Introduction

- Rosacea is a chronic, inflammatory disorder involving the face that is characterized by central facial erythema, flushing, telangiectasia, edema, papules, and pustules.
- Oral tetracyclines, such as doxycycline and minocycline, are among the common therapies that are used for treating the disorder with oral, sub-microbial doxycycline currently approved for this indication. However, these agents have been associated with antibiotic resistance, adverse side effects, such as gastrointestinal upset and permanent hyperpigmentation, and following treatment cessation, the tendency for disease relapse is high.
- The efficacy and safety of FMX103 1.5% topical minocycline foam in treating moderate-to-severe rosacea has previously been reported in two 12-week, double-blind, vehicle-controlled, Phase 3 studies (Study 11 and Study 12).
- Objective: To demonstrate the long-term safety, tolerability and efficacy of topical FMX103 1.5% minocycline foam in moderate to severe facial papulopustular rosacea for up to 52 weeks.

Methods

- FX2016-13 (Study 13) was an open-label, multicenter, 40-week extension study to evaluate the long-term safety, tolerability, and efficacy of FMX103 1.5% topical foam in the treatment of moderate-to-severe facial papulopustular rosacea (Figure 1).
- Subjects were eligible to enter Study 13 upon successful completion of either double-blind study (Study 11 or Study 12).
  - There was no limit on the number of subjects who could enter the open-label phase.
- Concomitant use of prescription or OTC medications that the subjects were taking or any change in dosage was permitted and recorded.
- Investigator Global Assessments (IGAs) were based upon a 5-point scale with 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, and 4 = severe.

![Figure 1. Study design](image)

Results

Subject Disposition and Double-Blind Baseline Demographics

- As shown in Figure 2, 504 subjects who completed the DB study (Study 11: N=217; Study 12: N=287) comprised the All Treated Safety population in the OL extension study (Study 13).

![Figure 2. Subject disposition](image)

Long-Term Efficacy

- Treatment with FMX103 1.5% during the 40-week OL extension study was associated with reduction in inflammatory lesions relative to the DB and OL baselines, regardless of previous treatment during the DB studies (Figure 4).

![Figure 4. Absolute (A) and percent (B) change from DB baseline in inflammatory lesions](image)

Safety and Tolerability

- Summary of all adverse events in the all treated population is shown in Table 2.
- The majority of the treatment-emergent adverse events (TEAEs) were considered mild or moderate in severity and no serious TEAEs were related to treatment.

![Figure 5. IGA treatment success](image)

Subject Satisfaction

- At the end of the open-label study there was a high rate of subject satisfaction with FMX103 1.5% for the treatment of papulopustular rosacea (Figure 6).

![Figure 6. Subject satisfaction questionnaire results at Week 52](image)

Summary

- Because of the nature of the open-label study, no inference can be made on comparability due to the absence of a vehicle-treated control.

Conclusions

- FMX103 1.5% appeared to be safe and well tolerated for the long-term treatment of papulopustular rosacea for up to 52 weeks of treatment.
- No minocycline-induced hyperpigmentation was observed.
- Throughout 52 weeks of treatment, FMX103 1.5% continued to be associated with a decreasing number of inflammatory lesions, as well as with improvement in overall disease severity, as assessed by IGA scores.
- Patient satisfaction levels were high, with >80% of all subjects either being satisfied or very satisfied with FMX103 1.5%.

Disclosures/Acknowledgments

Disclosures

- Dr. James Q. Del Rosso, DO, is a consultant for Foamix Pharmaceuticals. Dr. Hooper served as an investigator for Foamix Pharmaceuticals; she reports personal fees from DelRicht, and MilliporeSigma.
- Mr. Taieb is an employee of Foamix Pharmaceuticals. Dr. Del Rosso is a consultant for Aclaris, Almirall, Athenex, Cutanea, Dermira, Ferndale, Galderma, Genentech, Medac, Menlo Therapeutics Inc., and Meiji. Dr. Hooper serves as a consultant and investigator for Foamix Pharmaceuticals. Dr. Feldman serves as an investigator for Foamix Pharmaceuticals.
- The clinical trial was overseen by Foamix Pharmaceuticals.

Acknowledgments

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References