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

Emil A Tanghetti, MD[1]; Michael Gold, MD[2]; Neil Sadick, MD[3,4]; Fran E Cook-Bolden, MD[4,5]; Leon H Kircik, MD[6-8]; Linda Stein Gold, MD[9]; Stephen K Tyring, MD[10]; James Q Del Rosso, DO[11]; Eric Guenin, PharmD, PhD, MPH[12]

[1]Center for Dermatology and Laser Surgery, Sacramento, CA; [2]Tennessee Clinical Research Center, Nashville, TN; [3]Sadick Dermatology, New York, NY; [4]Weill Cornell Medical College, New York, NY; [5]Fran E. Cook-Bolden, MD, PLLC; [6]Indiana University School of Medicine, Indianapolis, IN; [7]Physicians Skin Care, PLLC, Louisville, KY; [8]Icahn School of Medicine at Mount Sinai, New York, NY; [9]Henry Ford Hospital, Detroit, MI; [10]University of Texas Health Science Center, Houston, TX; [11]JDR Dermatology Research/Thomas Dermatology, Las Vegas, NV; [12]Ortho Dermatologics,* Bridgewater, NJ

Ortho Dermatologics is a division of Bausch Health US, LLC

SYNOPSIS

- Excessive sebum production is a factor in facial acne development[1] and oily skin is a frequent complaint of dermatology patients with or without acne[2]
  - Larger pore sizes may be associated with higher rates of sebum production[3]
  - Skin oiliness and pore size can also differ by race, with larger amounts of sebum secretion and larger pore sizes observed in Black patients[2,4]
- Topical retinoids are a mainstay of acne treatment, though they are associated with cutaneous irritation, which may limit their use[5]
  - As vehicles formulated with emollients/moisturizers may reduce retinoid-associated irritation,[5] it is possible that naturally oily skin may also provide a protective effect
- Though its effects on sebum production are unknown, the topical retinoid, tazarotene 0.1% cream, has been shown to reduce apparent facial pore size[6]
- The lower-dose 0.045% tazarotene polymeric lotion has also demonstrated efficacy in reducing acne lesions and acne-induced sequalae such as hyperpigmentation with good tolerability and safety profiles[7]

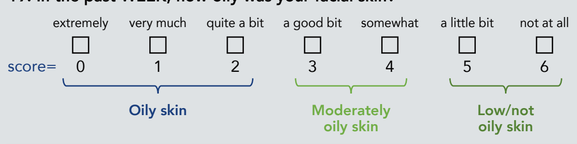
OBJECTIVE

- To evaluate efficacy, changes in skin oiliness, and safety/tolerability with tazarotene 0.045% lotion in participants with acne and oily skin, including Black participants

METHODS

- In two phase 3, double-blind, 12-week studies (NCT03168334; NCT03168321), participants aged ≥9 years with moderate-to-severe acne were randomized 1:1 to once-daily tazarotene 0.045% lotion or vehicle lotion
  - CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (L'Oreal, NY) were provided as needed for optimal moisturization/cleaning of the skin
- This pooled, post hoc analysis comprised participants categorized by self-reported skin oiliness at baseline on the Acne-Specific Quality of Life questionnaire item 19[8]
  - Scored from 0 (extremely oily) to 6 (not at all oily; **Figure 1**)
  - Only participants scoring 0–2 (oily skin) were included in this analysis
- Coprimary endpoints were inflammatory/noninflammatory lesion counts and treatment success (≥2-grade reduction from baseline in Evaluator's Global Severity Score [EGSS] and a score of 0 [clear] or 1 [almost clear])
- Changes in skin oiliness, treatment-emergent adverse events (TEAEs), and cutaneous safety and tolerability were also evaluated
  - A subset of participants with oily skin who self-reported race as Black were also analyzed for changes in skin oiliness and cutaneous safety and tolerability

FIGURE 1. Oily Skin Assessment



Baseline responses on the Acne-Specific Quality of Life questionnaire item 19 were used to categorize participants into 3 groups: oily, moderately oily, and low/not oily skin.

