Efficacy and Safety of Tazarotene 0.045% Lotion in Female Patients with Moderate-to-Severe Acne: Post Hoc Analysis by Age

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SYNOPSIS

- Acne is common among adolescents, occurring in 85% of this population[1]
- The overall prevalence of acne tends to decrease with age; however, acne can persist throughout adulthood, more often in females than males[2,3]
- In addition, older age and female sex are associated with greater negative impacts on quality of life[4]
- The first lotion formulation of tazarotene 0.045%, developed using a novel polymeric emulsion technology, was efficacious and well tolerated in two phase 3 studies of patients ≥9 years of age with moderate-to-severe acne (NCT03168334 and NCT03168321)[5]

OBJECTIVE

- To assess the effects of age on efficacy and safety of tazarotene 0.045% lotion in females with moderate-to-severe acne

METHODS

- In two phase 3 randomized, double-blind, vehicle-controlled studies, eligible participants aged ≥9 years with moderate-to-severe acne were randomized 1:1 to tazarotene 0.045% lotion or vehicle once daily for 12 weeks
  - CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (L'Oreal, NY) were provided as needed for optimal moisturization/cleaning of the skin
- Data from these studies were pooled and analyzed post hoc from female participants who were categorized by age: 13–19 years, 20–29 years, and 30+ years
- Efficacy assessments included mean reductions in inflammatory/noninflammatory lesion counts and percentage of participants achieving treatment success (≥2-grade reduction in Evaluator's Global Severity Score [EGSS] and rating of 'clear' or 'almost clear')
- Treatment-emergent adverse events (TEAEs) and cutaneous safety/tolerability were also assessed

RESULTS

Participants

- The pooled population included 1,013 adolescent and adult female participants: 13–19 years (tazarotene n=192, vehicle n=199); 20–29 years (n=238, n=241); 30+ years (n=72, n=71)
- >90% of female participants in each age group had an EGSS score of 3 ('moderate') at baseline: 13–19 years (91.6%), 20–29 years (93.1%), 30+ years (93.0%)

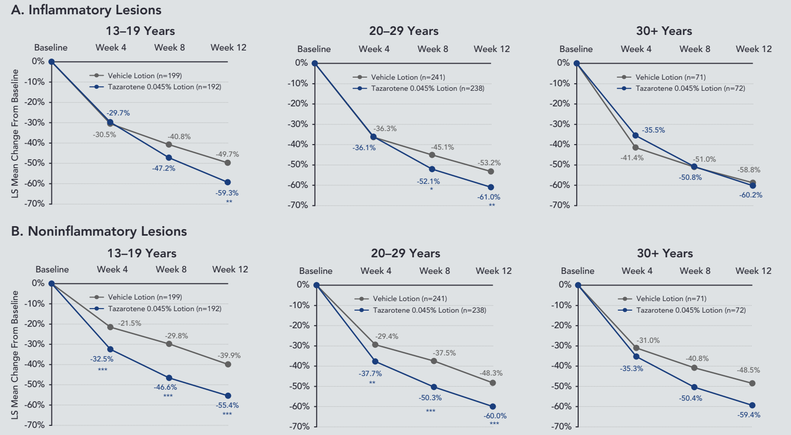
Efficacy

- Female participants in all 3 age groups had approximately 55–60% mean reductions from baseline in inflammatory and noninflammatory lesion counts with tazarotene 0.045% lotion (**Figure 1**)
  - In the younger groups (13–19 and 20–29 years), least-squares mean percent reductions in lesion counts were significantly greater with tazarotene versus vehicle at week 12
  - Similar reductions with tazarotene were observed in older participants (30+ years); however, the results were not statistically significant versus vehicle, possibly due to the smaller sample size and/or relatively larger vehicle response
  - In tazarotene-treated females, no significant differences were observed across age groups at any week
- At week 12, more females achieved treatment success with tazarotene versus vehicle: 13–19 years (26.4% vs 14.8%, *P*<0.01); 20–29 years (38.4% vs 25.5%, *P*<0.01); 30+ years (36.4% vs 25.7%, *P*>0.05); there was a significant difference across the 3 age groups (*P*<0.05)
- Images depicting acne improvement are shown in **Figure 2**

Safety

- No notable age-related patterns were found for safety outcomes
- Most treatment-related TEAEs with tazarotene were mild or moderate; application site pain and dryness were the most common treatment-related TEAEs (**Table 1**)
- Less than 10% of tazarotene-treated participants in any age group had hypopigmentation, burning, or stinging at baseline or week 12 (data not shown)
- Across all age groups, rates of erythema and hyperpigmentation—more common at baseline than scaling or itching—remained relatively unchanged or reduced from baseline to week 12 (**Figure 3**)

FIGURE 1. Lesion Reductions by Age Group and Visit (ITT Population, Pooled)

