Treating Acne in Obese and Morbidly Obese Patients With Tazarotene 0.045% Lotion: Post Hoc Analysis of Pooled Phase 3 Data

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SYNOPSIS

- Acne prevalence may be higher in obese individuals, potentially due to hormonal, inflammatory, and/or dietary factors.[1,2]
- However, the effect of obesity on the efficacy and safety of topical acne treatments is largely unknown
- The growing population of obese individuals in the United States, along with the negative impact of high body mass index (BMI) and acne on health-related quality of life, underscores the need to identify appropriate acne therapies in this population[3-5]
- A new, lower-dose tazarotene 0.045% lotion formulation (Arazlo®, Ortho Dermatologics) was developed utilizing polymeric emulsion technology
  - This easily spreadable lotion formulation allows for more efficient delivery of tazarotene into dermal layers while reducing potential skin irritation

OBJECTIVE

- To evaluate efficacy, safety, and impact on quality of life of tazarotene 0.045% lotion in obese and morbidly obese individuals with acne

METHODS

- In two identical phase 3 randomized, double-blind, vehicle-controlled studies (NCT03168321 and NCT03168334), participants aged ≥9 years with moderate-to-severe acne (Evaluator's Global Severity Score [EGSS] of 3 or 4) were randomized (1:1) to once-daily tazarotene 0.045% lotion or vehicle lotion for 12 weeks
  - In these studies, CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (L'Oreal, NY) were provided as needed for optimal moisturization/cleaning of the skin
- Outcomes comprised reductions in inflammatory and noninflammatory lesion counts, treatment success (proportion of participants achieving ≥2-grade reduction from baseline in EGSS and score of 0 [clear] or 1 [almost clear]), and Acne-Specific Quality of Life (Acne-QoL) questionnaire
- Cutaneous safety and tolerability were also evaluated
- Pooled data at week 12 were analyzed for the BMI subgroup ≥30 kg/m² (obese and morbidly obese)

RESULTS

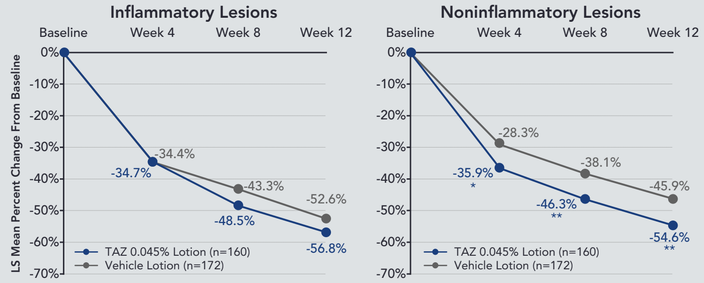
Participants

- A total of 332 participants with BMI ≥30 kg/m² were included for analysis
  - Of these, one-fifth (n=70) were morbidly obese (BMI ≥40 kg/m²)
- The BMI ≥30 kg/m² subgroup, compared to the overall pooled population (N=1614[6]), had more participants who were female (79.5% vs 65.9%), Black (23.8% vs 16.2%), older (mean age: 23.1 vs 20.5 years), and had an EGSS score of 3 (93.1% vs 90.9%)

Efficacy

- Tazarotene-treated obese and morbidly obese participants had an approximately 55% reduction in both inflammatory and noninflammatory lesions following 12 weeks of treatment (**Figure 1**)
  - Results were comparable to reductions seen in the overall population (57.9% and 56.0% reduction, respectively)[6]
- At week 12, just over one-third of participants treated with tazarotene 0.045% lotion achieved treatment success (BMI ≥30 kg/m² TAZ vs vehicle: 33.5% vs 21.9%; *P*<0.05), similar to the overall population (30.4% vs 17.9%; *P*<0.001)[6]

FIGURE 1. **Lesion Reductions in Participants With BMI ≥30 kg/m² (ITT Population, Pooled)**



*P<0.05 vs vehicle; **P=0.01 vs vehicle.
Overall population LS mean percent reductions from baseline to week 12 for TAZ (n=799) vs vehicle (n=815): inflammatory lesions, -57.9% vs -47.8% (*P*<0.001); noninflammatory lesions, -56.0% vs -42.0% (*P*<0.001).[6]
BMI, body mass index; ITT, intent to treat; LS, least squares; TAZ, tazarotene 0.045% lotion.

