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

Hilary Baldwin, MD; Lawrence Green, MD; Leon Kircik, MD; Eric Guenin, PharmD, PhD, MPH

1The Acne Treatment and Research Center, Morristown, NJ. 2Department of Dermatology, George Washington University School of Medicine, Washington, DC. 3Indiana University School of Medicine, Indianapolis, IN. 4Physicians Skin Care, PLLC, Louisville, KY. 5Icahn School of Medicine at Mount Sinai, New York, NY. 6Ortho Dermatologics, Bridgewater, NJ.

*Ortho Dermatologics is a division of Bausch Health US, LLC.

SYNOPSIS

- Acne is a common dermatologic issue in adolescence, though prevalence of acne in the adult population is increasing.
- Adult females are more likely to report acne than males across all age groups, with prevalence ranging from 50.9% (20-29 y) to 15.5% (50 y) in females and 42.5% (20-29 y) to 7.3% (50 y) in males.
- Adolescent and adult females are also more likely have worse acne-related quality of life.
- A novel tazarotene 0.045% lotion formulation was developed for the treatment of acne, utilizing polymer-inclusion emulsion technology resulting in a more uniform distribution of the active ingredient and minimizing occlusions at the surface of the skin.
- In a 12-week, randomized, double-blind, vehicle-controlled, parallel-group, phase 2 study (NCT03508048), tazarotene 0.045% lotion was superior to vehicle in inflammatory/noninflammatory lesion count reductions in patients with moderate-to-severe acne.
- In addition, tazarotene 0.045% lotion was as effective as the higher concentration tazarotene 0.1% cream.
- Adolescent and adult females are also more likely to have worse acne-related quality of life.
- Treatment-emergent AD (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 (Table 1).
- Taken together with the improved tolerability of tazarotene 0.045% lotion vs vehicle, and the observed significant reduction in lesion counts in females, this novel lotion formulation is a viable new treatment option for men and women with moderate-to-severe acne.

METHODS

In this phase 2 study, patients aged 12 years and older were randomized (2:2:1) 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.

A post hoc analysis was conducted in female and male patients, based on the following co-primary efficacy endpoints of the clinical trial:

- 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).
- Comparative treatment success versus vehicle (

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 inflammatory lesion counts (Figure 1).
- 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, this novel lotion formulation is a viable new treatment option that is as effective in cream with fewer AEs.

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, this novel lotion formulation is a viable new treatment option that is as effective in cream with fewer AEs.

REFERENCES

4. Green has served as speaker, consultant, or investigator for Arcutis, Abbvie, Amgen, Celgene, Dermavant, Jannsen, Lilly, MC2, Novartis, Ortho Dermatologics, Roche, Taro, Teva, and Valeant.
5. Dr. Hilary Baldwin has served as advisor, investigator, and on speakers bureau for Almiral, Foamix, Galderma and Ortho Dermatologics. Dr. Lawrence Kircik has served as advisor, investigator, and on speakers bureau for Arcutis, Talecris Biotherapeutics, Valeant, Greenfield, and Valeant.
6. AUTHORS RECEIVED UNEDITED MANUSCRIPT ON 10/20/2020; MANUSCRIPT MANUSCRIPT ACCEPTED 11/13/2020; MANUSCRIPT DECEMBER 14, 2020

AUTHOR DISCLOSURES

Dr. Hilary Baldwin has received grants for research, honoraria, consulting, and travel expenses from Arcutis, Foamix, and Valeant. Dr. Lawrence Kircik has received grants for research, honoraria, consulting, and travel expenses from Arcutis, Talecris Biotherapeutics, Valeant, Greenfield, and Valeant. Dr. Eric Guenin has received grants for research, honoraria, consulting, and travel expenses from Valeant, Greenfield, and Valeant. Dr. Lawrence Green has received grants for research, honoraria, consulting, and travel expenses from Valeant.