To order reprints or e-prints of JDD articles please contact sales@jddonline.com

doi:10.36849/JDD.2020.5125

Copyright © 2020 ORIGINAL ARTICLE

Novel Polymeric Tazarotene 0.045% Lotion for Moderate-to-Severe Acne: Pooled Phase 3 Analysis by Race/Ethnicity

Neal Bhatia MD,[a] Jonathan S. Weiss MD,[b] Neil Sadick MD,[c] Fran E. Cook-Bolden MD,[d] Stephen K. Tyring MD PhD,[e] Eric Guenin PharmD PhD MPH,[f] Anya Loncaric MS,[g] Susan Harris MS[h]

[a]Therapeutics Clinical Research, San Diego, CA

[b]Georgia Dermatology Partners, and Gwinnett Clinical Research Center, Inc., Snellville, GA

[c]Weill Cornell Medical College, New York, NY; Sadick Dermatology, New York, NY

[d]Fran E. Cook-Bolden, MD, PLLC; Mount Sinai Hospital Center, New York, NY

[e]University of Texas Health Science Center, Houston, TX

[f]Ortho Dermatologics,* Bridgewater, NJ

[g]Bausch Health US, LLC,* Petaluma, CA

[h]Bausch Health US, LLC,* Bridgewater, NJ

*Bausch Health US, LLC is an affiliate of Bausch Health Companies Inc. Ortho Dermatologics is a division of Bausch Health US, LLC.

ABSTRACT

Background: Acne vulgaris and inflammation-associated sequelae are highly prevalent in black and Hispanic populations. In a phase 2 study, a novel polymeric emulsion formulation of tazarotene 0.045% lotion had relatively fewer adverse events than tazarotene 0.1% cream, but with comparable efficacy. The objective was to evaluate tazarotene 0.045% lotion by race and ethnicity in the pivotal trials.

Methods: In two phase 3, double-blind, 12-week studies (NCT03168334; NCT03168321), participants with moderate-to-severe acne were randomized 1:1 to tazarotene 0.045% lotion or vehicle lotion (N=1,614). This pooled, post hoc analysis included subsets of participants that self-identified as white (n=1191) or black (n=262) and Hispanic (n=352) or non-Hispanic (n=1262). Coprimary endpoints were inflammatory/noninflammatory lesion counts and treatment success (defined as at least a 2-grade reduction from baseline in Evaluator's Global Severity Score and a score of 'clear' or 'almost clear'). Treatment-emergent adverse events (TEAEs) and cutaneous safety and tolerability were evaluated.

Results: At week 12, tazarotene 0.045% lotion led to significantly greater percent reductions in inflammatory and noninflammatory lesions compared with vehicle in white, Hispanic, and non-Hispanic participants ($P<0.05$, all). Black participants had significantly greater reductions in noninflammatory lesions following treatment with tazarotene 0.045% versus vehicle ($P<0.05$). Treatment success rates in all subpopulations were higher with tazarotene 0.045% lotion (29.4-34.1%) versus vehicle (16.4-23.1%). TEAE rates were similar across tazarotene-treated groups and most were mild-to-moderate in severity. The incidence of hyperpigmentation decreased in black tazarotene-treated participants from baseline to week 12.

Conclusions: Tazarotene 0.045% lotion demonstrated efficacy and was well tolerated across racial and ethnic subpopulations in this pooled analysis.

J Drugs Dermatol. 2020;19(7):727-734. doi:10.36849/JDD.2020.5125

INTRODUCTION

Acne vulgaris is one of the most common dermatologic conditions for which all patients seek treatment, including those with darker skin tones.[1] Given the growing non-white population, estimated to be nearly one-half of the United States population by 2050,[2] more information is needed regarding the effects of acne treatment in all skin types. Recent articles highlighting the treatment of acne in Asian patients,[3] Hispanic patients,[4] and women of color[5] have set the stage for understanding how race and ethnicity might affect treatment outcomes.

In all skin types, acne development has the same causes: follicular hyperkeratinization, increased sebum production, proliferation of *Cutibacterium acnes* (formerly *Propionibacterium acnes*) bacteria on the skin surface, and inflammation.[6,7] More highly pigmented skin can have properties that increase the risk of acne and inflammation-related sequalae.[6] These sequelae occur in 50%-75% of black women with acne and include dyspigmentation and scarring.[8,9] Post-inflammatory hyperpigmentation (PIH) can be associated with acne resolution or irritation from harsh treatments or skin care.[10-12] For many

This document contains proprietary information, images and marks of Journal of Drugs in Dermatology (JDD).
No reproduction or use of any portion of the contents of these materials may be made without the express written consent of JDD.
If you feel you have obtained this copy illegally, please contact JDD immediately at support@jddonline.com

To order reprints or e-prints of JDD articles please contact sales@jddonline.com

patients with darker skin tones, PIH is cited as the reason for seeking dermatological care.[12]

In these particular patients, using aggressive, non-irritating treatment is the recommended strategy to treat acne while reducing the risk of PIH and keloid scarring.[10] The first line of treatment for mild-to-moderate acne in patients of color is topical retinoids[6,10]—these disrupt desquamation pathways and inhibit multiple inflammatory pathways, which is important for the prevention of secondary PIH.[13]

One challenge of traditional formulations of topical retinoids—such as tazarotene, adapalene, and tretinoin—has been achieving uniform and consistent application with low rates of irritation, which may preclude effectiveness in real-world settings.[14] The development of tazarotene 0.045% lotion formulation utilizing polymeric emulsion technology improves topical delivery of a drug by suspending the active agent(s) with a polymer in a hydrating emulsion of solvents, emollients, and humectants without using surfactants. This new formulation can thereby reduce irritation and uniformly distribute these microscopic droplets across the skin surface in an aesthetically pleasing, easily spreadable lotion.[15] The adaptation of this technology to topical retinoids has the potential to reduce skin irritation while maintaining efficacy at a lower dosage, which may have particular benefits for patients with darker skin tones.[12,15]

