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

Linda Stein Gold, MD; Hilary Baldwin, MD; Fran E Cook-Bolden, MD; Lawrence Green, MD; Glynis Ablon, MD; Neil Sadick, MD; Jonathan Weiss, MD; Eric Guerin, PharmD, PhD, MPH

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8.4
20–29 Years
19.8
0
0
0.9
Cutaneous Safety and Tolerability by Age Group (Pooled Safety Population)

The overall prevalence of acne tends to decrease with age; however, acne can persist throughout adulthood, more often in females than males.1,2 In addition, older age and female sex are associated with greater negative impacts on quality of life.3 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 (NCT01368334 and NCT01368321).4

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.5 Cera Ease® hydrating cleanser and Cera Ease® moisturizing lotion (CeraMed, 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.6 Efficacy assessments included mean reductions in inflammatory/noninflammatory lesion counts and percentage of participants achieving treatment success (≤ 40% reduction in EASI score) in Evaluation’s Global Severity Score (EASI50) and rating of ‘clear’ or ‘almost clear’.7 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=197, vehicle n=199), 20–29 years (n=228, n=241), and ≥ 30 years (n=197, n=219).8 >90% of female participants in each age group had an EASI50 score of 3 (moderate) at baseline: 13–19 years (93.1%), 20–29 years (93.1%), and ≥ 30 years (90.5%).

Efficacy

Female participants in all 3 age groups had approximately 55–65% mean reductions from baseline in inflammatory and noninflammatory lesion counts with tazarotene 0.045% lotion (Figure 1).9 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 12.10 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.11 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 (36.4% vs. 14.8%, P<0.01), 20–29 years (38.4% vs. 25.5%, P<0.01), and ≥ 30 years (36.4% vs. 25.5%, P=0.03); there was a significant difference across the 3 age groups (10.05). In 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 were more common in one arm than scaling or itching—remained relatively unchanged or improved from baseline to week 12 (Figure 3).

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.12 No age-related trends for safety/tolerability were observed; erythema and hyperpigmentation remained relatively unchanged or improved with tazarotene 0.045% lotion.

REFERENCES


AUTHOR DISCLOSURES

Dr. Linda Stein Gold has served as investigator or consultant for Regeneron, Roche Laboratories, Samumed, Solta Medical, Storz Medical AG, Suneva Medical, Vanda Pharmaceuticals, and Venus Concept. Dr. Hilary Baldwin has served as investigator or consultant for DUSA Pharmaceuticals, Eclipse Medical, Eli Lilly and Company, Endo International, EndyMed Medical, Ferndale Laboratories, Galderma, Gerson Pharma, Almirall, Cassiopea, Ortho Dermatologics, Investigators Encore, Foamix, Hovione, Aclaris, Cutanea. Dr. Lawrence Green as served as investigator, consultant or speaker for Ortho Dermatologics, Sol Gel, and Sun Pharma. Dr. Fran Cook-Bolden has served as consultant, speaker, investigator for Galderma, LEO Pharma, Dermavant, Incyte, Novartis, AbbVie, Pfizer, Regeneron, and Roche Laboratories. Dr. Glynis Ablon has served as investigator, consultant or speaker for Ortho Dermatologics, LEO Pharma, Galderma, Ortho Dermatologics, Investigators Encore, and Foamix. Dr. Neil Sadick has served as investigator, consultant or speaker for Ortho Dermatologics, Galderma, Ortho Dermatologics, Sol Gel, and Sun Pharma. Dr. Jonathan Weiss has served as consultant, speaker, and investigator for Ortho Dermatologics, LEO Pharma, Dermavant, Incyte, Novartis, AbbVie, and Pfizer. Dr. Eric Guerin has served as consultant, speaker, and investigator for Ortho Dermatologics, LEO Pharma, Dermavant, Incyte, Novartis, AbbVie, and Pfizer. Dr. Lawrence Green has served as consultant, speaker, and investigator for Ortho Dermatologics, LEO Pharma, Dermavant, Incyte, Novartis, AbbVie, and Pfizer. Dr. Fran Cook-Bolden has served as consultant, speaker, investigator for Galderma, LEO Pharma, Dermavant, Incyte, Novartis, AbbVie, and Pfizer.