RESULTS

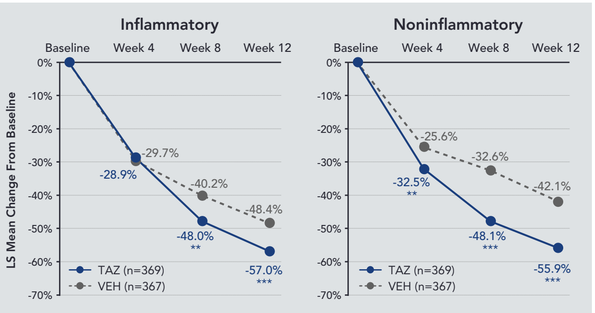
Demographics and Baseline Characteristics

- Of 1614 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 moderate EGSS at baseline
- Of 261 participants who identified as Black (ITT population), 150 had oily skin (57.4%)
  - They were slightly older (mean age 25.2 years), and a greater percentage were female (82.7%)
  - Most had moderate EGSS at baseline (94.7%)

Efficacy

- In all participants with oily skin, tazarotene 0.045% lotion provided significantly greater least-squares 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 (29.8% vs 19.2%; $P<0.01$)
  - These results are similar to those in the overall phase 3 pooled population for lesion reductions (see **Figure 2** footnote) and treatment success rates at week 12 (30.4% tazarotene and 17.9% vehicle; $P<0.001$[7])

FIGURE 2. Reductions in Acne Lesion Counts by Visit in All Participants with Oily Skin (ITT Population)

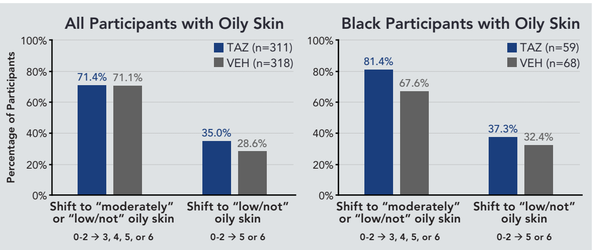


**$P<0.01$; ***$P<0.001$ vs vehicle.
Multiple imputation used to impute missing values.
Overall phase 3 pooled population at week 12: inflammatory TAZ -57.9% and VEH -47.8%; noninflammatory TAZ -56.0% and VEH -42.0%; $P<0.001$, both.[7]
ITT, intent to treat; LS, least squares; TAZ, tazarotene 0.045% lotion; VEH, vehicle lotion.

Skin Oiliness

- Most participants reported an improvement in skin oiliness to "moderately" or "low/not" oily with tazarotene 0.045% and vehicle; numerically more participants reported an improvement to "low/not" oily skin with tazarotene than vehicle (**Figure 3**)
- Most Black participants with oily skin also reported an improvement in skin oiliness to "moderately" or "low/not" oily with tazarotene and vehicle, with a numerically greater percentage in the tazarotene-treated group (**Figure 3**)

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

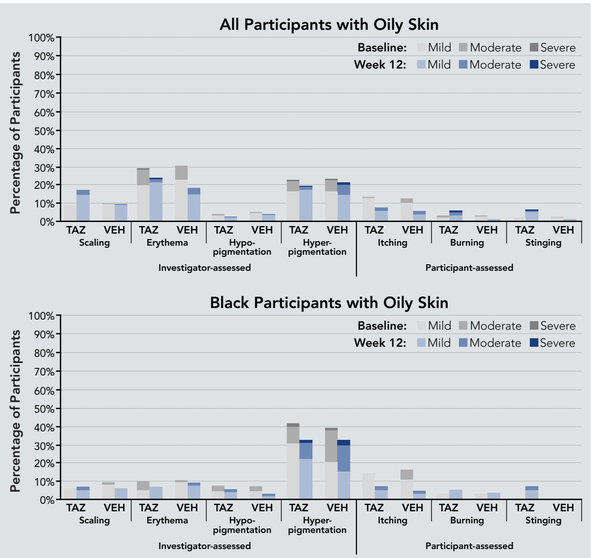


Categories based on Acne-Quality of Life questionnaire item 19 scores at baseline: low/not oily (score=5 to 6); moderately oily (score=3 to 4); oily (score=0 to 2; See **Figure 1**).
No imputation of missing data. N values indicate participants with "oily" skin at baseline who also had data at week 12.
ITT, intent to treat; TAZ, tazarotene 0.045% lotion; VEH, vehicle lotion.

Safety and Tolerability

- TEAE rates with tazarotene in all oily-skin patients (n=359; safety population) were similar to those observed in the overall tazarotene-treated population (n=779; safety population)[7] (any TEAE: 27.9% vs 26.8%; treatment-related TEAE: 11.7% vs 11.3%, respectively)
- 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**)
  - As expected, transient increases in mild-to-moderate itching, burning, stinging, scaling, and erythema were observed (data not shown)
- Similar trends were observed in Black participants with oily skin (tazarotene n=70, vehicle n=75; safety population), though Black participants had greater improvements in hyperpigmentation and fewer reports of erythema and scaling at week 12 (**Figure 4**)

FIGURE 4. Cutaneous Safety and Tolerability (Safety Population)



No imputation of missing data.
N values: all participants with oily skin baseline: TAZ n=359, VEH, n=353; week 12: TAZ n=312, VEH n=318; Black participants with oily skin baseline: TAZ n=70, VEH n=75; week 12: TAZ n=59, VEH n=68.
TAZ, tazarotene 0.045% lotion; VEH, vehicle lotion.