In a phase 2 trial in participants aged ≥12 years with moderate-to-severe acne, tazarotene 0.045% lotion provided numerically lower lesion counts and higher rates of treatment success compared with tazarotene 0.1% cream.[16] Promisingly, the incidence of treatment-emergent adverse events (TEAEs) was nearly 2-fold lower in the tazarotene 0.045% lotion group compared with the tazarotene 0.1% cream group.[16] Furthermore, two identical phase 3 double-blind, randomized, vehicle-controlled 12-week clinical studies demonstrated tazarotene 0.045% lotion was efficacious versus vehicle and well tolerated in participants with moderate-to-severe acne.[17] Pooled, post hoc analyses from these phase 3 studies were conducted to examine the potential effects of race and ethnicity on the efficacy and safety of tazarotene 0.045% lotion.

METHODS

Study Design and Participants

This pooled analysis includes data from NCT03168334 and NCT03168321, which were previously described.[17] Both trials were identical, multicenter, double-blind, randomized, vehicle-controlled, parallel-group phase 3 studies conducted at 89 study centers in the United States and Canada. Eligible participants were aged ≥9 years with Evaluator's Global Severity Score (EGSS) of 3 (moderate) or 4 (severe), and had facial acne inflammatory lesion counts between 20-50, facial acne noninflammatory lesion counts between 25-100, and ≤2 facial nodules. Participants were randomized (1:1) to tazarotene 0.045% lotion or vehicle lotion, applied to the face once daily for 12 weeks. Studies were conducted in accordance with the International Conference on Harmonization, the Declaration of Helsinki, Good Clinical Practice Guidelines, and local regulations. All participants or their legal guardians provided written informed consent. Studies were approved by relevant independent ethics committees or institutional review boards at each study site.

Study Assessments

Efficacy and safety assessments were performed at each study visit (baseline and at weeks 2, 4, 8, and 12). Blinded evaluators determined EGSS and measured the number of noninflammatory and inflammatory lesions as efficacy assessments. Treatment success was defined as the proportion of participants achieving ≥2-grade reduction from baseline in EGSS and a score of 'clear' (0) or 'almost clear' (1). Investigator-assessed cutaneous safety (scaling, erythema, hypopigmentation, hyperpigmentation) and participant-assessed tolerability (itching, burning, stinging) were evaluated using a 4-point scale where 0=none and 3=severe. Adverse events (AEs) and serious adverse events (SAEs) were also monitored throughout the study.

Statistical and Subgroup Analyses

The co-primary endpoints for the two phase 3 studies comprised absolute change from baseline to week 12 in mean inflammatory and noninflammatory lesion counts and the proportion of participants achieving treatment success at week 12. The intent-to-treat (ITT) population was defined as all participants who were randomized and received study drug. The safety population included all randomized participants who used study medication or vehicle at least once with a minimum of one post-baseline evaluation.

For this pooled post hoc analysis, data from a subset of participants were evaluated based upon self-reported race (white or black) and ethnicity (Hispanic or non-Hispanic). Race and ethnicity were not mutually exclusive. Least-squares (LS) mean percent changes from baseline in inflammatory and noninflammatory lesion counts at week 12 and treatment success at week 12 were analyzed for each subgroup.

An analysis of covariance (ANCOVA) was performed to test for superiority for lesion count data between treatment groups. Initial analyses of mean percent changes from baseline in noninflammatory and inflammatory lesion counts indicated significant skewness. To address this, a nonparametric method was used to rank transform data prior to performing ANCOVA, with factor of treatment and the respective baseline lesion count as a covariate. Logistic regressions (using Firth's Penalized Likelihood) were performed to analyze treatment success, with

This document contains proprietary information, images and marks of Journal of Drugs in Dermatology (JDD).
No reproduction or use of any portion of the contents of these materials may be made without the express written consent of JDD.
If you feel you have obtained this copy illegally, please contact JDD immediately at support@jddonline.com

To order reprints or e-prints of JDD articles please contact sales@jddonline.com

factor of treatment group. Statistical significance was defined as P=0.05 determined using 2-tailed tests of the null hypothesis. Values were adjusted for multiple imputations. Missing efficacy data of lesion counts and EGSS data were estimated using the Markov Chain Monte Carlo method. All statistical analyses were performed in SAS® version 9.3 or later. Cutaneous safety and tolerability assessments were summarized using descriptive statistics. AEs were recorded and classified using the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Imputations were not made for missing safety data.

RESULTS

Participants

The overall pooled study population in the phase 3 studies included 1614 participants who received tazarotene 0.045% lotion (n=799) or vehicle lotion (n=815).[17] In this post hoc analysis, the population was segmented by race (n=1191 white, n=262 black) and by ethnicity (n=352 Hispanic, n=1262 non-Hispanic; Table 1). The black subpopulation was, on average, slightly older and had a higher proportion of female participants compared with the white subpopulation. Disease characteristics were similar between the races, although a slightly higher proportion of white participants had an EGSS of 4 compared with black participants (10.0% versus 4.6%, respectively). The subpopulations defined by ethnicity were similar in age and sex. While the majority of both the Hispanic and non-Hispanic subgroups were white, the non-Hispanic subgroup had higher proportions of participants reporting black or Asian race (Table 1).

Efficacy

Inflammatory and noninflammatory lesion counts decreased over time across all racial and ethnic subpopulations. In white participants, LS mean percent change from baseline in inflammatory lesions was significantly greater in the tazarotene 0.045% lotion group compared with the vehicle group at week 12 (-57.6% vs -45.0%; P<0.001); significant improvements were also observed at week 8 (Figure 1). Tazarotene-treated black participants had a similar reduction in inflammatory lesions (-60.4%) to white participants at week 12, but with no significant differences relative to vehicle. For noninflammatory lesions, reductions from baseline were significantly greater with tazarotene 0.045% lotion than vehicle at week 12 for both race groups (P<0.001, white; P<0.05, black); significant improvements were observed as early as week 4 in white participants and week 8 in black participants (Figure 2).

