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

Zoe Draelos, MD[1]; Fran Cook-Bolden, MD[2]; Lawrence Green, MD[3]; Eric Guenin, PharmD, PhD, MPH[4]; Gina Martin, MOT[5]; Radhakrishnan Pillai, PhD[5]

[1]Dermatology Consulting Services, PLLC, High Point, NC; [2]Dept. of Dermatology, Mount Sinai Hospital Center, New York, NY; [3]Dept. of Dermatology, George Washington University School of Medicine, Washington, DC; [4]Ortho Dermatologics*, Bridgewater, NJ; [5]Bausch Health US, LLC*, Petaluma, CA

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SYNOPSIS

- Current formulations of tazarotene (gel/foam/cream) can cause irritation, which may limit their use[1]
- 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[2]
- In a 12-week phase 2 study (NCT02938494) in participants with moderate-to-severe acne, tazarotene 0.045% lotion was superior to vehicle for the coprimary endpoints (reduction in inflammatory and noninflammatory lesions and treatment success per Evaluator Global Severity Score grading)[2]
- In addition, tazarotene 0.045% lotion was as effective as Tazorac® (tazarotene 0.1% cream), but with fewer adverse events[2]

OBJECTIVE

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

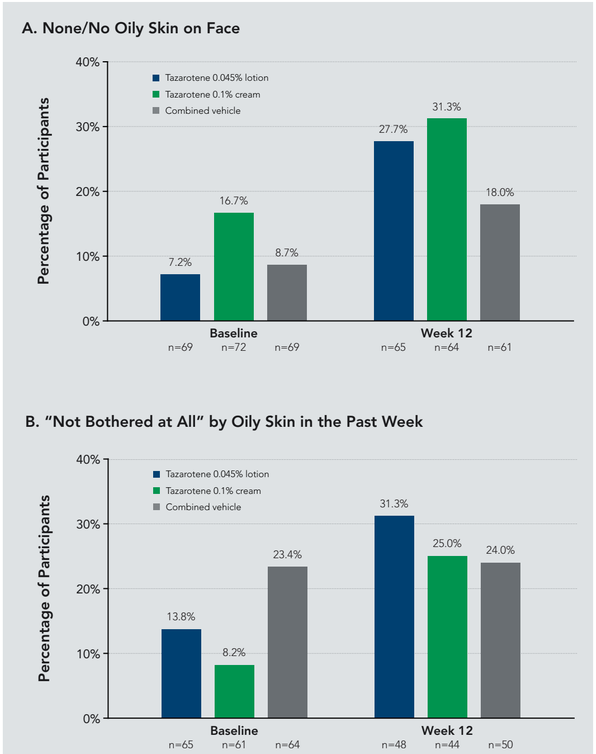
METHODS

- Participants aged 12 years and older were randomized (2:2:1:1) 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 (L'Oreal, 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

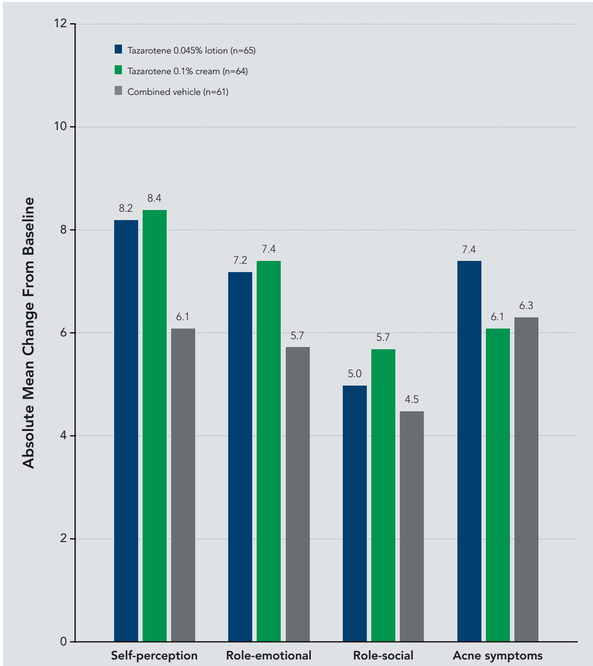
- The intent-to-treat population included 210 participants
- At week 12, the percentage of participants who reported "no oily or shiny skin on face" was similar between tazarotene 0.045% lotion and tazarotene 0.1% cream and greater than combined vehicle (**Figure 1A**)
  - Among participants with any 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 domains generally indicated greater improvement with both tazarotene formulations (lotion and cream) than with vehicle in all 4 domains (**Figure 2**)
- Per SSA 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**)

FIGURE 1. Percentage of Participants Reporting "None/No Oily Skin on Face" (A) and "Not Bothered at All" by Oily Skin in the Past Week (B) (ITT Population)



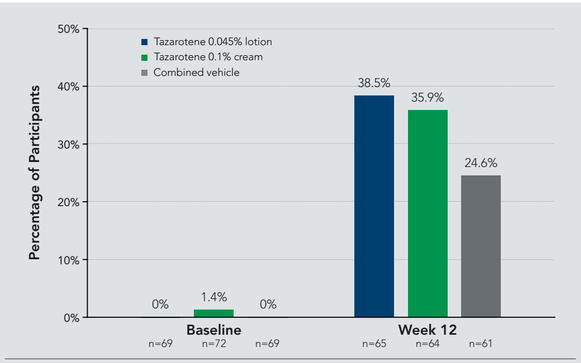
No imputation of missing values.
ITT, intent-to-treat.

FIGURE 2. Absolute Mean Change from Baseline to Week 12 in Acne-QoL (ITT Population)



Higher scores for each domain reflect improved health-related QoL. No imputation of missing values.
Self-perception domain assesses the extent facial acne has affected a particular area of self-perception (eg, feeling self-conscious, feeling unattractive, dissatisfaction with self appearance).[3]
Role-emotional domain assesses the emotional effect or impact of facial acne (eg, annoyance at spending time on face, worry/concern about medications working fast enough, bothersomeness of needing cover-up).[3]
Role-social domain assesses the impact of facial acne on a respondent's intersocial relationships (eg, going out in public, meeting new people, socializing).[3]
Acne symptoms assesses the physical symptoms experienced by facial acne (eg, bumps on face, scabbing, worry about scarring); the acne symptom domain score correlates inversely with acne severity.[3]
Acne-QoL, Acne-Specific Quality of Life Questionnaire; ITT, intent-to-treat.

FIGURE 3. Percentage of Participants Reporting 90-100% Clear Skin on the SSA (ITT Population)



No imputation of missing values.
ITT, intent-to-treat; SSA, Subject Self-Assessment.

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,[2] this novel lotion formulation may be a viable new treatment option that is as effective as cream with fewer adverse events

REFERENCES

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3. Acne-specific Quality of Life Questionnaire (Acne-QoL) Manual & Interpretation Guide. January 2003. http://www.anzctr.org.au/Steps11and12/376709-(Uploaded-11-01-2019-20-05-40)-Study-related%20document.pdf

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