Polymeric Emulsion Tazarotene 0.045% Lotion for the Once-Daily Treatment of Moderate-To-Severe Acne Vulgaris In Asian Participants

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PRESENTED AT:

SYNOPSIS/OBJECTIVE

SYNOPSIS

- Acne is a common dermatologic issue among Asian adolescents and adults[1]
- The skin pigmentation in Asian patients predisposes them to acne-related sequelae, including post-inflammatory hyperpigmentation and scarring[1]
- Topical retinoids, such as tazarotene, are a mainstay in the management of acne; however, they are associated with irritation, which can limit use, especially as some Asian subgroups are more prone to sensitive skin[1]
- To reduce irritation, a polymeric emulsion formulation of tazarotene 0.045% lotion was developed to evenly distribute tazarotene on the skin using less than half the concentration of the commercially available tazarotene 0.1% cream[2]
- In two phase 3 studies, treatment with tazarotene 0.045% lotion reduced acne lesions and inflammation-associated sequelae such as hyperpigmentation in the overall population and across a variety of populations, including Black and Hispanic participants[3,4]

OBJECTIVE

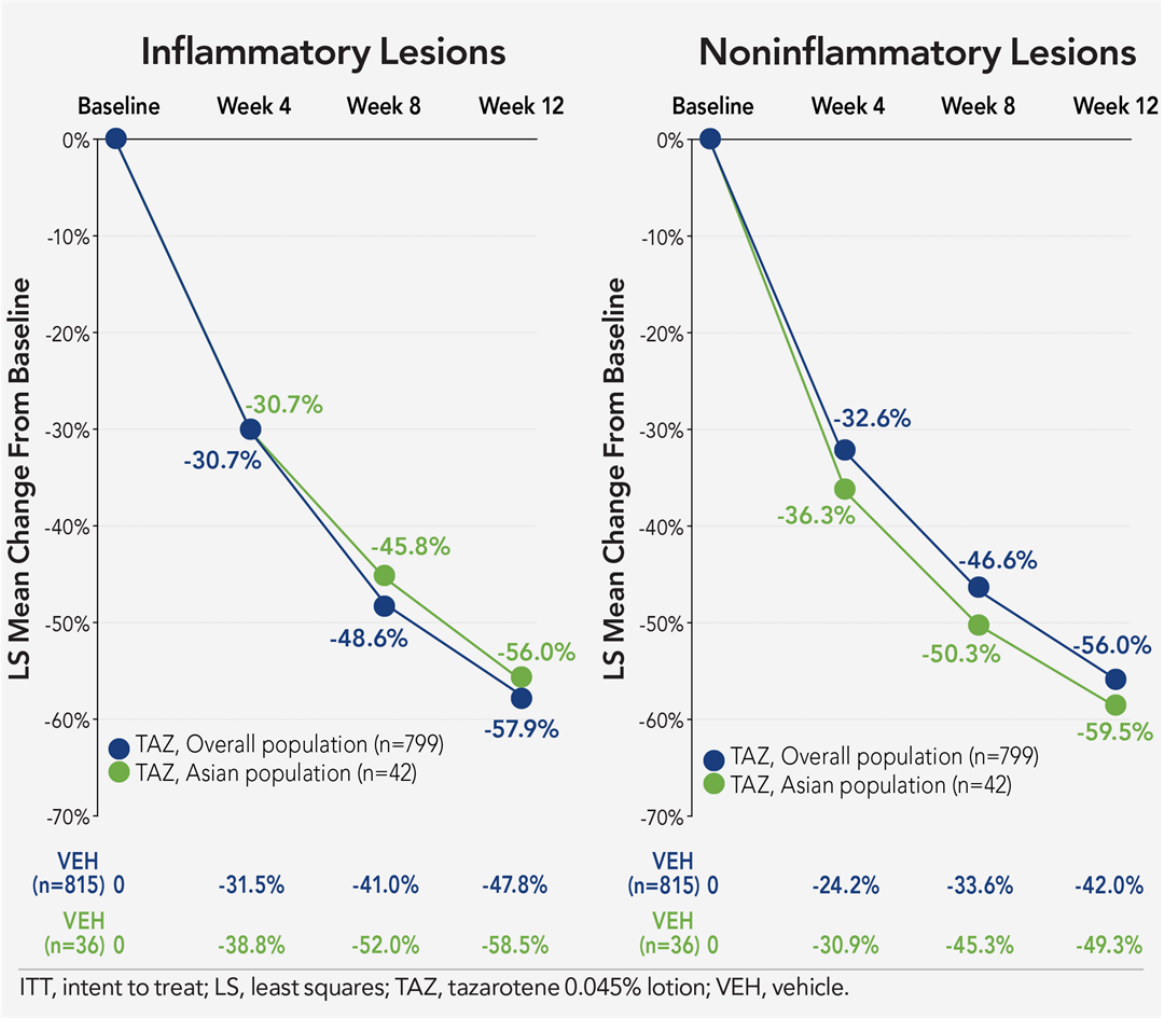
- To examine the efficacy, safety, and tolerability of tazarotene 0.045% lotion in a subset of Asian participants (self-identified) with moderate-to-severe acne