In the subpopulations defined by ethnicity, LS mean percent change in inflammatory lesion counts were significantly greater with tazarotene 0.045% lotion versus vehicle at week 12 in the Hispanic and non-Hispanic groups (P<0.01, Hispanic; P<0.001, non-Hispanic; Figure 3). Similar trends were observed in noninflammatory lesion counts, with significant improvements following treatment with tazarotene 0.045% lotion versus vehicle at week 12 (P<0.01, Hispanic; P<0.001, non-Hispanic; Figure 4). In non-Hispanic participants, significant decreases were observed as early as week 4 for noninflammatory lesions and week 8 for inflammatory lesions.

TABLE 1.

Participant Demographics and Baseline Characteristics (ITT Population, Pooled)

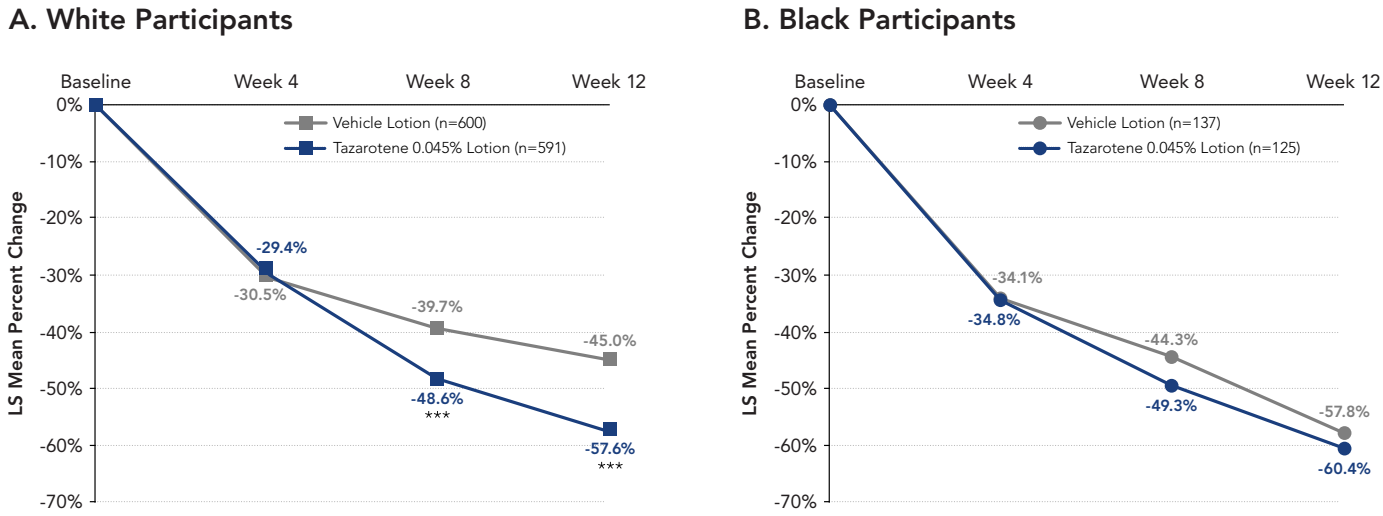
	Race		Ethnicity	
Characteristics	White (n=1191)	Black (n=262)	Hispanic (n=352)	Non-Hispanic (n=1262)
Age, mean (SD), y	19.6 (6.0)	24.0 (9.3)	20.7 (6.6)	20.4 (7.0)
Female, n (%)	753 (63.2)	205 (78.2)	225 (63.9)	839 (66.5)
Race, n (%)				
White	1191 (100)	0	307 (87.2)	884 (70.0)
Black/African American	0	262 (100)	15 (4.3)	247 (19.6)
Asian	0	0	2 (0.6)	76 (6.0)
Other[a]	0	0	28 (8.0)	55 (4.4)
Ethnicity, n (%)				
Non-Hispanic/Latino	884 (74.2)	247 (94.3)	0	1262 (100)
Hispanic/Latino	307 (25.8)	15 (5.7)	352 (100)	0
Inflammatory lesion count, mean (SD)	28.5 (7.3)	26.6 (6.0)	28.9 (7.8)	27.9 (6.9)
Noninflammatory lesion count, mean (SD)	40.9 (16.5)	40.6 (15.7)	41.3 (16.5)	41.0 (16.6)
Evaluator's Global Severity Score, n (%)				
3 – Moderate	1072 (90.0)	250 (95.4)	308 (87.5)	1159 (91.8)
4 – Severe	119 (10.0)	12 (4.6)	44 (12.5)	103 (8.2)

[a]Other comprises American Indian or Alaska Native; Native Hawaiian or Other Pacific Islander; and Other/Multiple.
ITT, intent to treat; SD, standard deviation.

This document contains proprietary information, images and marks of Journal of Drugs in Dermatology (JDD).
No reproduction or use of any portion of the contents of these materials may be made without the express written consent of JDD.
If you feel you have obtained this copy illegally, please contact JDD immediately at support@jddonline.com

To order reprints or e-prints of JDD articles please contact sales@jddonline.com

FIGURE 1. Mean percent change in inflammatory lesion counts, by race (ITT population, pooled).



