Efficacy and Safety of a Novel Tazarotene 0.045% Lotion in Females and Males With Moderate-to-Severe Acne

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SYNOPSIS

- Acne is a common dermatologic issue in adolescence, though prevalence of acne in the adult population is increasing[1]
- Adult females are more likely to report acne than males across all age groups, with prevalence ranging from 50.9% (20-29 y) to 15.3% (≥50 y) in females and 42.5% (20-29 y) to 7.3% (≥50 y) in males[2]
- Adolescent and adult females are also more likely have worse acne-related quality of life[3]
- A novel tazarotene 0.045% lotion formulation was developed for the treatment of acne, utilizing polymeric emulsion technology, resulting in a more uniform distribution of the active ingredient and hydrating excipients at the surface of the skin
- In a 12-week, randomized, double-blind, vehicle-controlled, parallel group, phase 2 study (NCT02938494), tazarotene 0.045% lotion was superior to vehicle on inflammatory/noninflammatory lesion count reductions in patients with moderate-to-severe acne[4]
- In addition, tazarotene 0.045% lotion was as effective as the higher concentration tazarotene 0.1% cream (already approved for acne), but with fewer adverse events (AEs)[4]

OBJECTIVE

- To evaluate the efficacy and safety of tazarotene 0.045% lotion in females and males

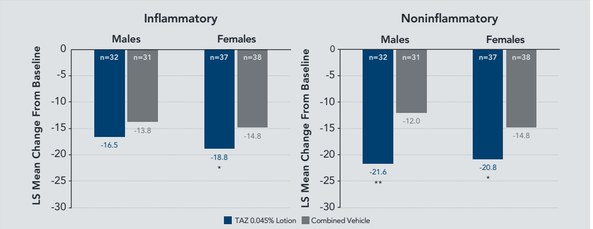
METHODS

- In this phase 2 study, patients aged 12 years and older were randomized (2:2:1:1) to receive tazarotene 0.045% lotion, tazarotene 0.1% cream (Tazorac), lotion vehicle, or cream vehicle
  - Participants must have had a score of 3 (moderate) or 4 (severe) on the Evaluator Global Severity Score (EGSS) at the screening and baseline visit
  - In this study, CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (L'Oreal, NY) were provided as needed for optimal moisturization/cleaning of the skin
- A post hoc analysis was conducted in female and male patients, based on the following co-primary efficacy endpoints of the clinical trial:
  - Mean absolute change in inflammatory and noninflammatory lesion counts from baseline to week 12
  - Treatment success, defined as percentage of patients achieving ≥2-grade reduction from baseline to week 12 in EGSS and a score of clear (0) or almost clear (1)
- Safety and adverse events (AEs) were also assessed

RESULTS

- The intent-to-treat population included 210 participants (males, n=94; females, n=116)
- At week 12, tazarotene 0.045% lotion-treated females and males had significantly greater absolute least-squares mean reductions from baseline versus vehicle in noninflammatory lesion counts; only females had significant mean reductions versus vehicle in inflammatory lesion counts (**Figure 1**)

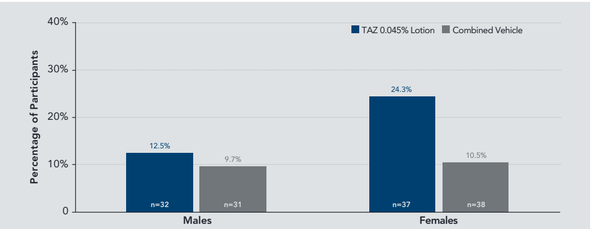
FIGURE 1. Mean Change From Baseline to Week 12 in Inflammatory and Noninflammatory Lesion Counts in Males and Females (ITT Population, Pooled)



*P<0.05 vs vehicle; **P<0.01 vs vehicle.
ITT, intent-to-treat; LS, least squares; TAZ, tazarotene.

