Improvements in Acne and Skin Oiliness with Tazarotene 0.045% Lotion in Acne Patients with Oily Skin

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SYNOPSIS

Excessive sebum production is a factor in facial acne development and oily skin is a frequent complaint of dermatology patients with or without acne. Larger pores may be associated with higher rates of sebum production, and skin oiliness and pore size can also be rated by patients, with larger amounts of sebum secretion and larger pores noted in Black patients. Topical retinoids are a mainstay of acne treatment, though they are associated with irritation, which may limit their use. As vehicle formulated with emulsifiers/moisturizers may reduce retinoid-associated irritation, it is possible that naturally oily skin may also provide a protective effect. Through its effects on sebum production and acne, the topical retinoid tazarotene 0.045% cream has been shown to reduce apparent facial pore size. The lower dose 0.045% tazarotene comes with a demonstrated efficacy in reducing acne lesions and acne-induced sequelae such as hyperpigmentation, and good tolerability and safety profiles.

METHODS

In two phase 3, double-blind, 12-week studies (NCT03188338; NCT03198321), patients aged 16–75 years with moderate-to-severe acne were randomized 1:1 to once-daily tazarotene 0.045% lotion or vehicle lotion. Concentration of tazarotene 0.045% (tazarotene 0.045% lotion, 0.045% emulsion, 0.045% moisturizing lotion, L’Oreal, NY) were applied as needed for optimal moisturization/cleaning of the skin. This pooled, post hoc analysis comprised participants categorized by self-reported skin oiliness on baseline on the Acne-Specific Quality of Life questionnaire item 19 scores: scored from 0 (extremely oily) to 6 (not at all oily). Only participants scoring 0–2 [oily skin] were included in this analysis. Cutaneous endpoints in inflammatory/noninflammatory lesion counts and treatment success rates (2-grade reduction from baseline in Evaluator’s Global Severity Score (EGSS)) and a score of 0 [clear] or 1 [almost clear]) were observed (data not shown). Changes in skin oiliness, treatment-emergent adverse events (TEAEs), and cutaneous safety and tolerability were also evaluated. The percentage of tazarotene-treated oily skin participants reporting “none” on item 19 was evaluated.

RESULTS

Demographics and Baseline Characteristics

- Of 1041 participants in the intent to treat population (ITT) of the two pooled phase 3 studies, 736 had oily skin (45.6%)
- They had a mean age of 21.6 years, 73% were female, and 69% were White; approximately 90% had EGSS baseline ≥ 5
- Of 261 participants who identified as Black (ITT population), 150 had oily skin; 19.2% were female and 78.2% were White
- Approximately 90% had EGSS baseline ≥ 5

Efficacy

- In all participants with oily skin, tazarotene 0.045% lotion demonstrated significantly greater reductions in mean percent reduction from baseline to week 12 in inflammatory and noninflammatory lesion counts vs vehicle (P<0.001, both; Figure 2)
- Treatment success rates at week 12 were significantly higher for all tazarotene-treated participants vs vehicle (P<0.001, both; Figure 2)
- These results are similar to those in the overall phase 3 pooled population for inflammatory and noninflammatory lesion counts and treatment success rates at week 12 (Figure 2)
- The percentage of tazarotene-treated oily skin participants reporting “none” on cutaneous safety and tolerability assessments at week 12 was generally similar to baseline values for most assessments (Figure 4)

Safety and Tolerability

- TEAE rates with tazarotene in all oily skin patients (n=359; safety population) were similar to those observed in the overall phase 3 pooled population (≤77%; safety population) (any TEAE: 27.9% vs 26.8%; treatment-related TEAE: 11.7% vs 11.3%, respectively)
- The most common treatment-related TEAE was folliculitis (11.7% vs 9.2%)
- Differences in changes to baseline oily skin scores from baseline to week 12 were evaluated (data not shown).

FIGURE 1. Oily Skin Assessment

19. In the past WEEK, how oily was your facial skin?

- Extremely oily skin
- Very oily skin
- Oily skin
- Moderately oily skin
- Not at all oily

- Baseline responses on the Acne-Specific Quality of Life questionnaire item 19 were used to categorize participants into oily skin (≥6), moderately oily, and not at all oily skin.

Skin Oiliness

- Most participants reported an improvement in skin oiliness to “moderately” or “low/not” skin oily skin with tazarotene vehicle, while nearly all Black participants reported an improvement to “low/not” skin oily skin with tazarotene vehicle than vehicle (Figure 3)
- Most Black participants with oily skin also reported an improvement in skin oiliness to “moderately” or “low/not” skin oily skin with tazarotene vehicle, with a numerically greater percentage in the treatment-treated group (Figure 3)

FIGURE 3. Improvements in Oily Skin from Baseline to Week 12 (ITT Population)

**FIGURE 4. Cutaneous Safety and Tolerability (Safety Population)**

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REFERENCES