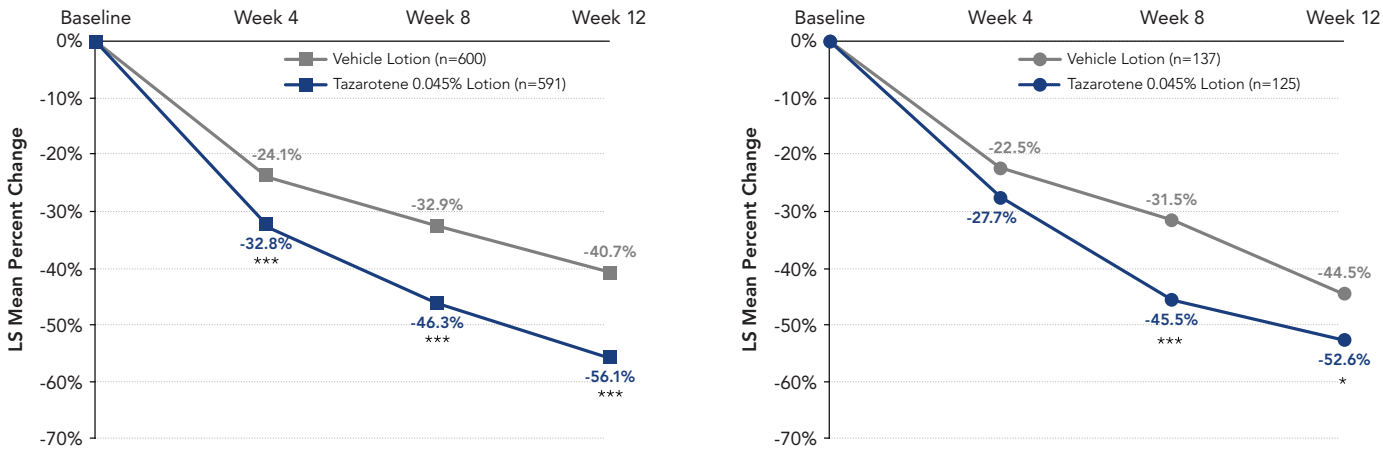
***P<0.001 versus vehicle.
ITT, intent to treat; LS, least squares.

Rates of treatment success were higher following treatment with tazarotene 0.045% lotion versus vehicle for all racial and ethnic subpopulations. At week 12, a significantly higher proportion of participants achieved treatment success with tazarotene 0.045% lotion compared with vehicle in the white, Hispanic, and non-Hispanic groups ($P<0.05$, all; Figure 5). Although a higher proportion of black participants achieved treatment success with tazarotene 0.045% lotion compared with vehicle, this difference was not significant. The size of black population subgroup may be responsible for the lack of statistical significance.

Safety

Rates of TEAEs were similar across the tazarotene 0.045% lotion-treated racial and ethnic subgroups (range, 20.2%–28.7%; Table 2). Overall, TEAE incidence was lower in the vehicle-treated groups compared with tazarotene. None of the SAEs were deemed related to treatment by study investigators. Most TEAEs were mild-moderate in severity; the incidence of moderate TEAEs was highest in white and the non-Hispanic subpopulations, regardless of treatment. The incidence of treatment-related TEAEs ranged from 9.8%–12.4% among the tazarotene 0.045% lotion-treated racial and ethnic subgroups.

FIGURE 2. Mean percent change in noninflammatory lesion counts, by race (ITT population, pooled).

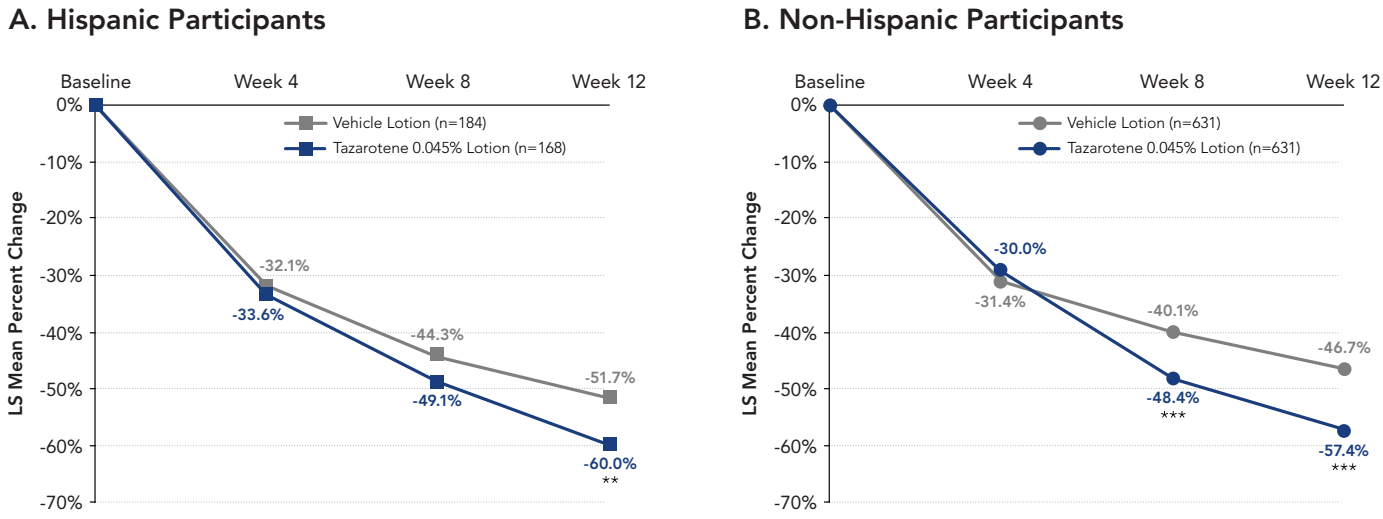


*P<0.05 versus vehicle; ***P<0.001 versus vehicle.
ITT, intent to treat; LS, least squares.

This document contains proprietary information, images and marks of Journal of Drugs in Dermatology (JDD).
No reproduction or use of any portion of the contents of these materials may be made without the express written consent of JDD.
If you feel you have obtained this copy illegally, please contact JDD immediately at support@jddonline.com

To order reprints or e-prints of JDD articles please contact sales@jddonline.com

FIGURE 3. Mean percent change in inflammatory lesion counts, by ethnicity (ITT population, pooled).

