Introduction & Objectives:

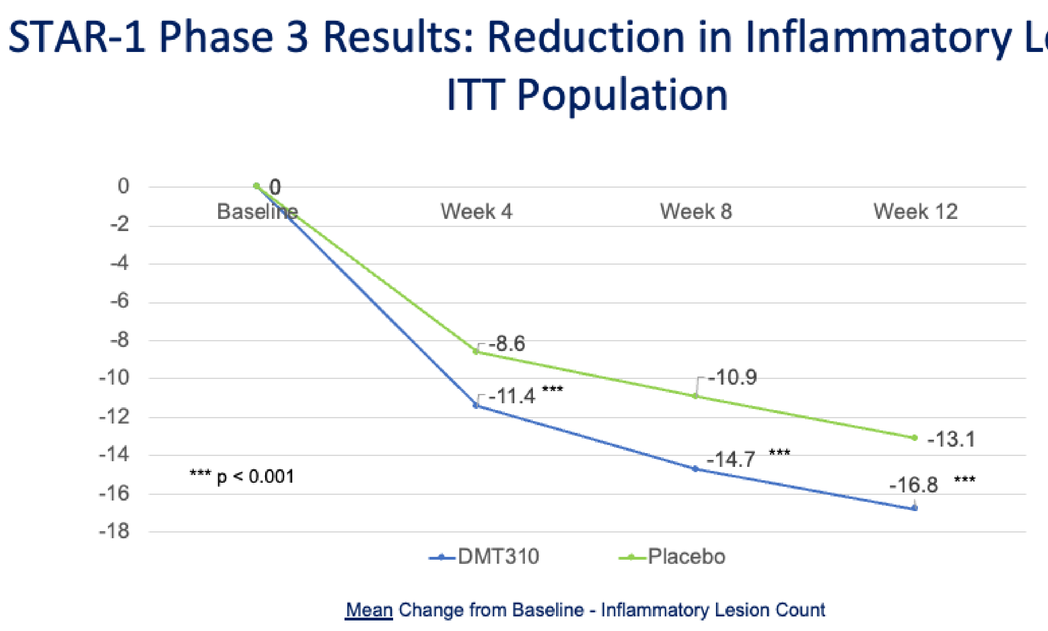
DMT310, a natural, topical product with a once-weekly application, has shown good efficacy and an excellent safety profile in Phase 2 studies for the treatment of acne vulgaris. Based on Phase 2 success, the STAR-1 study, a large, multicenter Phase 3 study was performed. The objective of this study was to confirm the efficacy and safety of DMT310 in treating moderate-to-severe acne vulgaris.

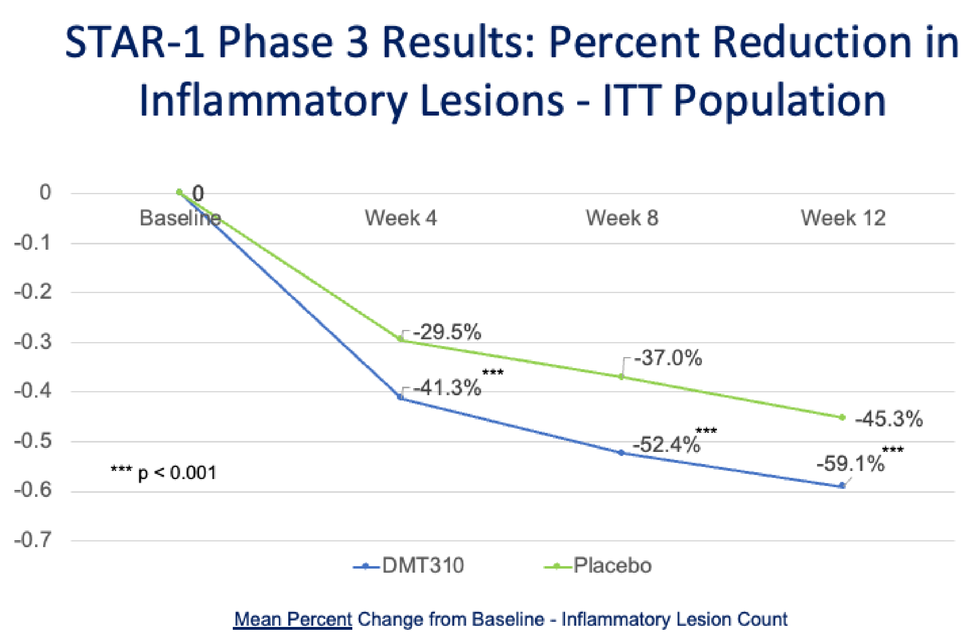
Materials & Methods:

