Oral tetracyclines, specifically doxycycline and minocycline, are mainstays of treatment for moderate-to-severe rosacea. At week 12, all facial local tolerability assessments showed improvement compared to baseline. Moderate and severe adverse events reported in the FMX103 1.5% foam group were similar to those reported in the vehicle foam group, with the exception of facial burning, which was more common in the FMX103 1.5% foam group.

**Methods**
- The 2 pivotal Phase 3 studies (FX2016-11, Study 11; FX2016-12, Study 12) were randomized, double-blind, vehicle-controlled studies. FX2016-11 (Study 11) and FX2016-12 (Study 12) have previously been presented.

**Results**

**Baseline Demographics and Disease Characteristics**
- 1522 subjects were included in the integrated efficacy population. Baseline demographics and disease characteristics are shown in Table 1.
- The majority of subjects were female (70.6%) and white (96.4%). The mean age was 50.0 and ranged from 18-88 years. At baseline, 86.9% and 13.1% of subjects had moderate (IGA=3) or severe (IGA=4) disease, respectively.

**Efficacy**
- FMX103 1.5% demonstrated statistically significant advantages over vehicle foam in both baseline disease severity subgroups (Figure 5).
- In both moderate (IGA=3) and severe (IGA=4) subpopulations, the change from baseline at week 12 in inflammatory lesions was significantly greater in the FMX103 1.5% group than in the vehicle foam group (Figure 4A).
- Similarly, a significantly greater number of subjects in the FMX103 1.5% group achieved IGA treatment success by week 12 than in the vehicle foam group, regardless of baseline disease severity (Figure 5).
- The treatment effect for FMX103 1.5% vs vehicle foam was more pronounced in the severe subgroup than in the moderate subgroup for both inflammatory lesions (Figure 4A) and IGA treatment success (Figure 5).

**Safety**
- FMX103 1.5% demonstrated a statistically significant advantage over vehicle foam for IGA treatment success beginning as early as week 4 (Figure 4).
- This statistical advantage over vehicle was maintained throughout the study, with approximately half of the subjects in the FMX103 1.5% group achieving treatment success by week 12.

**Summary**
- FMX103 1.5% demonstrated statistically significant advantage over vehicle foam in both baseline disease severity subgroups (Figure 5).
- In both moderate (IGA=3) and severe (IGA=4) subpopulations, the change from baseline at week 12 in inflammatory lesions was significantly greater in the FMX103 1.5% group than in the vehicle foam group (Figure 4A).
- Similarly, a significantly greater number of subjects in the FMX103 1.5% group achieved IGA treatment success by week 12 than in the vehicle foam group, regardless of baseline disease severity (Figure 5).
- The treatment effect for FMX103 1.5% vs vehicle foam was more pronounced in the severe subgroup than in the moderate subgroup for both inflammatory lesions (Figure 4A) and IGA treatment success (Figure 5).

**Figure 4. IGA treatment success over time**

**Figure 5. Efficacy of FMX103 1.5% across baseline disease severities**

**Figure 6. Summary of overall percentages of AEs in all groups**

**Figure 7. Facial local tolerability assessments at baseline and week 12 in FMX103 1.5% treatment group**

**Table 2. Summary of TEAEs and AEs in the integrated safety population**

**Table 3. Summary of non-cutaneous TEAEs in the integrated safety population by preferred term**

**Figure 8. Change from baseline in inflammatory lesion counts by visit**

**Figure 9. Change from baseline in IGA score**

**Table 4. Summary of TEAEs by severity**

**References**