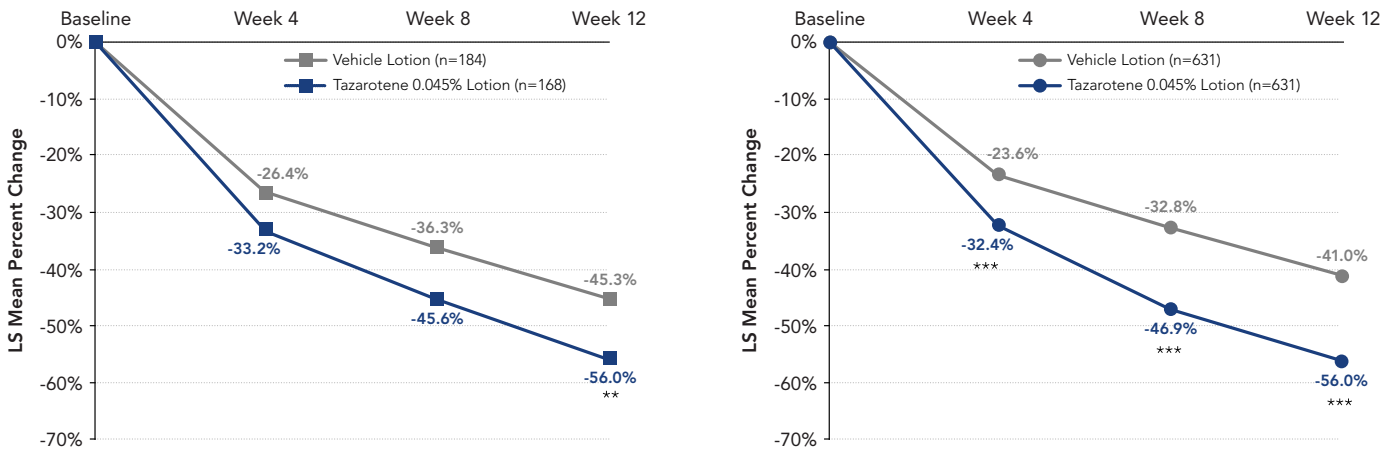


**$P<0.01$; ***$P<0.001$ versus vehicle.
ITT, intent to treat; LS, least squares.

The most common TEAEs were related to application site pain, dryness, and exfoliation (Table 2). Application site irritation was reported in ≤1.2% of each race and ethnic subgroup.

Among tazarotene-treated participants who had cutaneous safety and tolerability signs and symptoms, most had mild or moderate severity at baseline and week 12 (Figure 6). Across all tazarotene-treated subgroups, there were transient increases in severity (primarily mild or moderate) at weeks 2 or 4 relative to baseline for several of the cutaneous safety and tolerability evaluations (data not shown). Investigator-rated assessments indicated higher baseline rates (>20%) of hyperpigmentation in black participants and erythema in white, Hispanic, and non-Hispanic participants; however, all of these rates decreased by week 12. Patient-reported tolerability assessments of itching, burning, and stinging were generally low in all subgroups, with itching tending to decrease and burning/stinging tending to increase from baseline to week 12.

FIGURE 4. Mean percent change in noninflammatory lesion counts, by ethnicity (ITT population, pooled).

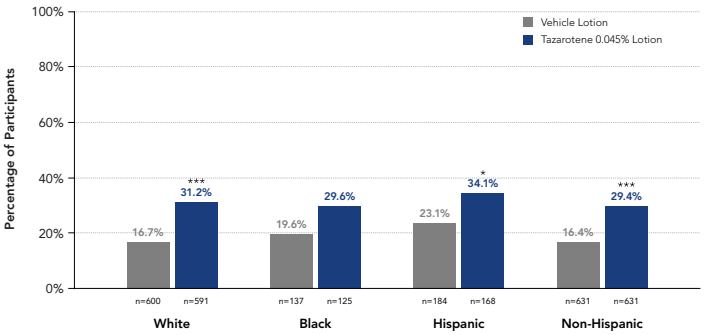


**$P<0.01$; ***$P<0.001$ versus vehicle.
ITT, intent to treat; LS, least squares.

This document contains proprietary information, images and marks of Journal of Drugs in Dermatology (JDD).
No reproduction or use of any portion of the contents of these materials may be made without the express written consent of JDD.
If you feel you have obtained this copy illegally, please contact JDD immediately at support@jddonline.com

To order reprints or e-prints of JDD articles please contact sales@jddonline.com

FIGURE 5. Percentage of participants with treatment success at week 12, by race and ethnicity (ITT population, pooled).



