX | XXXXXXXX / XXXXXXXX / Yes: XXXX |

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

Data Listing 16.2.8.1.1: Urine Pregnancy Test
 All Subjects Entering Open-Label Phase

| Site/ Subject | Double-Blind Phase Treatment Group | Childbearing Potential | Visit | Date of Test (Day)[1] | Result |
|------------------|---------------------------------------|------------------------|------------------|-----------------------|----------|
| XX/XXX | FMX-101,4% | XXXXXXXX | 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 | FMX-101,4% | Male | -- | -- | -- |

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

[1] Study day is calculated relative to the date of Day 1, the date of first study drug administration.

Foamix Pharmaceuticals, Inc.
Protocol No. FX2014-05, Open-Label Phase

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Data Listing 16.2.8.1.2: Home Pregnancy Test
All Subjects Entering Open-Label Phase

| Site/Subject | Double-Blind Phase | Childbearing Potential | Analysis Visit | Date (Day) [1] | Was a Home Pregnancy Test dispensed? | Positive Pregnancy Test since last Visit? | Date of Positive Pregnancy Test |
|--------------|--------------------|------------------------|------------------|----------------|--------------------------------------|---|---------------------------------|
| XX/XXX | FMX-101,4% | XXXXXX | 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] 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 16.2.8.2.1.X.1: Clinical Laboratory Tests
 All Subjects Entering Open-Label Phase
 [Hematology][Chemistry][Urinalysis]

| Site/Subject | Double-Blind Phase Treatment Group | Visit | Test Name | Test Date (Day)[1] | Result (Unit) | Abnormal? | Clinically Significant? | Reference Range |
|--------------|------------------------------------|------------------|-----------|--------------------|---------------|-----------|-------------------------|-----------------|
| XX/XXX | FMX-101,4% | 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] 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

Foamix Pharmaceuticals, Inc.
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Data Listing 16.2.8.2.2.1: Clinically Significant Clinical Laboratory Tests for Hematology, Chemistry and Urinalysis
 All Subjects Entering Open-Label Phase

| Site/Subject | Double-Blind Phase Treatment Group | Visit | Category of Laboratory Test | Test Name | Test Date (Day)[1] | Result (Unit) | Abnormal? | Reference Range |
|--------------|------------------------------------|------------------|-----------------------------|-----------|--------------------|---------------|-----------|-----------------|
| XX/XXX | FMX-101,4% | 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] Study day is calculated relative to the date of Day 1, the date of first study drug administration.

Foamix Pharmaceuticals, Inc.
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Data Listing 16.2.8.2.3.1: Out-of-Range (Abnormal) Clinical Laboratory Test Results for Hematology, Chemistry and Urinalysis
All Subjects Entering Open-Label Phase

| Site/Subject | Double-Blind Phase Treatment Group | Visit | Category of Laboratory Test | Test Name | Test Date (Day)[1] | Result (Unit) | Abnormal? | Clinically Significant |
|--------------|------------------------------------|-----------------|-----------------------------|-----------|--------------------|---------------|-----------|------------------------|
| XX/XXX | FMX-101,4% | 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] Study day is calculated relative to the date of Day 1, the date of first study drug administration.

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Data Listing 16.2.8.3.1: Vital Signs
 All Subjects Entering Open-Label Phase

| Site/ Subject | Double-Blind Phase Treatment Group | Analysis Visit | Date (Day) [1] | Weight (kg) | | Systolic Blood Pressure (mmHg) | | Diastolic Blood Pressure (mmHg) | | Pulse Rate (beats/minute) | |
|------------------|---|-----------------|----------------|-------------|------------|-----------------------------------|----------------|------------------------------------|-------|------------------------------|------|
| | | | | Observed | CFBL | Observed | CFBL | Observed | CFBL | Observed | CFBL |
| | | | | XX/XXX | FMX-101,4% | Baseline/Visit 1 | ddMMMyyyy (XX) | xxx.x | -- | xxx | -- |
| | | 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: 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] Study day is calculated relative to the date of Day 1, the date of first study drug administration.