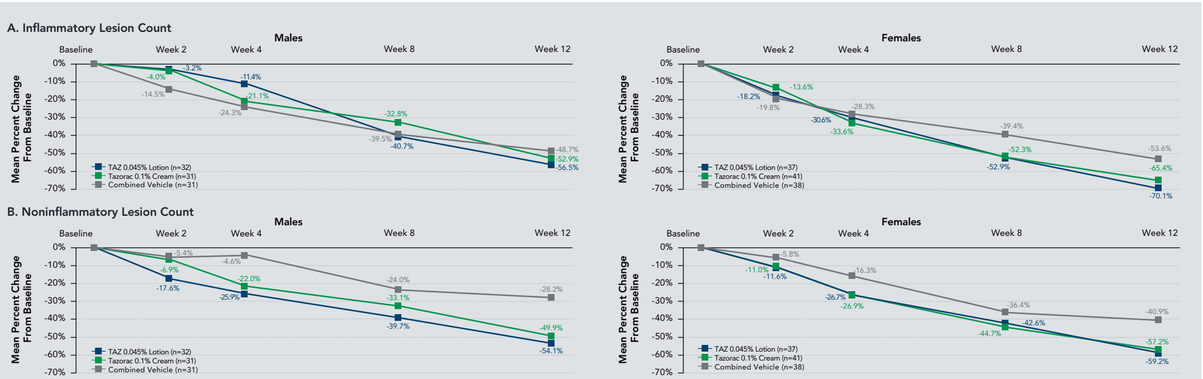
- Percent change from baseline in lesion counts by week are shown in **Figure 2**
- A larger percentage of tazarotene 0.045% lotion-treated females and males achieved treatment success versus vehicle (**Figure 3**), although this difference was not significant
- There were no significant differences between the sexes on inflammatory/noninflammatory lesion counts or treatment success at week 12, regardless of treatment with tazarotene 0.045% lotion or tazarotene 0.1% cream
- Treatment-emergent AE (TEAE) rates were higher in males than females for both tazarotene 0.045% lotion and tazarotene 0.1% cream; there were no differences with vehicle (**Table1**)

FIGURE 3. Percentage of Males and Females With Treatment Success at Week 12[a] (ITT Population, Pooled)



[a]Percentage of participants achieving ≥2-grade reduction from baseline to week 12 in EGSS and a score of clear (0) or almost clear (1).
Comparisons between TAZ 0.045% lotion and combined vehicle were not significant.
EGSS, Evaluator's Global Severity Score; ITT, intent-to-treat; TAZ, tazarotene.

FIGURE 2. Percent Change From Baseline in Inflammatory (A) and Noninflammatory (B) Lesion Counts in Males and Females (ITT Population, Pooled)



Statistical analyses were not performed between treatment groups. ITT, intent-to-treat; TAZ, tazarotene.

TABLE 1. Treatment-Emergent Adverse Events (Safety Population, Pooled)

	Males			Females		
Participants, n (%)	TAZ 0.045% Lotion (n=31)	Tazorac 0.1% Cream (n=30)	Combined Vehicle (n=30)	TAZ 0.045% Lotion (n=37)	Tazorac 0.1% Cream (n=41)	Combined Vehicle (n=37)
Reporting any TEAE	6 (19.4)	9 (30.0)	4 (13.3)	4 (10.8)	10 (24.4)	5 (13.5)
Reporting any SAE	0	0	0	0	0	0
Discontinued due to TEAE	0	1 (3.3)	0	0	0	0
Severity of TEAEs reported						
Mild	5 (16.1)	6 (20.0)	4 (13.3)	1 (2.7)	6 (14.6)	5 (13.5)
Moderate	0	3 (10.0)	0	2 (5.4)	4 (9.8)	0
Severe	1 (3.2)	0	0	1 (2.7)	0	0
Relationship to study drug						
Related	1 (3.2)	0	0	1 (2.7)	4 (9.8)	0
Unrelated	5 (16.1)	9 (30.0)	4 (13.3)	3 (8.1)	6 (14.6)	5 (13.5)

SAE, serious adverse event; TAZ, tazarotene; TEAE, treatment-emergent adverse event.

CONCLUSIONS

- Tazarotene 0.045% lotion was well tolerated and effective versus vehicle in reducing inflammatory and noninflammatory lesion counts in females and noninflammatory lesion counts in males
- Tazarotene 0.045% treated females had greater lesion count reductions and a greater percentage achieved treatment success than tazarotene-treated males, although these differences did not reach statistical significance
- Taken together with the improved tolerability of tazarotene 0.045% lotion vs tazarotene 0.1% cream,[4] this novel lotion formulation is a viable new treatment option that is as effective as cream with fewer AEs

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AUTHOR DISCLOSURES

Dr. Hilary Baldwin has served as advisor, investigator, and on speakers bureau for Almiral, Foamix, Galderma and Ortho Dermatologics. Dr. Lawrence Green has served as speaker, consultant, or investigator for Arcutis, Abbvie, Amgen, Celgene, Dermavant, Jannsen, Lilly, MC2, Novartis, Ortho Dermatologics, Sienna, SunPharma, and UCB. Dr. Leon Kircik has acted as an investigator, advisor, speaker, and consultant for Ortho Dermatologics. Dr. Eric Guenin is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company.

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