Tazarotene 0.045% Lotion for Females With Acne: Analysis of Two Different Adult Age Groups

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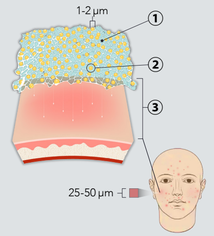
SYNOPSIS

- Acne is often regarded as an adolescent condition, but incidence among adults—especially females—is increasingly common[1]
- Acne in females ≥25 years of age (referred to as *adult female acne*) may have a different etiology, presentation, burden, and response to treatment than acne in females 18–24 years old (referred to as *postadolescent acne*)[1,2]
  - This may be due to a "transition period" for females aged 18–24 years, wherein some have acne that is more adolescent in nature, whereas older females in this cohort may be transitioning to acne associated with the adult female patient
- Adult female acne is also associated with dry skin, and treatment-related irritation is a significant concern[2]
- A recently approved, lower-dose tazarotene 0.045% lotion formulation (Arazlo®; Ortho Dermatologics) was developed utilizing polymeric emulsion technology (**Figure 1**)[3]
  - This highly spreadable lotion formulation was developed to allow for more efficient delivery of tazarotene into dermal layers while reducing the potential for irritation

FIGURE 1. **Polymeric Emulsion Technology for Tazarotene 0.045% Lotion**



① Polymeric matrix holds water and water-soluble hydrating agents within a 3-D mesh
② Droplets of tazarotene and oil-soluble moisturizing agents held apart by the 3-D mesh
③ 3-D mesh allows for uniform distribution of tazarotene and moisturizing agents

OBJECTIVE

- To evaluate efficacy, safety, and impact on quality of life of tazarotene 0.045% lotion in adult females ≥18 years or ≥25 years of age

METHODS

- In two phase 3, 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 for female participants categorized by age: ≥18 years or ≥25 years
- Endpoints included mean reductions in inflammatory/noninflammatory lesion counts, percentage of participants achieving treatment success (≥2-grade reduction in Evaluator's Global Severity Score [EGSS] and a score of 0 ['clear'] or 1 ['almost clear']), and the Acne-Specific Quality of Life questionnaire (Acne-QoL); treatment-emergent adverse events (TEAEs) were also assessed

RESULTS

Participants

- Of the 1614 participants in the pooled population, over 65% (n=1064) were females; of these, almost three-fourths were adults (≥18 years, n=744; ≥25 years, n=335)
- More than 90% of female participants in both age groups had a baseline EGSS score of 3 ('moderate'; **Table 1**)

TABLE 1. **Participant Demographics and Baseline Characteristics (ITT Population, Pooled)**

	Females ≥18 y (n=744)	Females ≥25 y (n=335)
Age, mean (SD), y	25.2 (6.4)	30.6 (5.9)
Age, median (range), y	24.0 (18–65)	29.0 (25–65)
Ethnicity, Hispanic/Latino, n (%)	153 (20.6)	71 (21.2)
Race, n (%)		
White	510 (68.5)	203 (60.6)
Black	161 (21.6)	97 (29.0)
Asian	37 (5.0)	19 (5.7)
Other[a]	36 (4.8)	16 (4.8)
Inflammatory lesion count, mean (SD)	27.3 (6.8)	26.9 (6.6)
Noninflammatory lesion count, mean (SD)	38.6 (14.6)	38.2 (14.7)
Evaluator's Global Severity Score, n (%)		
3 – moderate	687 (92.3)	312 (93.1)
4 – severe	57 (7.7)	23 (6.9)

[a]Includes American Indian or Alaska Native and Other/Multiple.
EGSS, Evaluator's Global Severity Score; ITT, intent to treat.

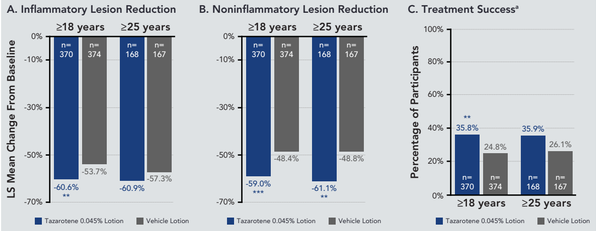
Efficacy and Quality of Life

- At week 12, female participants in both age groups had approximately 60% reductions from baseline in inflammatory and noninflammatory lesion counts with tazarotene 0.045% lotion (**Figure 2A–B**)
- Over one-third of tazarotene-treated females in both age groups achieved treatment success at week 12 (**Figure 2C**)
- All efficacy endpoints were significantly improved ($P<0.05$) with tazarotene versus vehicle for females ≥18 years, and noninflammatory lesions were significantly improved for females ≥25 years; the lack of statistical significance for females ≥25 years for inflammatory lesion reduction and treatment success may have been due to the smaller sample size and/or relatively larger vehicle response (**Figure 2**)
- Acne-QoL domain scores improved from baseline to week 12 in both age groups; improvements were generally similar between age groups and greater with tazarotene 0.045% lotion than with vehicle (**Figure 3**)
- Images of representative tazarotene-treated participants from each age group are shown in **Figure 4**.