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Data Listing 16.2.8.4.1: Physical Exam
Subjects Entering Open-Label Phase with Abnormal Results

| Site/ Subject | Double-Blind Phase Treatment Group | Analysis Visit | Date (Day) [1] | Body System | Result | Comment |
|------------------|---------------------------------------|------------------|----------------|--------------------|----------|------------|
| XX/XXX | FMX-101,4% | Baseline/Visit 1 | ddMMMyyyy (XX) | General Appearance | Abnormal | XXXXXXXXXX |
| | | Visit 6/Week 12 | ddMMMyyyy (XX) | Dermatological | Abnormal | XXXXXXXXXX |
| | | Visit 13/Week 52 | ddMMMyyyy (XX) | Dermatological | Abnormal | XXXXXXXXXX |

[1] Study day is calculated relative to the date of Day 1, the date of first study drug administration

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Foamix Pharmaceuticals, Inc.
 Protocol No. FX2014-05, Open-Label Phase

Data Listing 16.2.8.5.1: Tolerability Assessment for Face
 All Subjects Entering Open-Label Phase

| Site/ Subject | Double-Blind Phase Treatment Group | Analysis Visit | Date (Day) [1] | Symptoms | Intensity | Comment |
|------------------|---------------------------------------|----------------|----------------|--------------------|-----------|---------|
| XX/XXX | Vehicle Foam | 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 | |
| | | | | 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>

[1] Study day is calculated relative to the date of Day 1, the date of first study drug administration.

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Foamix Pharmaceuticals, Inc.
 Protocol No. FX2014-05, Open-Label Phase

Data Listing 16.2.8.5.2: Tolerability Assessment for Non-Facial Areas
 All Subjects Entering Open-Label Phase

| Site/ Subject | Double-Blind Phase Treatment Group | Analysis Visit | Date (Day) [1] | Symptoms | Affected Area [2] | Intensity[3] | Comment |
|------------------|---------------------------------------|----------------|----------------|--------------------|-------------------|--------------|---------|
| XX/XXX | Vehicle Foam | Visit 2/Week1 | ddMMMyyyy (XX) | Erythema | Non-face: Neck | 1=Mild | XXXXXX |
| | | | | Dryness | | 1=Mild | XXXXXX |
| | | | | Hyper-Pigmentation | | 1=Mild | |
| | | | | Skin Peeling | | 1=Mild | |
| | | | | Itching | | 1=Mild | |
| | | Visit 3/Week 3 | ddMMMyyyy (XX) | Erythema | Non-face: Neck | 1=Mild | XXXXXX |
| | | | | Dryness | | 1=Mild | XXXXXX |
| | | | | 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>

[1] Study day is calculated relative to the date of Day 1, the date of first study drug administration.

[2] For non-face area, region affected maximally is reported

[3] For non-face area, maximum intensity is reported

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

Foamix Pharmaceuticals, Inc

**Protocol No. FX2014-05
Novella Clinical No. CT991715**

***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**

Novella Clinical

PPD

*365 West Passaic Street
Rochelle Park, NJ 07662, USA*

December 7, 2017

PPD

**Senior Vice President, Research and Development
Foamix Pharmaceuticals, Inc**

PPD

| 10:52:17 EST

PPD

**Sr. Director, Data Management and Biostatistic
Novella Clinical**

PPD

| 14:10:44 EST

Tables – Open-Label Phase

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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-Vehicle 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-Vehicle 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-Vehicle 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.

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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-Vehicle 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)

| Visit | N | DB-FMX-101, 4% (N=XXX) | | | N | DB-Vehicle Foam (N=XXX) | | |
|------------------------------|-----|------------------------|--------|-----------|-----|-------------------------|--------|-----------|
| | | Mean (SD) | Median | Min, Max | | 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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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-Unlikely | XXX (XX.X) | | XXX (XX.X) |
| 5-Very Unlikely | XXX (XX.X) | | XXX (XX.X) |

