Efficacy and Safety of Halobetasol Propionate 0.01% Lotion in the Treatment of Moderate-to-Severe Plaque Psoriasis in a Hispanic Population: Post Hoc Analysis of Two Phase 3 Randomized Controlled Trials

Seemal R Desai, MD[1]; Brad Glick, DO, MPH[2]; James Q Del Rosso, DO[3]; Tina Lin, PharmD[4]

[1]Innovative Dermatology, PA, Plano, TX and The University of Texas Southwestern Medical Center, Dallas, TX; [2]GSI Clinical Research, Margate, FL; [3]JDR Dermatology Research/Thomas Dermatology, Las Vegas, NV; [4]Ortho Dermatologics*, Bridgewater, NJ

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SYNOPSIS

- Psoriasis is a chronic, immune-mediated disease that can have frequent exacerbations and remissions[1]
- Topical corticosteroids are the mainstay of psoriasis treatment, particularly for mild disease,[2] while systemic therapies may be useful in patients with severe disease; however, topical treatments are having an increasing role in moderate-to-severe psoriasis as an integral part of combination therapy
- A novel halobetasol propionate (HP) 0.01% lotion (Bryhali® Ortho Dermatologics, Bridgewater, NJ) has demonstrated efficacy versus vehicle in two phase 3 studies of patients with moderate-to-severe plaque psoriasis[3,4]
- Few studies have examined the efficacy and safety of topical therapies for the treatment of psoriasis in Hispanic patients

OBJECTIVE

- To evaluate the efficacy, safety, and tolerability following once-daily application of HP 0.01% lotion in Hispanic patients with moderate-to-severe plaque psoriasis

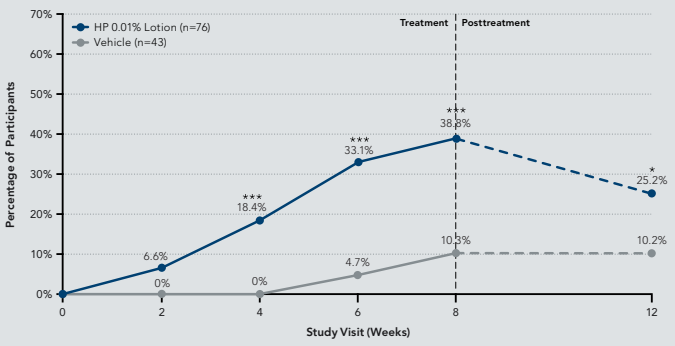
METHODS

- In two phase 3, multicenter, double-blind studies, patients were randomized 2:1 to receive HP 0.01% or vehicle lotion once-daily for 8 weeks, with a 4-week posttreatment follow-up[3,4]
  - At baseline, patients were required to have an Investigator Global Assessment (IGA) score of 3 or 4 (5-point scale; 0=clear and 4=severe) and affected Body Surface Area (BSA) of 3% to 12%
  - 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 were as follows:
  - Overall treatment success (≥2-grade improvement from baseline in IGA score and a score of 'clear' or 'almost clear' [primary endpoint])
  - Treatment success (≥2-grade improvement from baseline) in each individual sign of psoriasis (erythema, plaque elevation, and scaling) at the target lesion
  - Improvements from baseline in overall BSA
  - Reductions of ≥50% and ≥75% from baseline in IGAxBSA (IGAxBSA-50, IGAxBSA-75)
- Safety and treatment-emergent adverse events (TEAEs) were evaluated throughout the study

RESULTS

- This analysis included 119 Hispanic participants (HP 0.01% lotion, n=76; vehicle, n=43)
- At week 8, significantly more HP-treated participants achieved overall treatment success compared with vehicle-treated participants; this significant difference was achieved as early as week 4 and sustained posttreatment (**Figure 1**)

