Efficacy and Safety of Halobetasol Propionate 0.01%/Tazarotene 0.045% (HP/TAZ) Lotion in the Treatment of Moderate to Severe Plaque Psoriasis of the Lower Extremities

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SYNOPSIS
- Psoriasis is a chronic, immune-mediated disease that varies wildly in its clinical expression.
- Although plaque psoriasis can occur across different body regions, the lower extremities are one of the most commonly affected areas.
- Topical corticosteroids are the mainstay of plaque treatment; however, safety concerns limit their use.
- Recent phase 3 clinical data demonstrated the efficacy and tolerability of a fixed combination lotion containing halobetasol propionate 0.01% and tazarotene 0.045% (HP/TAZ; Ortho Dermatologics, Bridgewater, NJ) in patients with moderate-to-severe localized plaque psoriasis.

OBJECTIVE
To evaluate the efficacy and safety of HP/TAZ lotion in participants where the leg was identified as the target lesion.

METHODS

In two phase 3, multicenter, randomized, double-blind studies (NCT03424207; NCT02462122), participants with moderate-to-severe plaque psoriasis were randomized 3:1 to receive HP/TAZ lotion or vehicle once daily for 8 weeks, with a 4-week posttreatment follow-up.

At baseline, participants were required to have an Investigator Global Assessment (IGA) score of moderate (3) or severe (4) and Body Surface Area (BSA) of 3% to 12%.

In these studies, Cremophor EL (polyoxyl 40 castor oil) with Clobetasol (Ovend, NY) were provided as needed for optimal moisturization/cleansing of the skin.

A post hoc analysis was conducted in a subset of participants with plaque psoriasis of the lower extremities, with a target lesion of the leg.

For the primary analysis, participants provided a score of ≥3 (or at least 2 of 3 signs of psoriasis: erythema, plaque elevation, scaling: each on a 5-point scale; 0=clear and 4=severe), a sum of at least 8, and could not have scores >1 for any one of the signs.

The target could not be on an area covering bony prominences (3, 4, 9, knee); however, overall plaque psoriasis assessment (IGA and BSA) did not exclude the knees.

Efficacy assessments included: treatment success (≥2-grade improvement from baseline) in each individual sign of psoriasis at the target lesion; overall treatment success (≥2-grade improvement from baseline in IGA score and a score of ‘clear’ on at least one of the signs).

Safety assessments included: treatment-emergent adverse events (TEAEs) were evaluated throughout the study.

RESULTS

Participants
This analysis included 217 participants where the leg was identified as the target lesion (HP/TAZ, n=148; vehicle, n=70).

Efficacy
At the end of the 8-week treatment period, significantly more HP/TAZ-treated participants achieved treatment success in each individual sign of psoriasis (erythema, plaque elevation, and scaling) compared with vehicle-treated participants.

Significantly more participants achieved overall treatment success (per IGA scores) at week 8 with HP/TAZ compared with vehicle (Figure 2).

The HP/TAZ group also had a significantly greater mean percent reduction in BSA at week 8 versus vehicle (Figure 3).

Change from baseline in IGAxBSA composite score was significantly improved with HP/TAZ lotion versus vehicle at all study visits assessed (Figure 4).

Changes from baseline in IGAxBSA composite score were significantly increased with HP/TAZ lotion versus vehicle at all study visits assessed (Figure 4).

Safety
- The most frequently reported treatment-related TEAEs were contact dermatitis, skin pruritus, facial edema, and exacerbation; 11 participants treated with HP/TAZ lotion discontinued due to TEAEs (Table 1).

CONCLUSIONS
- Treatment with HP/TAZ lotion was associated with significant, rapid, and sustained reductions in disease severity in patients with moderate-to-severe plaque psoriasis where the leg was identified as the target lesion, with good tolerability and safety over 8 weeks of once-daily use.

REFERENCES


AUTHOR DISCLOSURES
- Stephen K. Tyring: SNC, Takeda, Amgen, AbbVie, Lilly, Sun Pharma, Ortho Dermatologics
- Leon H. Kircik: Ortho Dermatologics, Amgen, Lilly, Takeda, Sun Pharma
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