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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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.

Ceramide® hydrating cleanser and Ceramide® moisturizing lotion (Cerave®, NY) were provided as needed for optimal moisturization/cleaning of the skin.

Data from these studies were pooled and analyzed

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=228, n=241), 30+ years (n=72, n=71).

- ≥90% of female participants in each age group had an EASI 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 25–35% 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 (38.4% vs 25.5%, 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, 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 at week 12 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)

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

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

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.

REFERENCES
- Virtual

AUTHOR DISCLOSURES
- No author has a financial relationship with any commercial entity that has an interest in, or financial interest in, the subject matter or materials discussed in this presentation.
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