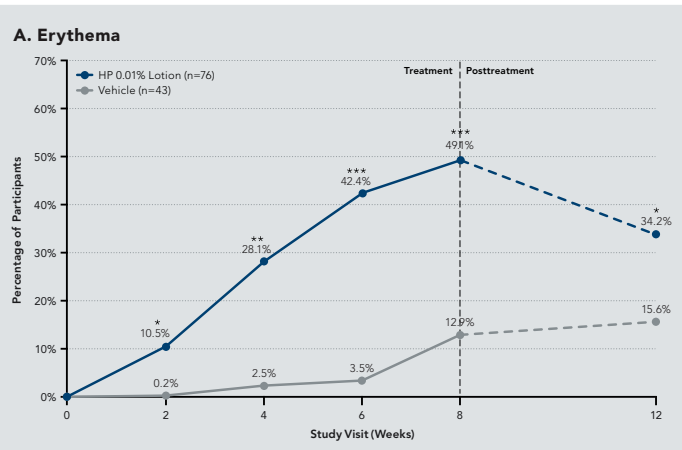
FIGURE 1. Overall Treatment Success[a] by Study Visit in Hispanic Participants (ITT Population, Pooled)

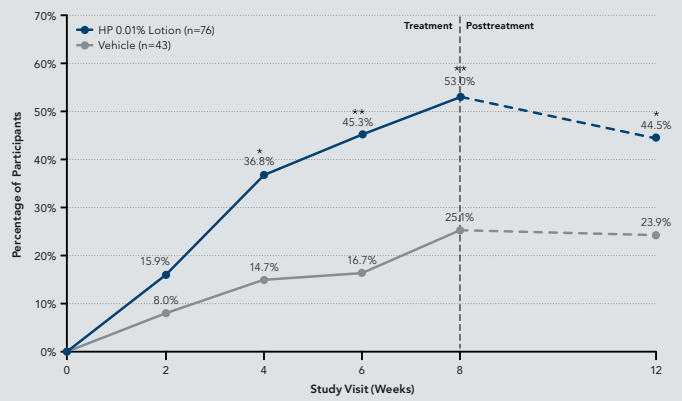


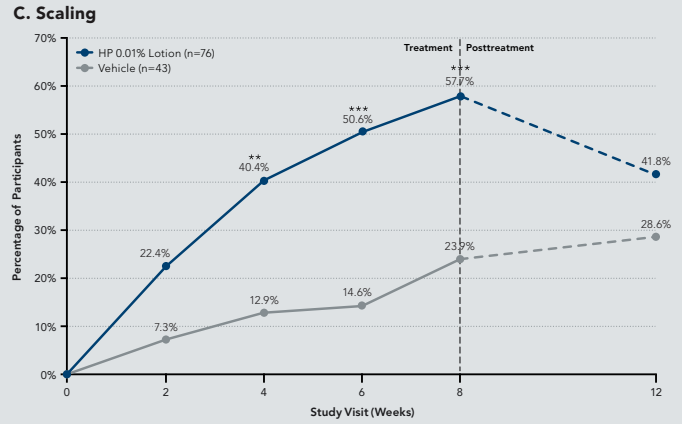
*P<0.05 vs vehicle; ***P≤0.001 vs vehicle.
[a]Treatment success was defined as a ≥2-grade improvement from baseline in IGA score and a score of 'clear' or 'almost clear' (0 or 1).
HP, halobetasol propionate; IGA, Investigator Global Assessment; ITT, intent-to-treat.

- Psoriasis signs were also reduced at week 8, with more HP-treated participants achieving ≥2-grade improvement in erythema, plaque elevation, and scaling at the target lesion compared with vehicle (**Figure 2**)
  - Significant differences versus vehicle were observed in all signs of psoriasis as early as week 4

FIGURE 2. Treatment Success[a] in Psoriasis Signs of Erythema (A), Plaque Elevation (B), and Scaling (C) at the Target Lesion by Study Visit in Hispanic Participants (ITT Population, Pooled)



