Introduction
Rosacea is a chronic skin condition characterized by erythema, inflammatory papules/pustules, or telangiectasia. It is estimated to affect ~16 million people in the US.1,2 FDA-approved treatment for rosacea includes topical agents, such as metronidazole, azelaic acid, sulfur, tetracyclines, and, recently, inotcelain, as well as oral doxycycline.1,2 Oral tetracyclines, particularly minocycline and doxycycline, may be prescribed for moderate-to-severe rosacea; however, there is use with associated systemic AEAs.1,2 A novel, foam formulation of minocycline – FMX-103 – has been developed to facilitate local application and bioavailability of minocycline while preserving its efficacy for the treatment of rosacea.3 This was a randomized, multicenter, double-blind study evaluating the safety and efficacy of 2 different doses of the topical minocycline foam, FMX-103 1.5% and 3%, in the treatment of papulopustular rosacea, as compared with vehicle.

Methods
Phase 2, randomized, multicenter (18 sites in Germany), double-blind, vehicle-controlled clinical trial. Evaluated the safety and efficacy of 2 doses of a topical once-daily minocycline foam (FMX-103 1.5% and 3%) compared with vehicle foam in the treatment of moderate-to-severe papulopustular rosacea (Figure 1). Subjects were randomized 1:1:1 to receive treatment once daily (in the evening) for 12 weeks. Safety and efficacy evaluations were performed at week 2, 4, 8, and 12, with an additional safety follow-up visit at week 16.

Results
233 subjects were randomized and received at least one dose of study drug (ITT population). 201 (86.6%) subjects completed 12 weeks of treatment and the follow-up visit. Baseline demographics and disease characteristics are shown in Table 1. 15% to 50% of subjects had severe rosacea, and the mean number of inflammatory lesions ranged from 30.6 to 34.5.

Safety
Both FMX-103 1.5% and 3% doses appeared to be generally safe and well tolerated, with no reported treatment-related systemic AEs. Overall, 47.3% (109/232) of subjects reported 1 TEAE (Table 2). The most common AEs (>2% of subjects) included nasopharyngitis, urinary tract infection, syphilis, and lymphadenopathy (Table 3). 11 (4.7%) subjects reported treatment-related TEAEs; 9 had treatment-related dermal reactions (application-site erythema). Only 3 subjects discontinued the study due to dermal-related TEAEs (application-site erythema).

Conclusions
At week 12, both FMX-103 1.5% and 3% were significantly better than vehicle in reducing the number of papules and pustules, improving IGA score by ≥2, reducing the number of facial lesions (papules/pustules) – improving IGA score by ≥2, and reducing the number of facial lesions (papules/pustules) – improving IGA score by ≥2. Safety profiles included all randomized subjects who applied at least one dose of study drug. Subjects experiencing ≥1 AE are counted only once for each AE term.

Table 1. Baseline demographics and disease characteristics

Table 2. Summary of treatment-related dermal reactions, serious TEAEs, and TEAEs leading to study discontinuation

References

Abbreviations
AE = adverse event; TEAE = treatment-emergent adverse event; IGA = investigator’s Global Assessment; ITT = intent-to-treat; SD = standard deviation.

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