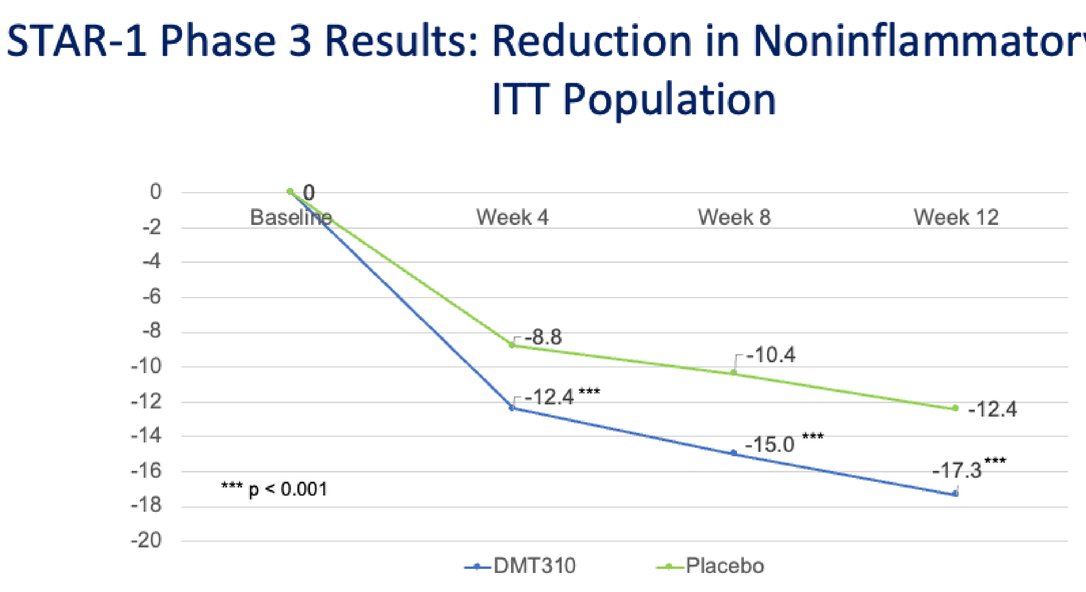
This 12-week, randomized, double blind, placebo-controlled, multicenter clinical trial enrolled patients, 9 years and older with moderate-to-severe acne with ≥ 20 inflammatory lesions (IL) and ≥ 20 non-inflammatory lesions (NIL) on the face, and an acne grade of 3 (moderate) or 4 (severe) on the Investigator's Global Assessment (IGA). Subjects were randomized 2:1 to once-weekly DMT310 or placebo after obtaining informed consent. Patients received once-weekly treatment for 12 weeks. The co-primary endpoint was the mean change in IL and NIL count from baseline and rate of treatment success (a score of 0 (clear) or 1 (almost clear) with a 2-grade improvement) according to the IGA at week 12. The secondary endpoints included percent change in IL and NIL lesion count at weeks 4 and 12, as well as 2-grade change in IGA.

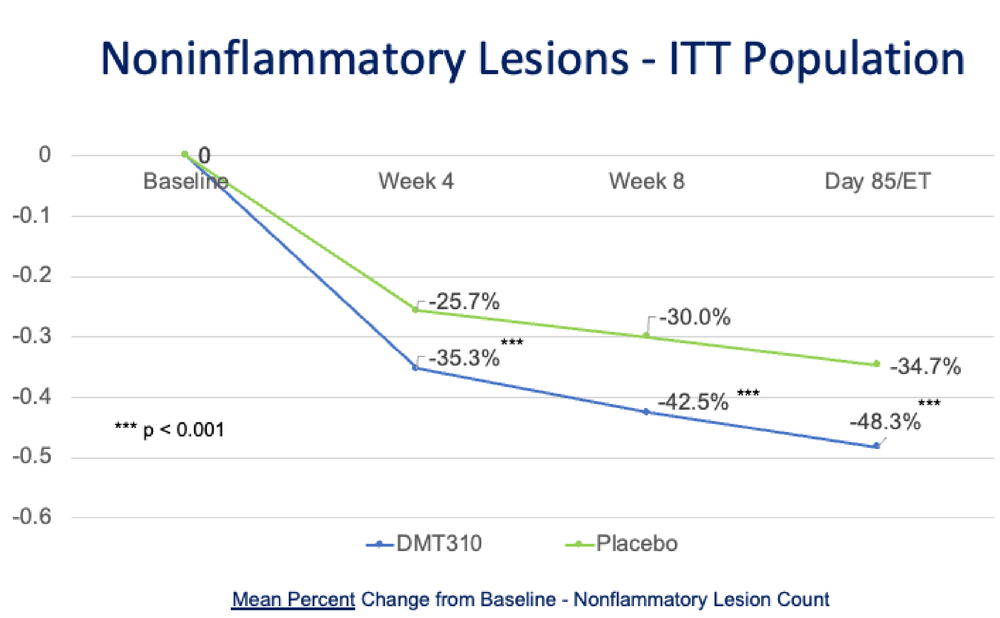
Results:

