Efficacy and Safety of Halobetasol Propionate 0.01% Lotion in the Treatment of Females With Moderate-to-Severe Plaque Psoriasis: 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]
- Psoriasis can also negatively impact patients' lives, particularly in female patients who have reported higher levels of stigmatization, stress, unhappiness, and loneliness compared with males[2]
- Topical corticosteroids are the mainstay of psoriasis treatment, particularly for mild disease,[3] 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
- Recent phase 3 clinical data demonstrated the efficacy and tolerability of a fixed combination lotion containing halobetasol propionate (HP) 0.01% lotion (Bryhali® Ortho Dermatologics, Bridgewater, NJ) in patients with moderate-to-severe plaque psoriasis[4,5]

OBJECTIVE

- To evaluate the efficacy, safety, and tolerability of HP 0.01% lotion in female and male patients with moderate-to-severe plaque psoriasis

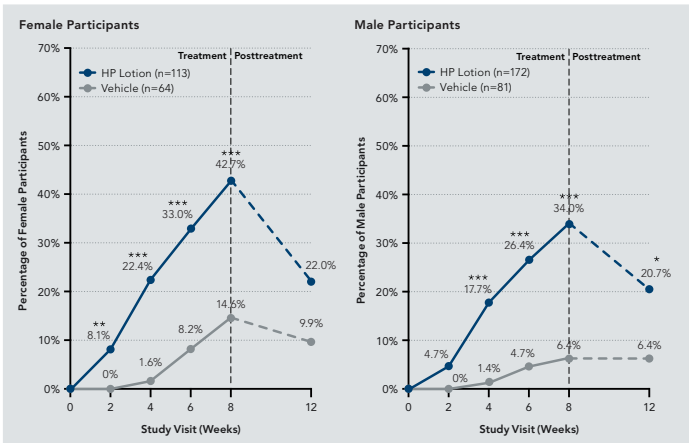
METHODS

- 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[4,5]
  - 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 female and male participants
- Efficacy assessments included treatment success (≥2-grade improvement from baseline in IGA score and score of 'clear' or 'almost clear' [primary endpoint]), impact on individual signs of psoriasis at the target lesion, and change in BSA affected
- Treatment-emergent adverse events (TEAEs) were evaluated

RESULTS

- This analysis included 177 female participants (HP lotion, n=113; vehicle, n=64) and 253 male participants (HP lotion, n=172; vehicle, n=81)
- By week 8, significantly more females and males achieved treatment success following treatment with HP 0.01% lotion versus vehicle; significant differences versus vehicle were observed as early as week 2 for females and week 4 for males (**Figure 1**)

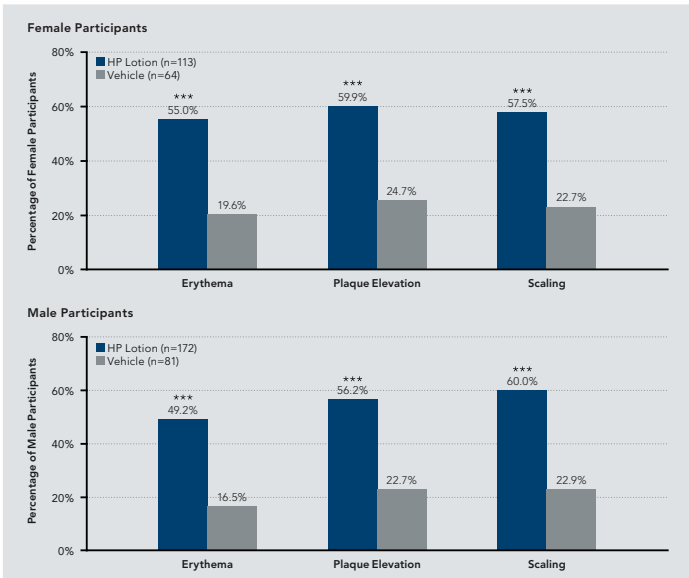
FIGURE 1. Overall Treatment Success[a] by Study Visit in Female and Male Participants (ITT Population, Pooled)



*P<0.05 vs vehicle; **P<0.01 vs vehicle; ***P<0.001 vs vehicle.
[a]Treatment success is 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 0.01%; IGA, Investigator Global Assessment; ITT, intent-to-treat.

- Psoriasis signs were also reduced by week 8, with more HP-treated females and males achieving ≥2-grade improvement in erythema, plaque elevation, and scaling compared with vehicle (**Figure 2**)

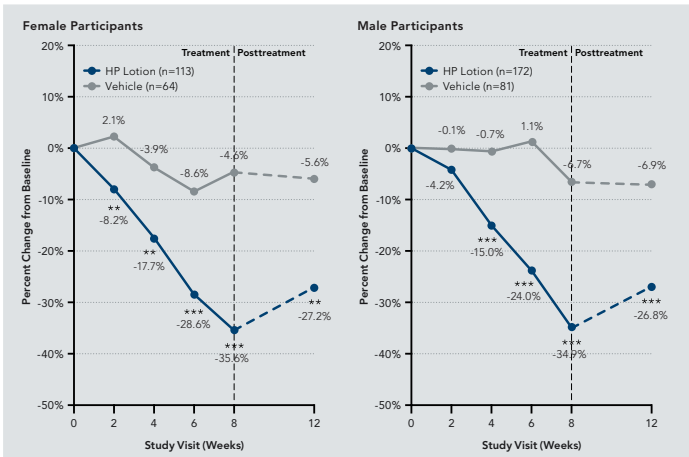
FIGURE 2. Treatment Success[a] in Psoriasis Signs at Week 8 in Female and Male Participants (ITT Population, Pooled)



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

- Females and males treated with HP lotion had a significantly greater reduction from baseline in affected BSA at week 8 versus vehicle, with significant differences observed as early as week 2 for females and week 4 for males; significant differences were sustained posttreatment for both females and males (**Figure 3**)

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



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

- All treatment-related TEAEs with HP lotion through week 8 were reported at the application site: discoloration (n=1 female), infection (n=1 male), dermatitis (n=2 males), and pruritus (n=1 male)

CONCLUSIONS

- Halobetasol propionate 0.01% lotion was associated with significant, rapid, and sustained reductions in disease severity in female as well as male patients with moderate-to-severe psoriasis, with good tolerability and safety over 8 weeks of once-daily use

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AUTHOR DISCLOSURES

Dr. Fran Cook-Bolden has served as a consultant, speaker, and/or investigator for Galderma, LEO Pharma, Almirall, Cassiopea, and Ortho Dermatologics, and investigator for Encore, Foamix, Hovione, Aclaris, and Cutanea. Dr. Jennifer Soung has received honoraria and/or research grants (speaker's bureau involvement, consultant, investigator, advisory board participant) for Celgene, Amgen, Eli Lilly, Abbvie, Pfizer, Allergan, Galderma, Actavis, Ortho Dermatologics, Actelion, Cassiopeia, GSK, National Psoriasis Foundation (non-profit), LEO, Boeringher Ingelheim, Novartis, Kadmon, Novan, Regeneron, Dr. Reddy, UCB, Janssen, Kyowa Kirin, Menlo, Dermira. Dr. Scott T Guenthner has served as a speaker for AbbVie, Pfizer, Allergan, Dermira, Aclaris, Encore Dermatology, Johnson and Johnson, and Janssen Pharmaceuticals. Drs. Brock Bumpass and Tina Lin are employees of Ortho Dermatologics and may hold stock and/or stock options in its parent company.

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