METHODS

- In two phase 3, double-blind, vehicle-controlled 12-week studies, eligible participants aged ≥9 years with moderate-to-severe acne were randomized (1:1) to receive once-daily tazarotene 0.045% lotion or vehicle lotion
    - CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (L'Oreal, NY) were provided as needed for optimal moisturization/cleaning of the skin
- This pooled post hoc analysis included the overall population and a subset of participants who self-reported as Asian; all data were analyzed using descriptive statistics
- Efficacy assessments included mean reductions from baseline to week 12 in inflammatory and noninflammatory lesion counts and the percentage of participants achieving ≥2-grade reduction in Evaluator's Global Severity Score (EGSS) and a clear/almost clear score (treatment success)
- Treatment-emergent adverse events (TEAEs) and cutaneous safety and tolerability were also assessed

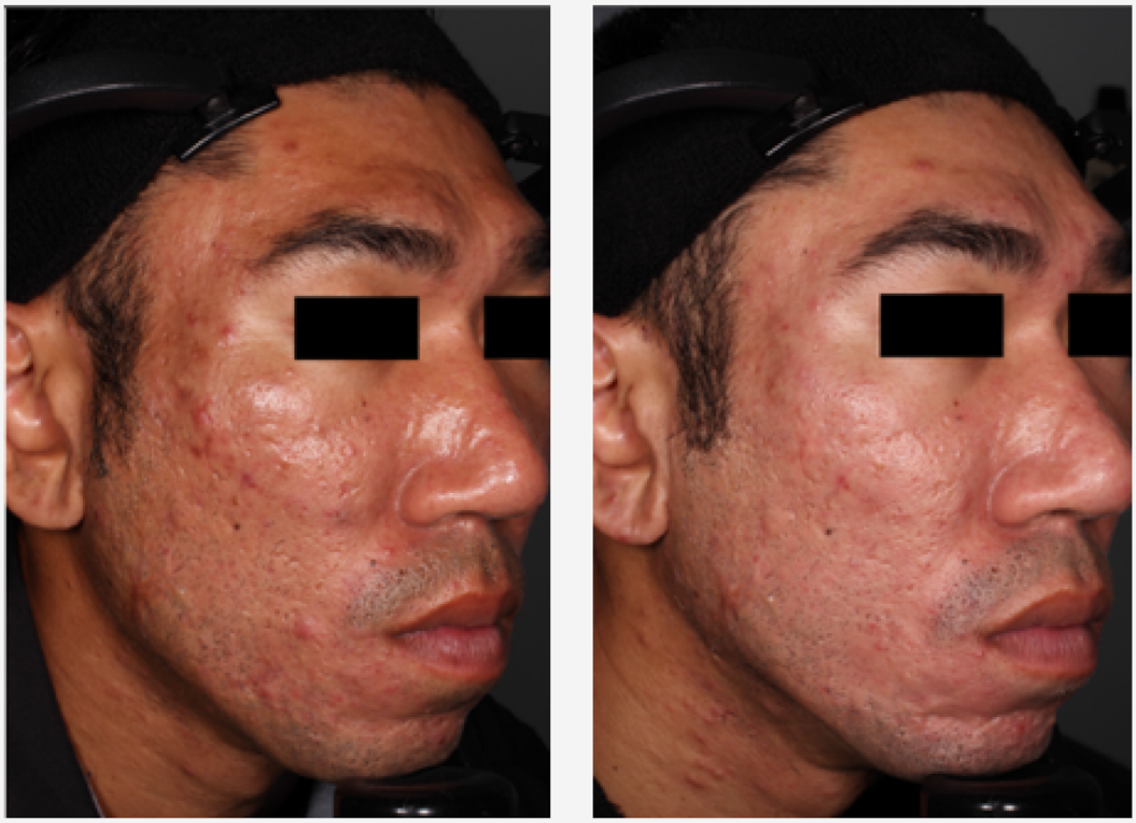
EFFICACY

Figure 1. Lesion Reductions by Study Visit (ITT Population, Pooled)



ITT, intent to treat; LS, least squares; TAZ, tazarotene 0.045% lotion; VEH, vehicle.