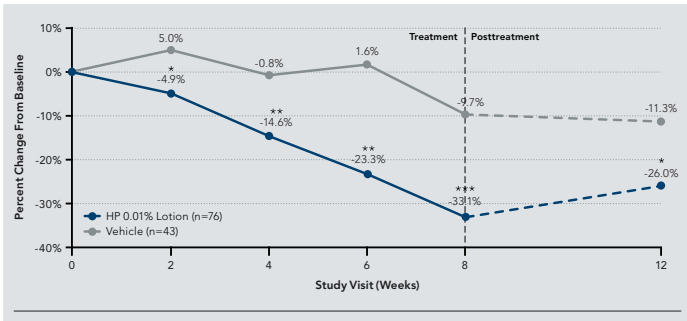




*P<0.05 vs vehicle; **P<0.01 vs vehicle; ***P<0.001 vs vehicle.
[a]Treatment success was defined as a ≥2-grade improvement from baseline in each individual sign of psoriasis at the target lesion.
HP, halobetasol propionate; ITT, intent-to-treat.

- Participants treated with HP 0.01% lotion achieved a significantly greater mean percent reduction from baseline in affected BSA at week 8 versus those treated with vehicle, with significant differences observed as early as week 2 (**Figure 3**)

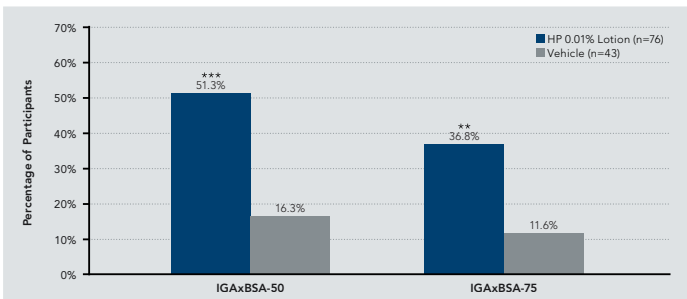
FIGURE 3. Mean Percent Reduction in Overall Affected Body Surface Area (BSA) by Study Visit in Hispanic Participants (ITT Population, Pooled)



*P<0.05 vs vehicle; **P≤0.01 vs vehicle; ***P≤0.001 vs vehicle.
HP, halobetasol propionate; ITT, intent-to-treat.

- At week 8, a clinically meaningful effect in overall psoriasis treatment was achieved by participants treated with HP 0.01% lotion versus those with vehicle (**Figure 4**)

FIGURE 4. Achievement of ≥50% (IGAxBSA-50) and ≥75% (IGAxBSA-75) Reduction in IGAxBSA at Week 8 in Hispanic Participants (ITT Population, Pooled)



**P<0.01 vs vehicle; ***P<0.001 vs vehicle.
BSA, Body Surface Area; HP, halobetasol propionate; IGA, Investigator Global Assessment; ITT, intent-to-treat.

- Treatment-related TEAEs with HP 0.01% lotion through week 8 were application site infection and application site dermatitis (n=1 each); the one treatment-related TEAE with vehicle was psoriasis

CONCLUSIONS

- Halobetasol propionate 0.01% lotion was associated with significant, rapid, and sustained reductions in disease severity in a Hispanic population with moderate-to-severe psoriasis, with few treatment-related TEAEs over 8 weeks of once-daily use

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AUTHOR DISCLOSURES:

Seemal R. Desai has served as a research investigator and/or consultant for Skinmedica, Ortho Dermatologics, Galderma, Pfizer, Dermavant, Almirall, Dermira, and Watson.
Brad Glick has served as investigator, advisor, and/or speaker for AbbVie, Celgene, Janssen, Sun Pharma, Lilly, Novartis, Dermira, Sanofi/Genzyme, Regeneron, Pfizer, Dermavant, ChemoCentryx, and Ortho Dermatologics; and is a stockholder in Top MD.
James Q Del Rosso has served as a consultant, investigator, and speaker for Ortho Dermatologics.
Tina Lin is an employee of Ortho Dermatologics and may hold and/or stock options in its parent company.

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