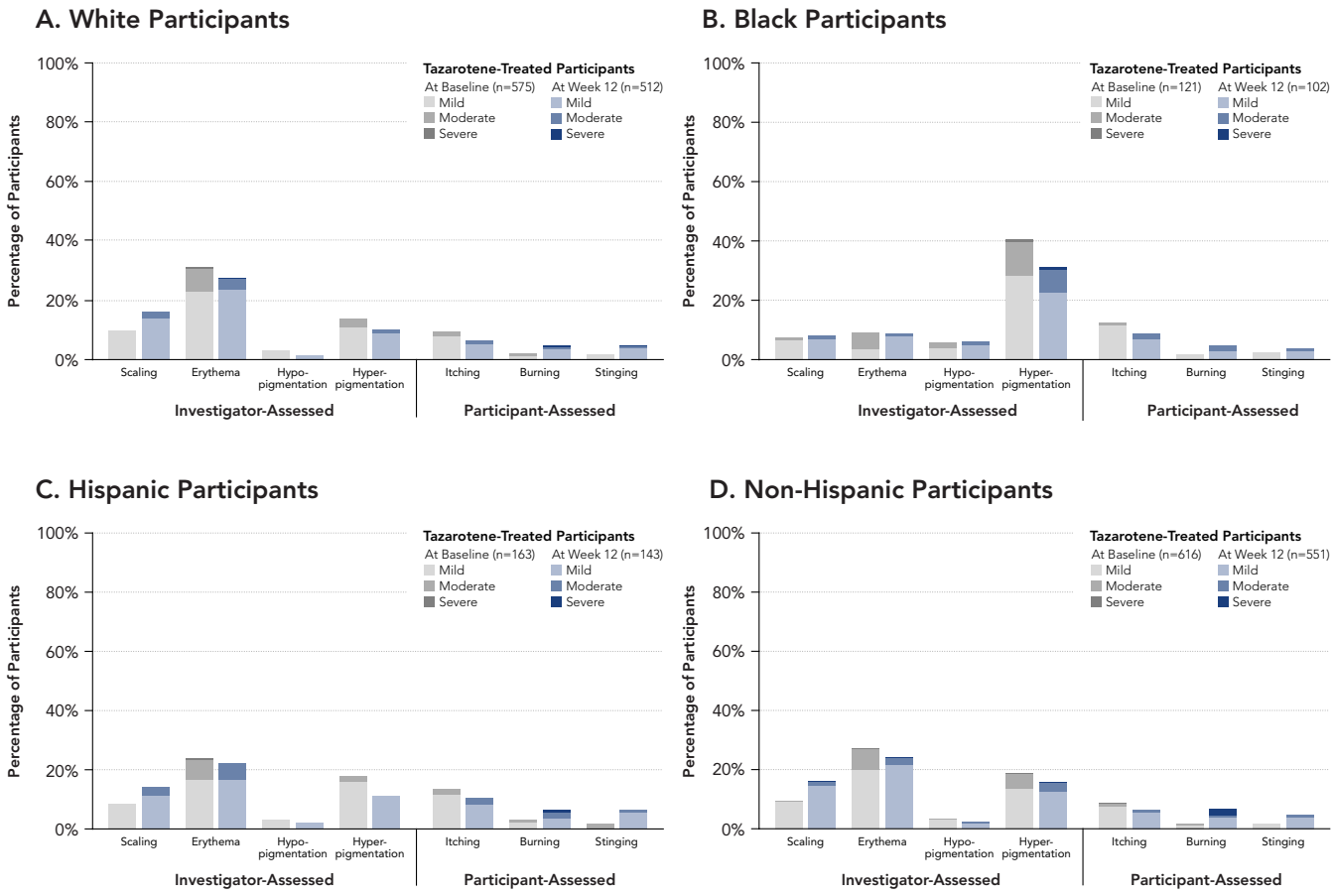
Treatment success = percentage of patients with at least a 2-grade reduction in EGSS relative to baseline and 'clear' or 'almost clear'.
*P<0.05 versus vehicle; ***P<0.001 versus vehicle.
EGSS, Evaluator's Global Severity Score; ITT, intent to treat.

DISCUSSION

This pooled, post hoc analysis of two phase 3 trials demonstrated that tazarotene 0.045% lotion applied once daily for 12 weeks improved acne symptoms and was well tolerated, regardless of race or ethnicity. Compared with vehicle lotion, treatment with tazarotene 0.045% lotion resulted in significant reductions in inflammatory and noninflammatory lesions and treatment success at week 12 in white, Hispanic, and non-Hispanic subpopulations. In black participants receiving tazarotene 0.045% lotion, there was a significant decrease in noninflammatory lesions compared with vehicle lotion. In all subpopulations, there were improvements in inflammation-associated sequelae of acne, including hyperpigmentation.

Clinical trials with topical retinoids have demonstrated efficacy for acne treatment in skin of color, but concerns remain on tolerability of some agents and formulations.[11,18,19] Our findings provide support for the use of tazarotene 0.045% lotion in the understudied setting of skin of color and concur with smaller

FIGURE 6. Cutaneous safety and tolerability assessments in tazarotene-treated participants, by race and ethnicity (safety population, pooled).



Data for "none" are not shown.

This document contains proprietary information, images and marks of Journal of Drugs in Dermatology (JDD).
No reproduction or use of any portion of the contents of these materials may be made without the express written consent of JDD.
If you feel you have obtained this copy illegally, please contact JDD immediately at support@jddonline.com

To order reprints or e-prints of JDD articles please contact sales@jddonline.com

TABLE 2.

Treatment-Emergent and Related Adverse Events Through Week 12 (Safety Population, Pooled)

Adverse Events, n (%)	White		Black		Hispanic		Non-Hispanic	
	TAZ 0.045% Lotion (n=575)	Vehicle Lotion (n=584)	TAZ 0.045% Lotion (n=121)	Vehicle Lotion (n=132)	TAZ 0.045% Lotion (n=163)	Vehicle Lotion (n=178)	TAZ 0.045% Lotion (n=616)	Vehicle Lotion (n=613)
Any TEAE	165 (28.7)	118 (20.2)	30 (24.8)	17 (12.9)	33 (20.2)	17 (9.6)	176 (28.6)	134 (21.9)
Any SAE[a]	3 (0.5)	3 (0.5)	1 (0.8)	1 (0.8)	0	0	4 (0.6)	4 (0.7)
Severity of TEAEs								
Mild	103 (17.9)	63 (10.8)	22 (18.2)	8 (6.1)	21 (12.9)	10 (5.6)	115 (18.7)	73 (11.9)
Moderate	54 (9.4)	53 (9.1)	7 (5.8)	7 (5.3)	11 (6.7)	7 (3.9)	52 (8.4)	57 (9.3)
Severe	8 (1.4)	2 (0.3)	1 (0.8)	2 (1.5)	1 (0.6)	0	9 (1.5)	4 (0.7)
Relationship to study drug								
Related	68 (11.8)	8 (1.4)	15 (12.4)	1 (0.8)	16 (9.8)	0	72 (11.7)	9 (1.5)
Unrelated	97 (16.9)	110 (18.8)	15 (12.4)	16 (12.1)	17 (10.4)	17 (9.6)	104 (16.9)	125 (20.4)
Most common TEAEs[b]								
Application site pain	30 (5.2)	2 (0.3)	8 (6.6)	0	10 (6.1)	0	31 (5.0)	2 (0.3)
Application site dryness	24 (4.2)	1 (0.2)	4 (3.3)	0	4 (2.5)	0	26 (4.2)	1 (0.2)
Application site exfoliation	8 (1.4)	0	6 (5.0)	0	4 (2.5)	0	12 (1.9)	0
Viral upper respiratory tract infection[a]	25 (4.3)	25 (4.3)	6 (5.0)	2 (1.5)	1 (0.6)	2 (1.1)	35 (5.7)	29 (4.7)