Figure 2. Acne Improvements in an Asian Male Treated with Tazarotene 0.045% Lotion



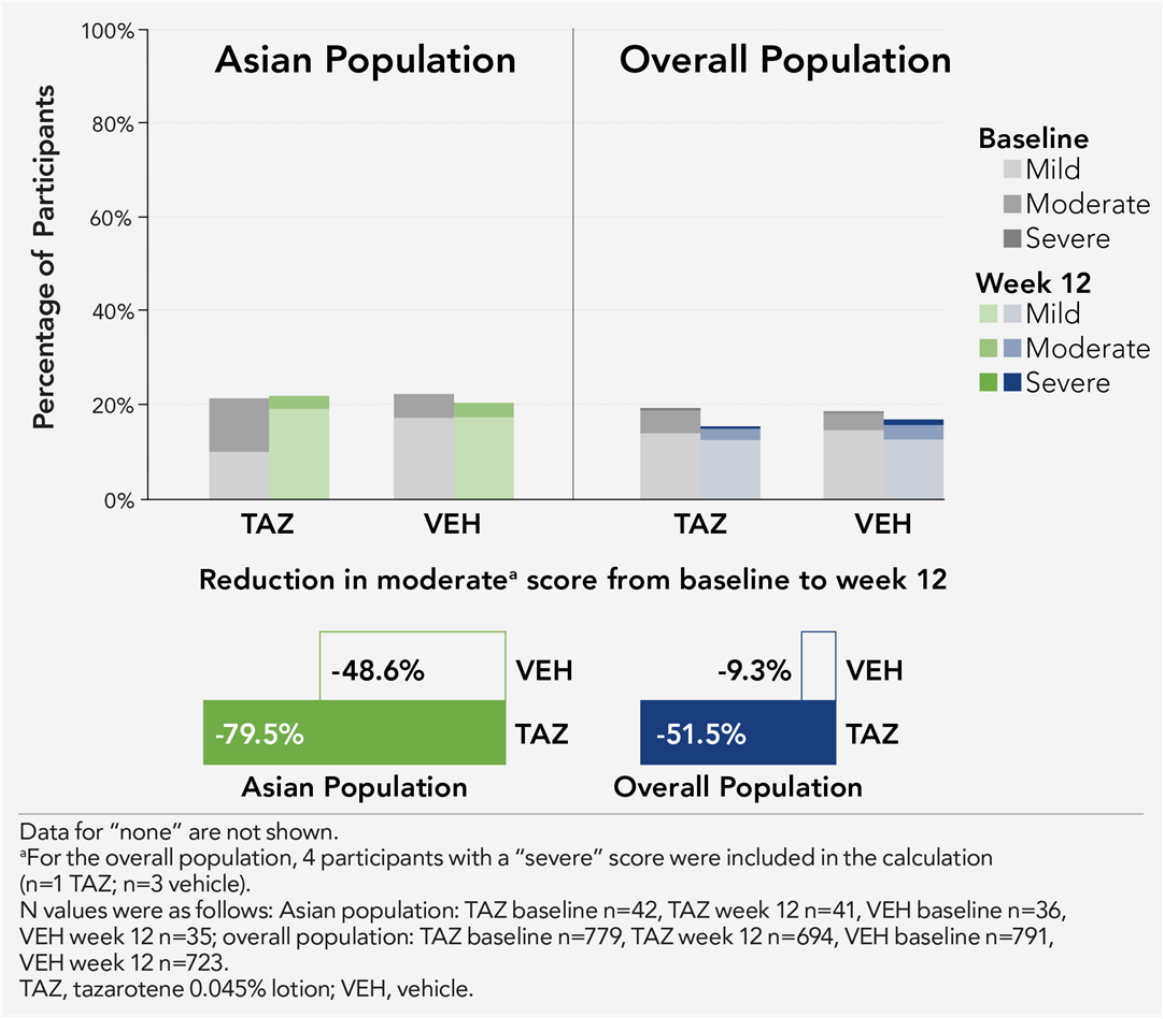
Baseline
EGSS = 4 (Severe)

Week 12
EGSS = 2 (Mild)

Photographs from 1 representative participant. Participant also had 88% reduction in inflammatory lesions and 89% reduction in noninflammatory lesions. Individual results may vary.
EGSS, Evaluator's Global Severity Score.

