**INTRODUCTION**

Acne vulgaris (AV) is the most common skin disorder in the United States, affecting nearly 85% of all people at some point in their lives. Systemic antibiotics, such as minocycline and doxycycline, are a standard of care in the management of moderate and severe acne; however, they are associated with systemic side effects in some patients.

FMX101 is a novel and stable topical formulation of minocycline for the treatment of moderate to severe AV.

**STUDY OBJECTIVES**

- Assess the safety of FMX101 minocycline foam topical application in subjects with AV
- Detect clinically significant effects of FMX101 minocycline foam topical application on the course of disease in moderate to severe AV
- Establish a safe and effective dose of FMX101 minocycline foam

**METHODS**

- Phase 2 prospective, multicenter, randomized, double-blind, vehicle-controlled, parallel-group study to evaluate the efficacy, safety, and tolerability of 2 strengths of topical FMX101 minocycline foam to the treatment of AV
- Concluded at 3 study centers in Israel by 3 independent investigators

**RESULTS**

- Daily topical application of minocycline foam or vehicle
- Lesion counts and Investigator’s Global Assessment of Improvement of AV severity were recorded at each visit using a rating scale where 0 = clear or better than prior to study
- Increments of 0.5 (eg, a score of 2.5) could be used

**CONCLUSIONS**

- FMX101 was effective for the treatment of moderate to severe acne, producing a clinically and statistically significant effect as early as 3-6 weeks after initiation of treatment
- The effectiveness was dose-dependent: FMX101 4% was more effective than FMX101 1%
- Both FMX101 and foam Vehicle were safe and well tolerated, with very few transient and mild AEs
- No new AEs were considered to be related to the study medication
- A majority of subjects reported that the foam formulation was more effective than other topical products previously used
- Phase 3 studies are planned to continue the development of FMX101 4% for the treatment of moderate to severe acne

Disclosures

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**REFERENCES**