Safety

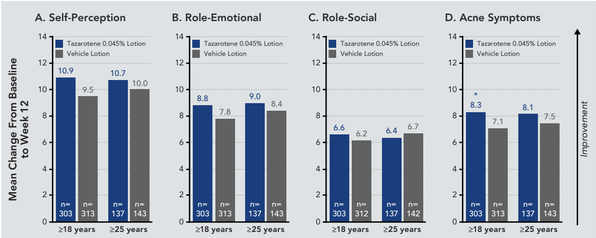
- TEAE rates/severity/relationship to study drug and the most common TEAEs were generally similar for tazarotene-treated females in both age groups (**Table 2**); most TEAEs were mild to moderate in severity
  - Rates of treatment-related application site dryness and exfoliation were slightly higher among females ≥25 years than females ≥18 years, consistent with the association between adult female acne and dry skin
- Rates of application site irritation related to tazarotene treatment were low for both female age groups (≥18 years, 1.1%; ≥25 years, 0.6%)

FIGURE 2. **Efficacy Outcomes at Week 12 by Age Group (ITT Population, Pooled)**



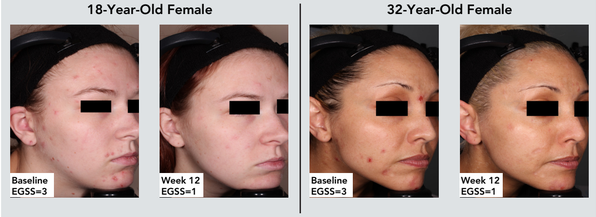
**$P<0.01$; ***$P<0.001$ vs vehicle.
[a]Defined as ≥2-grade reduction from baseline in Evaluator's Global Severity Score and a score of 0 ('clear') or 1 ('almost clear').
ITT, intent to treat; LS, least-squares.

FIGURE 3. **Acne-QoL Improvements at Week 12 by Age Group (ITT Population, Pooled)**



*$P<0.05$ vs vehicle.
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.
Acne-QoL, Acne-Specific Quality of Life; ITT, intent to treat.

FIGURE 4. **Acne Improvements in Tazarotene-Treated Adult Females**



Individual results may vary.
EGSS, Evaluator's Global Severity Score.

TABLE 2. **Treatment-Emergent Adverse Events (Safety Population, Pooled)**

	Females ≥18 years		Females ≥25 years	
Participants, n (%)	TAZ 0.045% Lotion (n=358)	Vehicle Lotion (n=359)	TAZ 0.045% Lotion (n=162)	Vehicle Lotion (n=158)
Reporting any TEAE	117 (32.7)	61 (17.0)	54 (33.3)	23 (14.6)
Discontinued due to a TEAE[a]	14 (3.9)	4 (1.1)	6 (3.7)	1 (0.6)
Severity of TEAEs reported				
Mild	75 (20.9)	27 (7.5)	36 (22.2)	11 (7.0)
Moderate	35 (9.8)	31 (8.6)	17 (10.5)	11 (7.0)
Severe	7 (2.0)	3 (0.8)	1 (0.6)	1 (0.6)
Relationship to study drug				
Related	53 (14.8)	8 (2.2)	27 (16.7)	2 (1.3)
Unrelated	64 (17.9)	53 (14.8)	27 (16.7)	21 (13.3)
Most common treatment-related TEAEs[b]				
Application site pain	23 (6.4)	2 (0.6)	10 (6.2)	0
Application site dryness	19 (5.3)	1 (0.3)	11 (6.8)	0
Application site exfoliation	12 (3.4)	0	7 (4.3)	0
Application site erythema	7 (2.0)	0	3 (1.9)	0

[a]Includes participants who discontinued study drug or prematurely discontinued from study.
[b]Reported in ≥2% of participants in any treatment group.
TAZ, tazarotene; TEAE, treatment-emergent adverse event.

CONCLUSIONS

- Efficacy and tolerability of topical treatments is important for all patients with acne; among adult females aged ≥18 years and ≥25 years—who comprised a large percentage of the pooled study population—treatment with tazarotene 0.045% lotion reduced inflammatory and noninflammatory lesions by approximately 60%
- Quality of life improvements were similar for both age groups, though improvements across all four Acne-QoL domains following tazarotene treatment were more substantial in these female participants than the overall population[4] (data not shown)
  - These results are not unexpected, as studies have shown that in females with acne, anxiety/depression are more likely and acne improvements positively affect quality of life[5]; furthermore, females of all ages have been shown to have relatively greater quality of life improvements with tazarotene 0.045% lotion than males[6]
- Tazarotene lotion was well tolerated in both female age groups; although treatment-related irritation is of particular concern for females ≥25 years,[2] application site irritation with tazarotene 0.045% lotion was <1% in this population
- These results demonstrate that tazarotene 0.045% lotion is a viable treatment option for females with either postadolescent or adult female acne

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