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 Americas Inc., Petaluma, CA

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

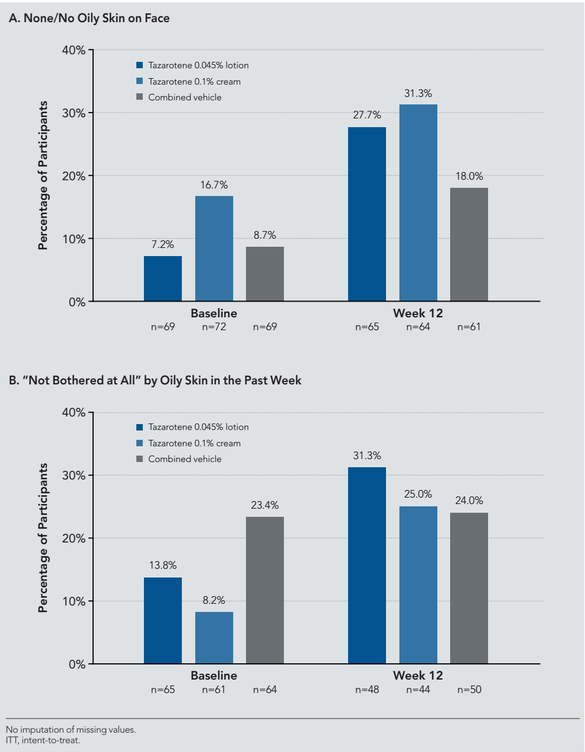
METHODS

- 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**)

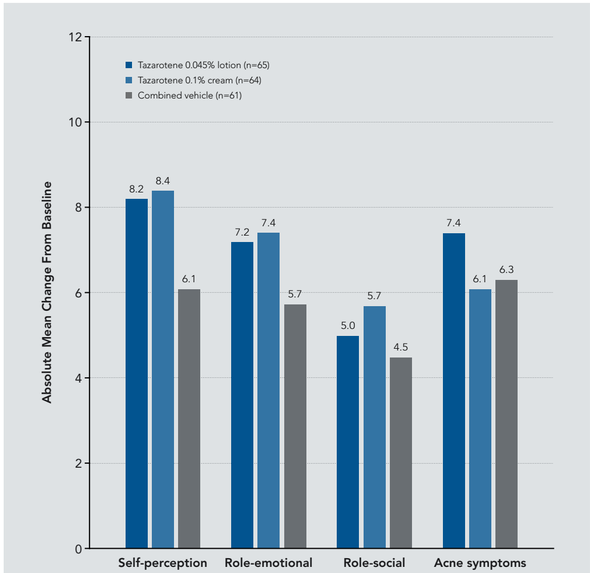
FIGURE 1. Percentage of Participants Reporting "None/No Oily Skin on Face" (A) and "Not Bothered at All" by Oily Skin in the Past Week (B) (ITT Population)



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

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



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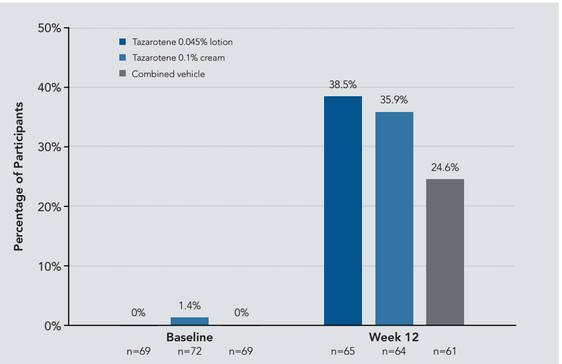
Acne-QoL, Acne-Specific Quality of Life Questionnaire; ITT, intent-to-treat.

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

1. Zaenglein AL, et al. *J Am Acad Dermatol*. 2016;74(5):945-973.
2. Tanghetti EA, et al. *J Drugs Dermatol*. 2019;18(6):542-548.

AUTHOR DISCLOSURES

Dr. Zoe Draelos received funding from Ortho Dermatologics to conduct the research presented in this poster.
Dr. Fran Cook-Bolden has served as consultant, speaker, and/or investigator for Galderma, LEO Pharma, Almirall, Cassiopea, Ortho Dermatologics, Investigators Encore, Foamix, Hovione, Aclaris, and Cutanea.
Dr. Lawrence Green has served as consultant, speaker, and/or investigator for Almirall, Cassiopea, Ortho Dermatologics, Sol Gel, and Sun Pharmaceuticals.
Dr. Eric Guenin is an employee of Ortho Dermatologics.
Ms. Gina Martin and Dr. Radhakrishnan Pillai are employees of Bausch Health Americas.

ACKNOWLEDGEMENTS: Medical writing support was provided by Prescott Medical Communications Group (Chicago, IL) with financial support from Ortho Dermatologics | *Presented at the Fall Clinical Dermatology Conference • October 17-20, 2019 • Las Vegas, NV*