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 Kirck, MD; Ashlie M Caronia, FNP; 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; Physicians Skin Care, PLLC, Louisville, KY; and 4Icahn School of Medicine at Mount Sinai, New York, NY; 5Premier Clinical Research, Spokane, WA; 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 15.3% (≥50 y) in females and 42.5% (20-29 y) to 2.7% (≥50 y) in males.
- Adolescent and adult females are also more likely to have some acne-related quality of life.
- A novel tazarotene 0.045% lotion formulation was developed for the treatment of acne, utilizing polymers 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 (NCT03695946), tazarotene 0.045% lotion was superior to vehicle in inflammatory/noninflammatory lesion count reductions in patients with moderate-to-severe acne.

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

METHODS
- In this 2-phase study, patients aged 12 years and older were randomized (2:1:1) to receive tazarotene 0.045% lotion, tazarotene 0.1% cream (Tazorac), lotion vehicle, or cream vehicle.
- Participants had to have a score of ≥3 (moderate) or ≥4 (severe) on the Investigator’s Global Severity Score (IGSS) at the screening and baseline visits.
- In the study, CeraVe® hydrating cleanser and CeraVe® moisturizer lotion (CeraVe, 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 endpoints of the clinical trial:
  - Mean change from baseline 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 and a score of clear (0) or almost clear (1).

RESULTS
- The intent-to-treat population included 210 participants (males, n=96; females, n=114).
- 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).

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 versus tazarotene 0.1% cream, this novel lotion formulation is a viable treatment option that is as effective as cream with fewer AEs.

REFERENCES

AUTHOR DISCLOSURES
- No author has any potential conflicts of interest.

ACKNOWLEDGEMENTS
Medical writing support was provided by Precision Medical Communications Group (Chicago, IL) with financial support from Ortho Dermatologics; Ortho Dermatologics is a division of Bausch Health US, LLC. For 2020 Fall Clinical Dermatology Conference® for PAs & NPs • April 3-5, 2020 • Orlando, FL