Efficacy, Safety, and Tolerability of a Halobetasol 0.01%/Tazarotene 0.045% Fixed Combination in the Treatment of Moderate-to-Severe Plaque Psoriasis in a Hispanic Population: Post Hoc Analysis of Two Phase 3 Randomized Controlled Trials

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SYNOPSIS

- Psoriasis is a chronic, immune-mediated disease that can have frequent exacerbations and remissions[1,2]
- Topical corticosteroids are the mainstay of psoriasis treatment[3]; however, safety concerns limit their use[4]
- Combination therapy may optimize efficacy while minimizing safety and tolerability concerns
- Few studies have examined the efficacy and safety of topical therapies for the treatment of psoriasis in Hispanic patients

OBJECTIVE

- To investigate the efficacy, safety, and tolerability following once-daily application of a fixed combination lotion containing halobetasol propionate 0.01% and tazarotene 0.045% (HP/TAZ; Duobrii™ Ortho Dermatologics, Bridgewater, NJ) in Hispanic patients with moderate-to-severe plaque psoriasis

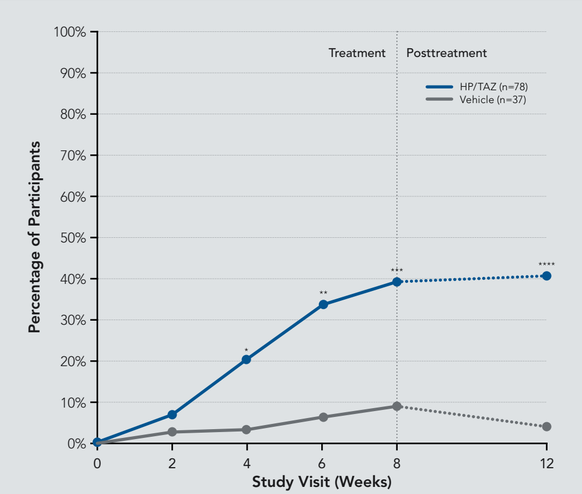
METHODS

- In two phase 3, multicenter, double-blind, vehicle-controlled studies (NCT02462070 and NCT02462122), participants were randomized (2:1) to receive HP/TAZ or vehicle once-daily for 8 weeks, with a 4-week posttreatment follow-up[5]
  - In these studies, CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (L'Oreal, NY) were provided as needed for optimal moisturization/cleaning of the skin
- Data from these two studies were pooled and analyzed post hoc in a subset of self-identified Hispanic participants
- Efficacy assessments included treatment success (≥2-grade improvement from baseline in the Investigator Global Assessment [IGA] score and a score of 'clear' or 'almost clear' [primary endpoint]), impact on individual signs of psoriasis (erythema, plaque elevation, and scaling) at the target lesion, Body Surface Area (BSA), and reduction from baseline in mean IGAxBSA
- Safety and treatment-emergent adverse events (TEAEs) were evaluated throughout the study