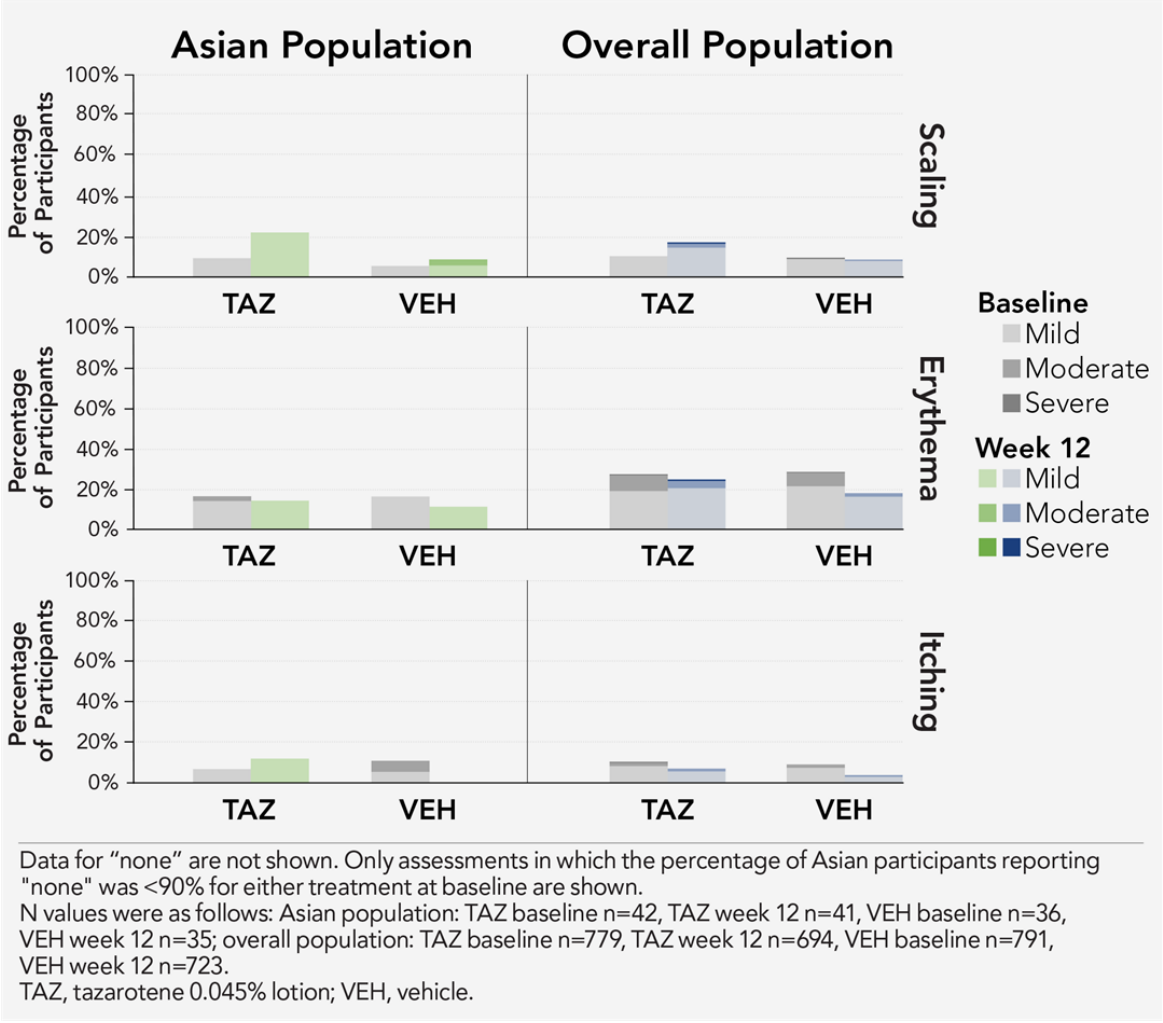
SAFETY AND TOLERABILITY

Figure 3. Hyperpigmentation (Safety Population, Pooled)



Data for "none" are not shown.
[a]For the overall population, 4 participants with a "severe" score were included in the calculation (n=1 TAZ; n=3 vehicle).
N values were as follows: Asian population: TAZ baseline n=42, TAZ week 12 n=41, VEH baseline n=36, VEH week 12 n=35; overall population: TAZ baseline n=779, TAZ week 12 n=694, VEH baseline n=791, VEH week 12 n=723.
TAZ, tazarotene 0.045% lotion; VEH, vehicle.

Figure 4. Other Cutaneous Safety and Tolerability Measures (Safety Population, Pooled)



Data for "none" are not shown. Only assessments in which the percentage of Asian participants reporting "none" was <90% for either treatment at baseline are shown.
N values were as follows: Asian population: TAZ baseline n=42, TAZ week 12 n=41, VEH baseline n=36, VEH week 12 n=35; overall population: TAZ baseline n=779, TAZ week 12 n=694, VEH baseline n=791, VEH week 12 n=723.
TAZ, tazarotene 0.045% lotion; VEH, vehicle.