The intent-to-treat population (ITT) included a total of 520 subjects (DMT310, N = 342; Placebo, N = 178). Subjects in the ITT and safety populations were 9 to 66 years of age, with a mean age of 21.4 years. The majority of subjects were female (62.3%) and either white (69.4%) or black/African American (24.8%). Subjects who identified as Hispanic or Latino or not Hispanic or Latino were approximately equally represented (52.1% and 47.4%, respectively). At baseline, all subjects had an IGA of either moderate or severe. Baseline lesion counts for DMT310 and placebo for IL (25 vs 25) and NIL (30 vs 30) were balanced between the treatment groups. The proportion of patients graded 3 and 4 on the IGA at baseline were also balanced between treatment groups. The mean absolute reduction from baseline in lesion counts was statistically significant favoring DMT310 over placebo at Weeks 4, 8, and 12:

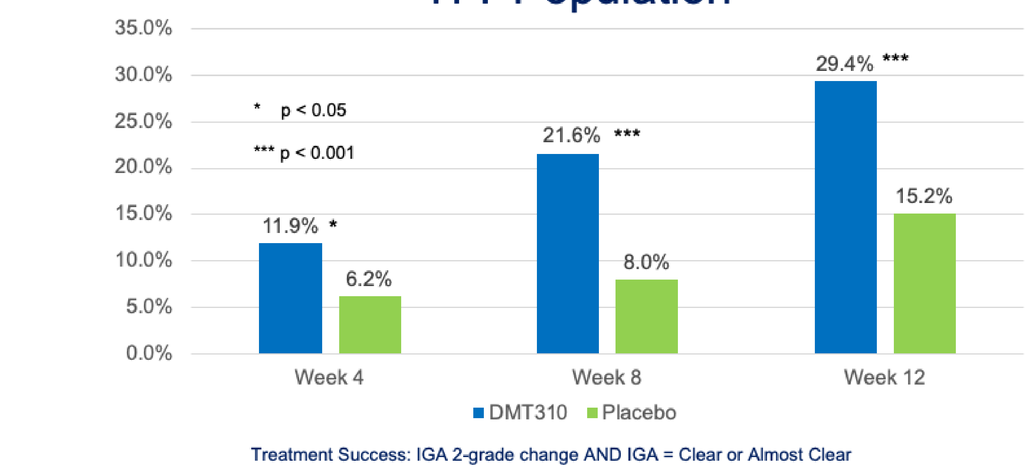


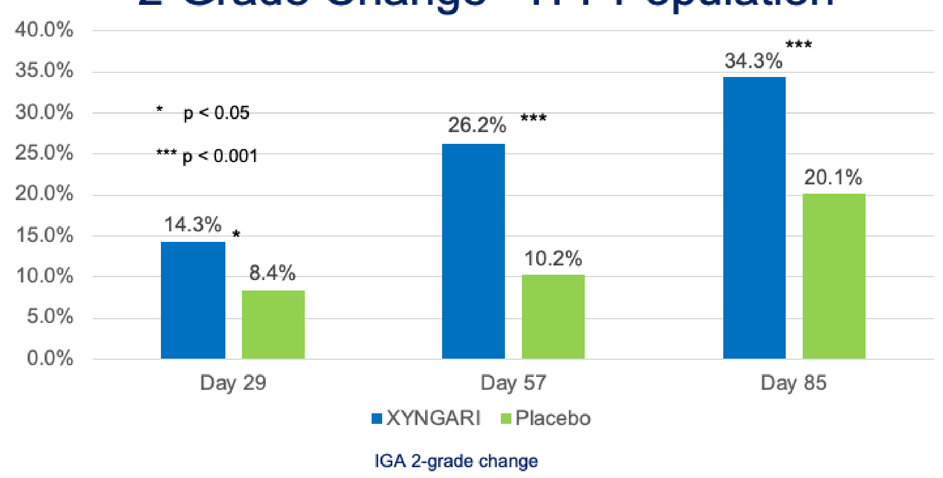






The percentage of subjects with treatment success in IGA was significantly higher in the





DMT310 was generally safe and well tolerated. Application site related adverse events were reported in less than 2% of subjects treated with DMT310. There were no treatment related serious adverse events.

Conclusion:

DMT310 once-weekly topical treatment significantly reduced both inflammatory and noninflammatory lesions as early as Week 4, had a greater proportion of IGA treatment success in patients with moderate-to-severe acne, and was generally safe and well tolerated.