DB= Double-Blind

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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] Number of treatment-emergent AEs | XX (XX.X) XXX | XX (XX.X) XXX | XX (XX.X) XXX |
| Subjects with any serious TEAE (SAE), n (%) Number of serious TEAEs (SAE) | XXX (XX.X) XXX | XXX (XX.X) XXX | XXX (XX.X) XXX |
| Subjects with any treatment-related TEAE, n (%) Number of treatment-related TEAEs | XXX (XX.X) XXX | XXX (XX.X) XXX | XXX (XX.X) XXX |
| Subjects with any TEAE leading to study discontinuation, n (%) Number of TEAEs leading to study discontinuation | XXX (XX.X) XXX | XXX (XX.X) XXX | XXX (XX.X) 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 starting 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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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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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.

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

Foamix Pharmaceuticals, Inc.
 Protocol No. FX2014-05, 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.

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

Foamix Pharmaceuticals, Inc.
 Protocol No. FX2014-05, Open-Label Phase

Page X of Y

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.

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

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.

Foamix Pharmaceuticals, Inc.
 Protocol No. FX2014-05, 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.

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

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.

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.

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.

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

Foamix Pharmaceuticals, Inc.
 Protocol No. FX2014-05, 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 XXXXXXXXXXXX

[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 XXXXXXXXXXXX

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 XXXXXXXXXXXX

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 XXXXXXXXXXXX

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 XXXXXXXXXXXX

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) | XXXXXXXX |
| XX/XXX | ddMMMyyyy | ddMMMyyyy | ddMMMyyyy (XX) | ddMMMyyyy (XX) | ddMMMyyyy (XX) | XXXXXXXX |

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

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

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 | XXXXXXXXXX | Retrained on protocol |
| XX/XXX | Missed Visit | XXXXXXXXXX | 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(yyyyyyyy)/ xxxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxxxxxx | xxxxx/xxx | xxx/xxxxx | ddMMMyyyy (XX)/ ddMMMyyyy (XX) |
| XX/XXX | xxxxxxxxx(yyyyyyyy)/ xxxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxxxxxx | 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 | xxxxxxxx(xxxxxx)/ xxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxx | xxxxx/xxx | xxx/xxxxx | ddMMMyyyy (XX)/ -- | Y |
| XX/XXX | xxxxxxxx(xxxxxx)/ xxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxx | 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(yyyyyyyy)/ xxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxxxxxx | xxxxx/xxx | xxx/xxxxx | ddMMMyyyy (XX)/ -- |
| XX/XXX | xxxxxxxxx(yyyyyyyy)/ xxxxxxxxxxxxxxx | xxxxxxxxxxxxxxxxxxxxxxxx | 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.

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

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.

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

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

| Site/Subject | Analysis Visit [1] | Date (Day) [2] | Inflammatory Lesions (IL) | | | Noninflammatory Lesions (NIL) | | | | | |
|--------------|--------------------|----------------|---------------------------|----------|---------|-------------------------------|----------------|------------------|-----------|-----------|---------------------|
| | | | 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.

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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.

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 | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Inside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXX / XXXXXXXXX / XXXXXXXXX | XXXXXXXXX / XXXXXXXXX / Yes: XXXX |
| | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Outside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXX / XXXXXXXXX / XXXXXXXXX | XXXXXXXXX / XXXXXXXXX / No |
| XX/XXX | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Inside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXX / XXXXXXXXX / XXXXXXXXX | XXXXXXXXX / XXXXXXXXX / 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 | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Inside Treatment Area | ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXX / XXXXXXXXX / XXXXXXXXX | XXXXXXXXX / XXXXXXXXX / Yes: XXXX |
| | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Outside Treatment Area | ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXX / XXXXXXXXX / XXXXXXXXX | XXXXXXXXX / XXXXXXXXX / No |
| XX/XXX | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Inside Treatment Area | ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXX / XXXXXXXXX / XXXXXXXXX | XXXXXXXXX / XXXXXXXXX / 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 | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Inside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXXX / XXXXXXXXXX / XXXXXXXXXX | XXXXXXXXXX / XXXXXXXXXX / Yes: XXXX |
| | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Outside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXXX / XXXXXXXXXX / XXXXXXXXXX | XXXXXXXXXX / XXXXXXXXXX / No |
| XX/XXX | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Inside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXXX / XXXXXXXXXX / XXXXXXXXXX | XXXXXXXXXX / XXXXXXXXXX / 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.