RESULTS

Participants

- The pooled intent-to-treat population included 1614 participants
  - Asian: tazarotene n=42, vehicle n=36 (ITT and safety)
  - Overall: tazarotene n=799, vehicle n=815 (ITT); n=779, n=791 (safety)
- In both the Asian and the overall population, approximately two-thirds of participants were female
- At baseline, ~90% of Asian and overall participants had an EGSS score of 3 ('moderate')

Efficacy

- At week 12, least-squares mean percent reductions from baseline in inflammatory and noninflammatory lesion counts ranged from 56–60%, and were comparable between tazarotene-treated Asian participants and the overall population (**Figure 1**)
  - In the vehicle-treated groups, a stronger treatment response was noted in the Asian subgroup compared with the overall population
- More than a quarter of tazarotene-treated participants achieved treatment success in the Asian (29.1%) and overall populations (30.4%), with over a third achieving ≥2-grade reduction in EGSS (Asian 34.5%; overall: 33.9%)
  - In both instances, the Asian subgroup showed a greater response to vehicle than the overall population (success: 33.1% vs 17.9%; ≥2-grade EGSS reduction: 38.5% vs 20.9%)
- Images depicting acne improvement in a tazarotene-treated Asian male are shown in **Figure 2**

Safety

- Rates of TEAEs and treatment-related TEAEs were lower in tazarotene-treated Asian participants (9.5% and 4.8%, respectively) than the overall population (26.8% and 11.3%)
  - In the vehicle-treated groups, rates of TEAEs and related TEAEs were similar between Asian participants (19.4% and 0%, respectively) and the overall population (19.1% and 1.1%)
- TEAEs were mild to moderate in severity in all Asian participants and >98% of the overall population
- The percentage of tazarotene-treated Asian participants reporting moderate hyperpigmentation (score of 2) decreased by 79.5% from baseline to week 12 (11.9% to 2.4%; **Figure 3**)
  - This constitutes a numerically greater reduction from baseline to week 12 compared to the overall tazarotene-treated population (-79.5% vs -51.5%; **Figure 3**)
- All other cutaneous safety (scaling, erythema, hypopigmentation) and tolerability assessments (burning, stinging, and itching) were rated as none (score of 0) or mild (1) at week 12 in tazarotene-treated Asian participants (**Figure 4**; data not shown for hypopigmentation, burning, or stinging)

CONCLUSIONS

- The polymeric emulsion tazarotene 0.045% lotion formulation numerically reduced inflammatory and noninflammatory lesion counts by 56–60% in Asian participants with moderate-to-severe acne, similar to reductions observed in the overall population
  - Asian participants had a robust response to the vehicle, which may be amplified by the small sample size
- Tazarotene 0.045% lotion was also well tolerated and resulted in decrease of hyperpigmentation severity in Asian participants

DISCLOSURES

Dr. Fran Cook-Bolden has served as consultant, speaker, investigator for Galderma, LEO Pharma, Almirall, Cassiopea, Ortho Dermatologics, Investigators Encore, Foamix, Hovione, Aclaris, Cutanea.

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Dr. Lawrence Green has served as investigator, consultant, or speaker for: Almirall, Cassiopea, Galderma, Ortho Dermatologics, Sol Gel, Sun Pharma, and Vyne.

Dr. Linda Stein Gold has served as investigator/consultant or speaker for Ortho Dermatologics, LEO Pharma, Dermavant, Incyte, Novartis, AbbVie, Pfizer, Sun Pharma, UCB, Arcutis, and Lilly.

Dr. George Han is or has been an investigator, consultant/advisor, or speaker for AbbVie, Athenex, Boehringer Ingelheim, Bond Avillion, Bristol-Myers Squibb, Celgene, Eli Lilly, Novartis, Janssen, LEO Pharma, MC2, Ortho Dermatologics, PellePharm, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB.

Dr. Eric Guenin is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company.

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ABSTRACT

Introduction: Acne is a common dermatologic issue among Asian adolescents and adults.

REFERENCES

1. See JA, et al. *J Dermatol*. 2018;45(5):522-528.
2. Tanghetti EA, et al. *J Dermatolog Treat*. 2019:1-8.
3. Tanghetti EA, et al. *J Drugs Dermatol*. 2020;19(1):70-77.
4. Bhatia N, et al. *J Drugs Dermatol*. 2020;19(7):727-734