RESULTS

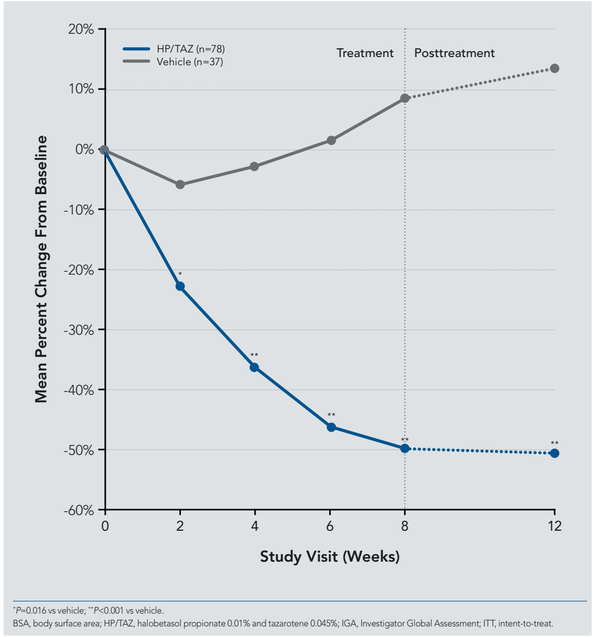
- A total of 115 Hispanic participants were included in this analysis
- By Week 8, 39.3% of participants achieved treatment success with HP/TAZ compared with 9.3% on vehicle (*P*=0.002); this effect was sustained posttreatment (**Figure 1**)
- HP/TAZ lotion was also significantly superior in reducing psoriasis signs; at Week 8, significantly more HP/TAZ-treated participants achieved ≥2-grade improvement in erythema (46.8%), plaque elevation (58.1%), and scaling (63.2%) compared with vehicle (12.7%, 11.2%, and 22.2%, respectively; *P*<0.001 all)
- Participants treated with HP/TAZ lotion achieved a 40.7% mean reduction from baseline in BSA at Week 8 versus a 10.1% increase with vehicle (*P*=0.002), and a 50.5% mean reduction in IGAxBSA score versus an 8.5% increase with vehicle (*P*<0.001); effects were sustained posttreatment (**Figure 2**)
- HP/TAZ lotion demonstrated rapid reduction in disease severity, with significant improvements versus placebo observed by Week 2 for IGAxBSA reduction and by Week 4 for treatment success

FIGURE 1. Percentage of Participants Achieving Treatment Success[a] by Study Visit (ITT Population; Pooled Data)



*P=0.034 vs vehicle; **P=0.003 vs vehicle; ***P=0.002 vs vehicle; ****P<0.001 vs vehicle.
[a]Treatment success was defined as ≥2-grade improvement from baseline in IGA score and a score of 'clear' or 'almost clear'.
HP/TAZ, halobetasol propionate 0.01% and tazarotene 0.045%; IGA, Investigator Global Assessment; ITT, intent-to-treat.

FIGURE 2. Mean Percent Change From Baseline in IGAxBSA by Study Visit (ITT Population; Pooled Data)



*P=0.016 vs vehicle; **P<0.001 vs vehicle.
BSA, body surface area; HP/TAZ, halobetasol propionate 0.01% and tazarotene 0.045%; IGA, Investigator Global Assessment; ITT, intent-to-treat.

- The most frequently reported treatment-related TEAEs were contact dermatitis (3.9%) and skin atrophy (3.9%; **Table 1**)
  - Four participants (5.3%) treated with HP/TAZ lotion discontinued due to TEAEs

TABLE 1. Summary of Treatment-Emergent Adverse Events Through Week 8 (Safety Population; Pooled Data)

n (%)	HP/TAZ Lotion (n=76)	Vehicle Lotion (n=36)
Participants reporting any TEAEs	26 (34.2)	8 (22.2)
Participants reporting any SAEs	1 (1.3)	0
Deaths	0	0
Participants discontinuing due to TEAEs	4 (5.3)	2 (5.6)
Severity of TEAEs		
Mild	11 (14.5)	4 (11.1)
Moderate	12 (15.8)	3 (8.3)
Severe	3 (3.9)	1 (2.8)
Relationship to study drug		
Related	14 (18.4)	3 (8.3)
Unrelated	12 (15.8)	5 (13.9)
Treatment-Related TEAEs reported in ≥2% of participants		
Contact dermatitis	3 (3.9)	0
Skin atrophy	3 (3.9)	0
Burning sensation	2 (2.6)	1 (2.8)
Pruritis	1 (1.3)	1 (2.8)
Psoriasis	0	1 (2.8)

HP/TAZ, halobetasol propionate 0.01% and tazarotene 0.045%; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

CONCLUSIONS

- HP/TAZ lotion was associated with significant, rapid, and sustained reductions in disease severity in a Hispanic population with moderate-to-severe psoriasis, with good tolerability and safety over 8 weeks of once-daily use

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