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

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 | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Inside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXXX / XXXXXXXXXX / XXXXXXXXXX | XXXXXXXXXX / XXXXXXXXXX / Yes: XXXX |
| | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Outside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXXX / XXXXXXXXXX / XXXXXXXXXX | XXXXXXXXXX / XXXXXXXXXX / No |
| XX/XXX | XXXXXXXXX / XXXXXXXXX / (XXXXXXXXX) | Inside Treatment Area | Y / ddMMMyyyy (XX) – ddMMMyyyy (XX) | XXXXXXXXXX / XXXXXXXXXX / XXXXXXXXXX | XXXXXXXXXX / XXXXXXXXXX / 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.

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

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 | XXXXXXXX | Baseline/Visit 1 Visit 2/Week 1 Visit 3/Week 3 Visit 4/Week 6 Visit 5/Week 9 Visit 6/Week 12 Visit 13/Week 52 | ddMMMyyyy (XX) ddMMMyyyy (XX) ddMMMyyyy (XX) ddMMMyyyy (XX) ddMMMyyyy (XX) ddMMMyyyy (XX) ddMMMyyyy (XX) | Negative Negative Negative Negative Negative Negative 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.

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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.

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 | No | xxxx, xxxx |
| | | xxxx | ddMMMyyyy (XX) | xxxx (xxxx) | Normal | | xxxx, xxxx |
| | | 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.

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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.

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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.

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 | CFBL | 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.

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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 | XXXXXXXXXX |
| | Visit 6/Week 12 | ddMMMyyyy (XX) | Dermatological | Abnormal | XXXXXXXXXX |
| | Visit 13/Week 52 | ddMMMyyyy (XX) | Dermatological | Abnormal | XXXXXXXXXX |

[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/Week 1 | ddMMMyyyy (XX) | Erythema | 1=Mild | XXXXXX |
| | | | Dryness | 1=Mild | |
| | | | Hyper-Pigmentation | 1=Mild | |
| | | | Skin Peeling | 1=Mild | |
| | | | Itching | 1=Mild | |
| | Visit 3/Week 3 | ddMMMyyyy (XX) | Erythema | 1=Mild | XXXXXX |
| | | | 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/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>

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.

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

NOTE TO FILE

DATE: 04OCT2018
PROJECT: FX2014-05
AUTHOR: PPD
FILE:
SUBJECT: RERUNNING THE DOUBLE-BLIND ADVERSE EVENTS, CONCOMITANT MEDICATIONS AND LAB TABLES AND LISTINGS

Summary: This Note-to-File provides details regarding the rerunning of the double-blind adverse events, concomitant medications and laboratory (chemistry and hematology) tables and listings.

Narrative:

The double-blind database was locked on 19MAR2017. The adverse events (AEs) and concomitant medications (CMs) eCRF pages were not locked during the double-blind database lock, which was appropriate in order to ensure that the AEs and CMs could be updated through the double-blind and open-label phase of the study. As a result, the coding of several AEs and CMs were updated and several double-blind phase AEs and CMs were added to the database after the double-blind database lock. Therefore, the double-blind tables and listings that were run on the 19MAR2017 data were not reflective of the final data. Therefore, the double-blind AE and CM tables and listing were rerun to reflect the final data for the entire study.

There was also a programming error in the SAS laboratory data export from DSG which resulted in records being inadvertently missing from the lab data extract. This error was discovered by Novella in AUG2018 and communicated to DSG and Foamix. DSG identified the source of the issue, corrected the issue, and properly exported the data. The exported data was verified by DSG using their standard process. The laboratory listing and tables for the double-blind and open-label phase were rerun on 27AUG2018 to reflect the properly exported data.

AUTHOR SIGNATURE / DATE:

PPD

08-OCT-2018

PPD

SPONSOR SIGNATURE/DATE:

PPD

08-oc T-2018