[a]No instances were considered by the investigator to be treatment related.
[b]Reported in ≥3% of participants in any treatment arm across all subgroups.
SAE, serious adverse event; TAZ, tazarotene; TEAE, treatment-emergent adverse event.

studies conducted exclusively in patients with darker skin tones. For example, in a separate study of less than 80 participants, tazarotene 0.1% cream improved facial PIH compared with baseline in participants with Fitzpatrick skin type III–VI.[20] This benefit of tazarotene 0.045% lotion is not a universal effect of topical retinoids. A clinical trial comparing adapalene 0.1%, adapalene 0.3%, and tretinoin 0.05% found that 90 days of treatment with adapalene 0.3% or tretinoin 0.05% was associated with lower counts of noninflammatory and inflammatory acne lesions.[11] However, study participants receiving either treatment reported higher rates of PIH and overall adverse events compared with participants in the adapalene 0.1% arm.[11]

Despite the large number of participants in our pooled analysis overall, the small proportion of participants who self-identified as black may have limited our findings. Our analyses found trends for improvement but no significant differences between tazarotene 0.045% lotion and vehicle lotion groups for two efficacy assessments: change in inflammatory lesion counts and treatment success by week 12. The lack of a statistical difference between tazarotene and vehicle lotion in the reduction of inflammatory lesions is likely due to the high response rate to vehicle in black participants (Figure 1B), whereas the statistical analysis of treatment success may have been limited in part by the small sample size. Although the proportions of black participants in these phase 3 trials were similar to other clinical trials in dermatology, having larger sample sizes could have increased the ability to confirm numerically small differences.[21] Furthermore, racial identification does not necessarily reflect skin color or all skin characteristics.[22] Additional trials of tazarotene 0.045% lotion and other acne treatments in skin of color from all backgrounds could prove useful in developing evidence-based guidelines for the diverse skin types affected by this condition.

The tolerability of tazarotene 0.045% lotion in all subgroups analyzed here was consistent with the overall population of the pooled analysis.[17] The majority of TEAEs were mild or moderate in severity, and approximately 11% of TEAEs were considered related to tazarotene 0.045% lotion. Further, the incidence of application-site irritation was ≤1.2% in each group. Cutaneous irritation is a well-established adverse event associated with topical retinoids, and has been reported in 2-18% of patients for tazarotene 0.1%, 2-5.6% for various adapalene formulations, and 3.8-23.6% for various tretinoin formulations.[23] While irritation can reduce treatment compliance in any patient population,[14] it can also induce PIH in patients with skin of color.[12] Cutaneous safety and tolerability ratings from the current analysis suggest that the lower-dose tazarotene 0.045% lotion formulation produced benefits in terms of inflammation-associated sequelae such as hyperpigmentation and erythema.

CONCLUSIONS

Tazarotene 0.045% lotion using novel polymeric emulsion technology demonstrated efficacy in this pooled analysis of two

This document contains proprietary information, images and marks of Journal of Drugs in Dermatology (JDD).
No reproduction or use of any portion of the contents of these materials may be made without the express written consent of JDD.
If you feel you have obtained this copy illegally, please contact JDD immediately at support@jddonline.com

To order reprints or e-prints of JDD articles please contact sales@jddonline.com

identical phase 3 trials, regardless of race and ethnicity, with fewer acne lesions and improved treatment success over a 12-week course of therapy. This new formulation of tazarotene had good tolerability compared with vehicle lotion as well as lower rates of irritation-related TEAEs compared with retinoid-based treatments. Tazarotene 0.045% lotion does not appear to induce post-inflammatory hyperpigmentation and may be an effective and well tolerated treatment option for patients with skin of color.

DISCLOSURES

Neal Bhatia has received honoraria and investigator grants from Bausch Health. Jonathan S. Weiss is a consultant, speaker, advisor, and/or researcher for Abbvie, Ortho Dermatologics/ Bausch Health US, Galderma, Foamix, Promius/Dr. Reddy's, LEO Pharma, Novartis, Sanofi/Regeneron, Aclaris, Endo International, Dermira, and Almirall. 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, and Cutanea. Stephen K. Tyring has acted as an investigator for Ortho Dermatologics. Eric Guenin is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company. Anya Loncaric and Susan Harris are employees of Bausch Health US, LLC and may hold stock and/or stock options in its parent company. Bausch Health US, LLC is an affiliate of Bausch Health Companies Inc. Ortho Dermatologics is a division of Bausch Health US, LLC.

ACKNOWLEDGMENTS

Medical writing and editorial support were provided by Prescott Medical Communications Group (Chicago, IL) with financial support from Ortho Dermatologics. Ortho Dermatologics is a division of Bausch Health US, LLC.

