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, MD1; Brad Glick, DO, MPH2; James Q Del Rosso, DO3; Tina Lin, PharmD4

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

*Ortho Dermatologics is a division of Bausch Health US, LLC

SYNOPSIS
Psoriasis is a chronic, immune-mediated disease that can have frequent exacerbations and remissions.

Topical corticosteroids are the mainstay of psoriasis treatment, particularly for mild disease. 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.

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. At baseline, patients were required to have an Investigator Global Assessment (IGA) score of 3 or 4 (0-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%, 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 Successa by Study Visit in Hispanic Participants (ITT Population, Pooled)

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.

REFERENCES

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, Jansen, Sun Pharma, Lilly, Novartis, Dermira, Sanofi/Genzyme, Regeneron, Pfizer, Dermavant, ChemoCentryx, and Ortho Dermatologics, and is a stockholder in Top MD.
James Q Dell 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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