Comparison of a Novel Tazarotene 0.045% Lotion to Tazarotene 0.1% Cream: Patient-Reported Outcomes from a Phase 2 Clinical Trial

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SYNOPSIS

- Current formulations of tazarotene (gel/foam/cream) can cause irritation, which may limit their use.
- A novel tazarotene 0.045% lotion formulation was developed utilizing polymeric emulsion technology, resulting in a more uniform distribution of the active ingredient and of the moisturizing excipients at the skin’s surface.
- In a 12-week phase 2 study (NCT029138494), participants with moderate-to-severe acne, tazarotene 0.045% lotion was superior to vehicle for the coprimary endpoints in inflammatory and noninflammatory lesions and treatment success per Evaluator Global Severity Score grading.
- In addition, tazarotene 0.045% lotion was as effective as Tazorac6 (tazarotene 0.1% cream), but with fewer adverse events.

OBJECTIVE

To examine the participant-reported outcomes from this phase 2 study of tazarotene 0.045% lotion.

METHODS

- Participants aged 12 years and older were randomized (2:1:1) to receive double-blind treatment with tazarotene 0.045% lotion, tazarotene 0.1% cream, lotion vehicle, or cream vehicle.
- In this study, Cerave® hydrating cleanser and CeraVe® moisturizing lotion (1:0:1:0:1, NY) were provided as needed for optimal moisturization/cleaning of the skin.
- Participant-reported outcomes included: oily/shiny skin, Acne-Specific Quality of Life Questionnaire (Acne-QoL), and Subject Self-Assessment (SSA).
- Data were analyzed descriptively in participants with available data at Week 12, data for the cream and lotion vehicles were combined for this analysis.

RESULTS

- The intent-to-treat population included 210 participants.
- At week 12, the percentage of participants who reported “no oily or shiny skin on face” was similar between tazarotene 0.045% lotion and tazarotene 0.1% cream and greater than combined vehicle (Figure 1A).
- Among participants with any oily/shiny skin, the percentage who were “not bothered at all” was higher with lotion than with cream or vehicle (Figure 1B).
- Mean changes from baseline to week 12 in Acne-QoL domain generally indicated greater improvement with both tazarotene formulations (lotion and cream) than with vehicle in all 4 domains (Figure 2).
- For ISA ratings, the percentage of participants who reported having 90-100% clear skin was similar between tazarotene lotion and cream and greater than vehicle (Figure 3).

CONCLUSIONS

- Consistent with the clinician-assessed primary endpoints, participant-reported skin oiliness, QoL, and acne severity were improved with tazarotene 0.045% lotion versus vehicle.
- Taken together with the improved tolerability and similar efficacy of tazarotene 0.045% lotion versus tazarotene 0.1% cream, this novel lotion formulation may be a viable new treatment option that is as effective as cream with fewer adverse events.

REFERENCES


AUTHOR DISCLOSURES

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