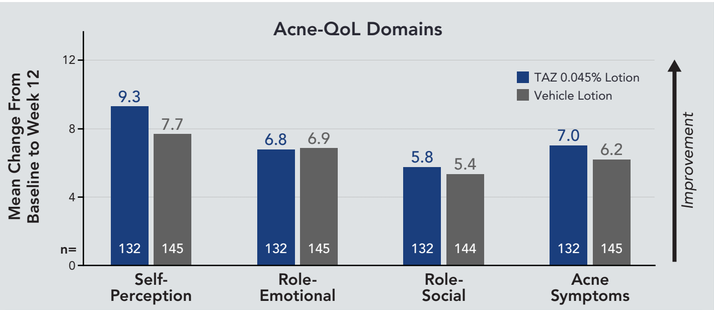
Quality of Life

- Acne-QoL domain scores improved from baseline to week 12 in obese and morbidly obese participants, with the greatest improvements observed in the Acne-QoL domains of "self-perception" and "acne symptoms" (**Figure 2**)
  - Improvements across all four Acne-QoL domains following tazarotene treatment were more substantial in obese and morbidly obese participants than the overall population[7]

Safety

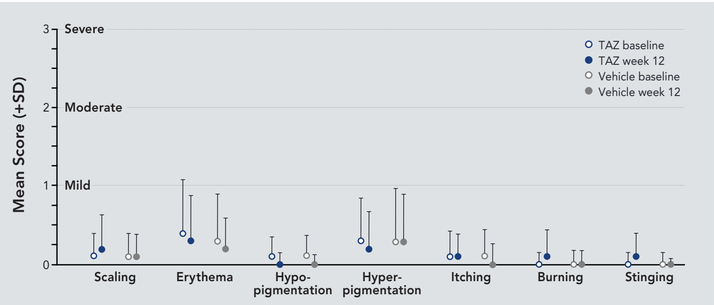
- Mean cutaneous safety and tolerability scores were low for both tazarotene 0.045% lotion and vehicle lotion (scored from 0=none to 3=severe; **Figure 3**)
  - With both tazarotene and vehicle, mean scores at baseline and week 12 were ≤0.2 for scaling, hypopigmentation, itching, burning, and stinging
  - Slight improvements at week 12 versus baseline were observed for erythema, hypopigmentation, and hyperpigmentation with tazarotene
  - Results were similar to the overall population[6] (data not shown)

FIGURE 2. **Acne-QoL Improvements at Week 12 in Participants With BMI ≥30 kg/m² (ITT Population, Pooled)**



Higher scores for each domain in Acne-QoL reflect increased health-related quality of life. Self-perception, role-emotional, and acne symptoms domain score ranges are 0 to 30; role-social domain score range is 0 to 24; a positive mean change indicates a favorable result. Overall population mean change from baseline to week 12 for TAZ (n=690) vs vehicle (n=723 [n=722 for role-social]): self-perception, 7.5 vs 6.7; role-emotional, 6.0 vs 5.5; role-social, 4.7 vs 4.1; acne symptoms, 6.4 vs 5.3.[7]
Acne-QoL, Acne-Specific Quality of Life; BMI, body mass index; ITT, intent to treat; TAZ, tazarotene 0.045% lotion.

FIGURE 3. **Mean Cutaneous Safety and Tolerability Scores in Participants With BMI ≥30 kg/m² (Safety Population, Pooled)**



N values were as follows: TAZ baseline n=153, TAZ week 12 n=133, vehicle baseline n=162, vehicle week 12 n=145.
BMI, body mass index; SD, standard deviation; TAZ, tazarotene 0.045% lotion.

CONCLUSIONS

- In obese and morbidly obese participants with moderate-to-severe acne, tazarotene 0.045% lotion reduced inflammatory and noninflammatory lesions by over half, with one-third of participants achieving clear/almost clear skin
- Quality of life improvements with tazarotene 0.045% lotion were substantially greater in obese and morbidly obese participants versus the overall study population[7]
  - These results may be due to both the worse QoL at baseline (data not shown) and the higher percentage of females in the ≥30 kg/m² group compared with the overall population
  - Studies have shown that females with acne are more likely to develop anxiety/depression, and improvements in acne positively affect quality of life[8]; furthermore, females have been shown to have relatively greater quality of life improvements with tazarotene 0.045% lotion than males[7]
- Cutaneous safety and tolerability scores with tazarotene lotion were generally similar between baseline and week 12
- Tazarotene 0.045% lotion was efficacious and well tolerated in obese and morbidly obese individuals with acne, and led to large improvements in the quality of life of these participants
  - These results are notable given the limited clinical data of acne treatments in this growing population

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AUTHOR DISCLOSURES

Jonette Keri has served on speaker's bureau for Vyne Therapeutics. Leon Kircik has acted as an investigator, advisor, speaker, and consultant for Ortho Dermatologics. Lawrence Green has served as investigator, consultant, or speaker for Almirall, Cassiopea, Galderma, Ortho Dermatologics, Sol Gel, Sun Pharma, and Vyne. Glynis Ablon has served as a consultant and advisory board member for Galderma, Sinclair, Thermi-Almirall, Enthonia, Sunetics, Nutrafol, and Lifes2Good. William Philip Werschler has served as an investigator for Ortho Dermatologics. Emil Tanghetti has served as speaker for Novartis, Ortho Dermatologics, Sun Pharma, Lilly, Galderma, AbbVie, and Dermira; served as a consultant/clinical studies for Hologic, Ortho Dermatologics, and Galderma; and is a stockholder for Accure. Zoe Draelos received funding from Ortho Dermatologics to conduct the research presented in this poster. Eric Guenin is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company.

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