CONCLUSIONS

- Nearly three-fourths of all participants treated with tazarotene 0.045% lotion—including Black participants—had subjective reductions in skin oiliness by week 12, with over a third reporting low/not oily skin
- It is possible the improvements in oiliness observed with tazarotene lotion were due to the unique, non-greasy excipients/emulsifiers contained in the polymeric emulsion lotion vehicle; this emulsion technology provides fast, uniform, and complete release of the humectants, oil droplets, and other excipients contained in the vehicle onto the skin[9]
- Tazarotene lotion also demonstrated efficacy and safety in the treatment of moderate-to-severe acne in participants with oily skin, with rates similar to the overall population
- Once-daily treatment with tazarotene 0.045% lotion may help improve patient-perceived skin oiliness in those with moderate-to-severe acne

REFERENCES

1. Moradi Tuchayi S, et al. *Nat Rev Dis Primers*. 2015;1:15029.
2. Endly DC, et al. *J Clin Aesthet Dermatol*. 2017;10(8):49-55.
3. Roh M, et al. *Br J Dermatol*. 2006;155(5):890-894.
4. Pappas A, et al. *Dermatoendocrinol*. 2013;5(2):319-324.
5. Leyden J, et al. *Dermatol Ther (Heidelb)*. 2017;7(3):293-304.
6. Kang S, et al. *J Am Acad Dermatol*. 2005;52(2):268-274.
7. Tanghetti EA, et al. *J Drugs Dermatol*. 2020;19(3):272-279.
8. Martin AR, et al. *Clin Exp Dermatol*. 2001;26(5):380-385.
9. Tanghetti EA, et al. *J Dermatol Treat*. 2021;32(4):391-398

AUTHOR DISCLOSURES

Emil A Tanghetti has served as speaker for Novartis, Ortho Dermatologics, Sun Pharma, Lilly, Galderma, AbbVie, and Dermira; served as a consultant/clinical studies for Hologic, Ortho Dermatologics, and Galderma; and is a stockholder for Accure. Michael Gold has acted as an investigator, advisor, speaker, and consultant for Ortho Dermatologics. Neil Sadick has served on advisory boards, as a consultant, investigator, speaker, and/or other and has received honoraria and/or grants/research funding from Almirall, Actavis, Allergan, Anacor Pharmaceuticals, Auxilium Pharmaceuticals, Bausch Health, Bayer, Biorasi, BTG, Carma Laboratories, Cassiopea, Celgene Corporation, Cutera, Cynosure, DUSA Pharmaceuticals, Eclipse Medical, Eli Lilly and Company, Endo International, EndyMed Medical, Ferndale Laboratories, Galderma, Gerson Lehrman Group, Hydropeptide, Merz Aesthetics, Neostrata, Novartis, Nutraceutical Wellness, Palomar Medical Technologies, Prescriber's Choice, Regeneron, Roche Laboratories, Samumed, Solta Medical, Storz Medical AG, Suneva Medical, Vanda Pharmaceuticals, and Venus Concept. Fran E Cook-Bolden has served as consultant, speaker, investigator for Galderma, LEO Pharma, Almirall, Cassiopea, Ortho Dermatologics, Investigators Encore, Foamix, Hovione, Aclaris, Cutanea. Leon H Kircik has acted as an investigator, advisor, speaker, and consultant for Ortho Dermatologics. Linda Stein Gold has served as investigator/consultant or speaker for Ortho Dermatologics, LEO Pharma, Dermavant, Incyte, Novartis, AbbVie, Pfizer, Sun Pharma, UCB, Arcutis and Lilly. Stephen K Tyring is has acted as an investigator for Ortho Dermatologics. James Q Del Rosso has served as a consultant, investigator, and/or speaker for Ortho Dermatologics, Abbvie, Amgen, Arcutis, Dermavant, EPI Heath, Galderma, Incyte, LEO Pharma, Lilly, MC2 Therapeutics, Pfizer, Sun Pharma, and UCB. Eric Guenin is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company.

ACKNOWLEDGEMENTS: Medical writing support was provided by Prescott Medical Communications Group (Chicago, IL) with financial support from Ortho Dermatologics; Ortho Dermatologics is a division of Bausch Health US, LLC • *Presented at Fall Clinical Dermatology Conference • October 21-24, 2021 • Las Vegas, NV*