REFERENCES

1. Davis SA, Narahari S, Feldman SR, et al. Top dermatologic conditions in patients of color: an analysis of nationally representative data. *J Drugs Dermatol.* 2012;11(4):466-473.
2. Kundu RV, Patterson S. Dermatologic conditions in skin of color: part I. Special considerations for common skin disorders. *Am Fam Physician.* 2013;87(12):850-856.
3. Han G, Armstrong AW, Desai SR, Guenin E. Novel tretinoin 0.05% lotion for the once-daily treatment of moderate-to-severe acne vulgaris in an Asian population. *J Drugs Dermatol.* 2019;18(9):910-916.
4. Alexis AF, Cook-Bolden F, Lin T. Treatment of moderate-to-severe acne vulgaris in a hispanic population: a post-hoc analysis of the efficacy and tolerability of clindamycin 1.2%/benzoyl peroxide 3.75% gel. *J Clin Aesthet Dermatol.* 2017;10(6):36-43.
5. Rendon MI, Rodriguez DA, Kawata AK, et al. Acne treatment patterns, expectations, and satisfaction among adult females of different races/ethnicities. *Clin Cosmet Investig Dermatol.* 2015;8:231-238.
6. Lawson CN, Hollinger J, Sethi S, et al. Updates in the understanding and treatments of skin & hair disorders in women of color. *Int J Womens Dermatol.* 2017;3(1 Suppl):S21-S37.
7. Dreno B, Pecastaings S, Corvec S, et al. Cutibacterium acnes (Propionibacterium acnes) and acne vulgaris: a brief look at the latest updates. *J Eur Acad Dermatol Venereol.* 2018;32 Suppl 2:5-14.
8. Callender VD, Alexis AF, Daniels SR, et al. Racial differences in clinical characteristics, perceptions and behaviors, and psychosocial impact of adult female acne. *J Clin Aesthet Dermatol.* 2014;7(7):19-31.
9. Perkins AC, Cheng CE, Hillebrand GG, et al. Comparison of the epidemiology of acne vulgaris among caucasian, Asian, Continental Indian and African American women. *J Eur Acad Dermatol Venereol.* 2011;25(9):1054-1060.
10. Yin NC, McMichael AJ. Acne in patients with skin of color: practical management. *Am J Clin Dermatol.* 2014;15(1):7-16.
11. Tirado-Sanchez A, Espindola YS, Ponce-Olivera RM, Bonifaz A. Efficacy and safety of adapalene gel 0.1% and 0.3% and tretinoin gel 0.05% for acne vulgaris: results of a single-center, randomized, double-blinded, placebo-controlled clinical trial on Mexican patients (skin type III-IV). *J Cosmet Dermatol.* 2013;12(2):103-107.
12. Alexis AF. Acne vulgaris in skin of color: understanding nuances and optimizing treatment outcomes. *J Drugs Dermatol.* 2014;13(6):s61-65.
13. Leyden J, Stein-Gold L, Weiss J. Why topical retinoids are mainstay of therapy for acne. *Dermatol Ther (Heidelb).* 2017;7(3):293-304.
14. Hoffman LK, Bhatia N, Zeichner J, Kircik LH. Topical vehicle formulations in the treatment of acne. *J Drugs Dermatol.* 2018;17(6):s6-s10.
15. Tanghetti EA, Stein Gold L, Del Rosso JQ, et al. Optimized formulation for topical application of a fixed combination halobetasol/tazarotene lotion using polymeric emulsion technology. *J Dermatolog Treat.* 2019:1-8.
16. Tanghetti EA, Kircik LH, Green LJ, et al. A phase 2, multicenter, double-blind, randomized, vehicle-controlled clinical study to compare the safety and efficacy of a novel tazarotene 0.045% lotion and tazarotene 0.1% cream in the treatment of moderate-to-severe acne vulgaris. *J Drugs Dermatol.* 2019;18(6):542.
17. Tanghetti EA, Werschler WP, Lain T, et al. Tazarotene 0.045% lotion for once-daily treatment of moderate-to-severe acne vulgaris: results from two phase 3 trials. *J Drugs Dermatol.* 2020;19(1):70-77.
18. DuBois J, Ong GCW, Petkar G, et al. Patient-reported outcomes in acne patients with skin of color using adapalene 0.3%-benzoyl peroxide 2.5%: a prospective real-world study. *J Drugs Dermatol.* 2019;18(5):514.
19. Callender VD, Preston N, Osborn C, et al. A meta-analysis to investigate the relation between fitzpatrick skin types and tolerability of adapalene-benzoyl peroxide topical gel in subjects with mild or moderate acne. *J Clin Aesthet Dermatol.* 2010;3(8):15-19.
20. Grimes P, Callender V. Tazarotene cream for postinflammatory hyperpigmentation and acne vulgaris in darker skin: a double-blind, randomized, vehicle-controlled study. *Cutis.* 2006;77(1):45-50.
21. Charrow A, Xia FD, Joyce C, Mostaghimi A. Diversity in dermatology clinical trials: a systematic review. *JAMA Dermatol.* 2017;153(2):193-198.
22. He SY, McCulloch CE, Boscardin WJ, et al. Self-reported pigmentary phenotypes and race are significant but incomplete predictors of Fitzpatrick skin phototype in an ethnically diverse population. *J Am Acad Dermatol.* 2014;71(4):731-737.
23. Culp L, Moradi Tuchayi S, Alinia H, Feldman SR. Tolerability of topical retinoids: Are there clinically meaningful differences among topical retinoids? *J Cutan Med Surg.* 2015;19(6):530-538.

AUTHOR CORRESPONDENCE

Neal Bhatia MD
E-mail:..... dsbconsulting37@gmail.com

This document contains proprietary information, images and marks of Journal of Drugs in Dermatology (JDD).
No reproduction or use of any portion of the contents of these materials may be made without the express written consent of JDD.
If you feel you have obtained this copy illegally, please contact JDD immediately at support@jddonline.com