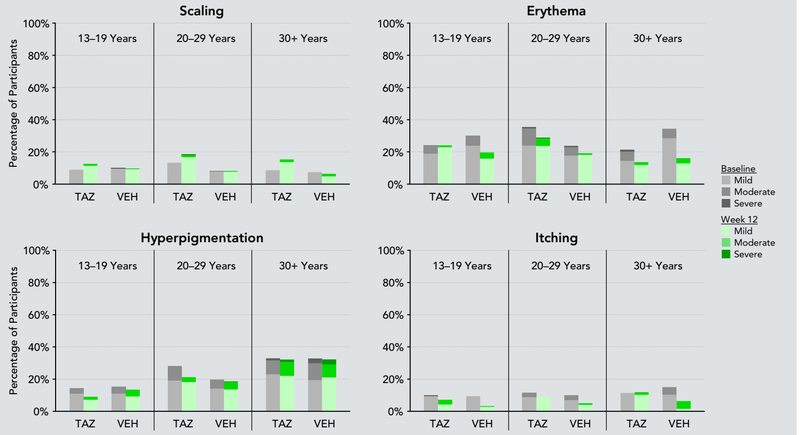


*P<0.05; **P<0.01; ***P≤0.001 vs vehicle.
No significant differences between age groups at weeks 4, 8, or 12.
ITT, intent to treat; LS, least-squares.

FIGURE 2. Acne Improvements in Females Treated with Tazarotene 0.045% Lotion

Individual results may vary.
EGSS, Evaluator's Global Severity Score (0=clear, 1=almost clear, 2=mild, 3=moderate, 4=severe).

FIGURE 3. Cutaneous Safety and Tolerability by Age Group (Pooled Safety Population)



Data for 'none' are not shown.
N values were as follows: 13–19 years: TAZ baseline n=190, TAZ week 12 n=166, VEH baseline n=197, VEH week 12 n=184; 20–29 years: TAZ baseline n=228, TAZ week 12 n=198, VEH baseline n=231, VEH week 12 n=198; 30+ years: TAZ baseline n=70, TAZ week 12 n=59, VEH baseline n=67, VEH week 12 n=62.
TAZ, tazarotene 0.045% lotion; VEH, vehicle lotion.

TABLE 1. Treatment-Emergent Adverse Events by Age Group (Pooled Safety Population)

	13–19 Years		20–29 Years		30+ Years	
Percentage of participants	TAZ (n=190)	VEH (n=197)	TAZ (n=228)	VEH (n=231)	TAZ (n=70)	VEH (n=67)
Any TEAE	28.4	19.8	35.5	18.2	25.7	16.4
Treatment-related TEAEs	14.7	1.0	16.2	2.2	12.9	1.5
Intensity of treatment-related TEAEs						
Mild	8.4	0.5	10.5	0.9	10.0	0
Moderate	5.3	0.5	4.4	0.9	2.9	1.5
Severe	1.1	0	1.3	0.4	0	0
Common treatment-related TEAEs[a]						
Application site pain	6.8	0.5	6.6	0.4	7.1	0
Application site dryness	4.2	0	6.6	0.4	2.9	0
Application site erythema	4.2	0	1.8	0	0	0
Application site exfoliation	2.6	0	3.9	0	1.4	0
Application site pruritus	2.6	0	0.4	0	1.4	0

[a]Reported in ≥2% of tazarotene-treated participants in any age group.
TAZ, tazarotene 0.045% lotion; TEAE, treatment-emergent adverse event; VEH, vehicle lotion.

CONCLUSIONS

- Treatment with tazarotene 0.045% lotion reduced inflammatory and noninflammatory lesions by approximately 55–60% in adolescent and adult females with moderate-to-severe acne
- No age-related trends for safety/tolerability were observed; erythema and hyperpigmentation remained relatively unchanged or improved with tazarotene 0.045% lotion

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AUTHOR DISCLOSURES

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. Hilary Baldwin has served as advisor, investigator, and on speakers' bureaus for Almirall, Cassiopea, Foamix, Galderma, Ortho Dermatologics, Sol Gel, and Sun Pharma. Fran Cook-Bolden has served as consultant, speaker, investigator for Galderma, LEO Pharma, Almirall, Cassiopea, Ortho Dermatologics, Investigators Encore, Foamix, Hovione, Aclaris, Cutanea. Lawrence Green as 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, Erchonia, Sunetics, Nutrafol, and Lifes2Good. Neil Sadick has served on advisory boards, as a consultant, investigator, speaker, and/or other and has received honoraria and/or grants/research funding from Almirall, Actavis, Allergan, Anacor Pharmaceuticals, Auxilium Pharmaceuticals, Bausch Health, Bayer, Biorasi, BTG, Carma Laboratories, Cassiopea, Celgene, Cutera, Cynosure, DUSA Pharmaceuticals, Eclipse Medical, Eli Lilly and Company, Endo International, EndyMed Medical, Ferndale Laboratories, Galderma, Gerson Lehrman Group, Hydropeptide, Merz Aesthetics, Neostrata, Novartis, Nutraceutical Wellness, Palomar Medical Technologies, Prescriber's Choice, Regeneron, Roche Laboratories, Samumed, Solta Medical, Storz Medical AG, Suneva Medical, Vanda Pharmaceuticals, and Venus Concept. Jonathan Weiss is a consultant, speaker, advisor, and/or researcher for AbbVie, Ortho Dermatologics, Jansen Biotech, Dermira, Almirall, Brickell Biotech, DermTech, Soynexis. Eric Guenin is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company.

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