Fixed-Combination Halobetasol Propionate 0.01% and Tazarotene 0.045% Lotion and Halobetasol Propionate 0.01% Lotion for Plaque Psoriasis on Areas With Body Hair: Maintenance of Treatment Effect

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OBJECTIVE

- To report remittance of disease following treatment cessation of fixed-combination halobetasol propionate (0.01%) and tazarotene (0.045%) lotion (HP/TAZ) versus HP 0.01% lotion in men with plaque psoriasis on the leg (a representative population with body hair)

CONCLUSIONS

- Following treatment cessation, HP/TAZ was associated with increased rates of treatment and erythema success in men with plaque psoriasis on the leg, whereas HP was associated with decreased rates
- Participants receiving HP/TAZ maintained plaque elevation and scaling success following treatment cessation, whereas rates declined with HP
- These findings suggest tazarotene combined with HP provides remittance of disease in hair-bearing areas
- Although use of HP/TAZ was limited to 8 weeks in this study, its duration of use is not limited by its prescribing information; therefore, efficacy outcomes of HP/TAZ may have been hindered by the study design

SYNOPSIS

- Using topical corticosteroids for psoriasis on hair-bearing body areas may be challenging because hair may reduce penetration of active ingredients and disease rebound often occurs following treatment cessation[1-3]
- An appropriate vehicle for hair-bearing areas may increase penetration, and a combination of corticosteroid and tazarotene may improve remittance of disease following cessation[4-7]
- HP/TAZ and HP 0.01% lotion are indicated for the topical treatment of plaque psoriasis in adults and contain a vehicle optimized for dermal penetration[6-9]
- Previously, a post hoc analysis of phase 3 trials demonstrated the efficacy and safety of HP/TAZ and HP in treating men with plaque psoriasis on the leg, a representative area with body hair[10]
  - The analysis presented here expands on the prior analysis by examining remittance of disease following treatment cessation in this population

METHODS

- In phase 3 trials, participants with moderate-to-severe plaque psoriasis were randomized to treatment or vehicle once daily for 8 weeks (HP/TAZ, n=276; vehicle, n=142; HP, n=285; vehicle, n=145)[11,12]
  - This 8-week treatment period aligns with the duration of use recommended in the prescribing information for HP, whereas the HP/TAZ prescribing information does not limit duration of use; for both therapies, discontinuation is recommended after disease control is achieved[8,9]
- Participants were assessed at 2-week intervals and at 4 weeks after treatment cessation (week 12)[11,12]
- Participants included in this post hoc analysis were men with a target lesion on the leg (a representative population with body hair)
  - Men were assumed to have leg hair
- Endpoints included treatment success (≥2-grade improvement in investigator's global assessment [IGA] score from baseline and a score of clear or almost clear); erythema, plaque elevation, and scaling success (≥2-grade improvement from baseline for each); remittance of disease; and safety
  - Remittance of disease was defined as the proportion of participants who achieved treatment, erythema, plaque elevation, or scaling success at week 8 (end of treatment period) and maintained success at week 12 (4-week follow-up)
  - Because HP/TAZ and HP were evaluated in separate trials, treatment comparisons were indirect

RESULTS

Subgroup demographics

- Of participants in phase 3 trials, 87 receiving HP/TAZ and 91 receiving HP were men with target lesions on the leg
  - Average scores of baseline disease assessments were similar between participants receiving HP/TAZ and HP (Table)

Table. Baseline Disease Assessments

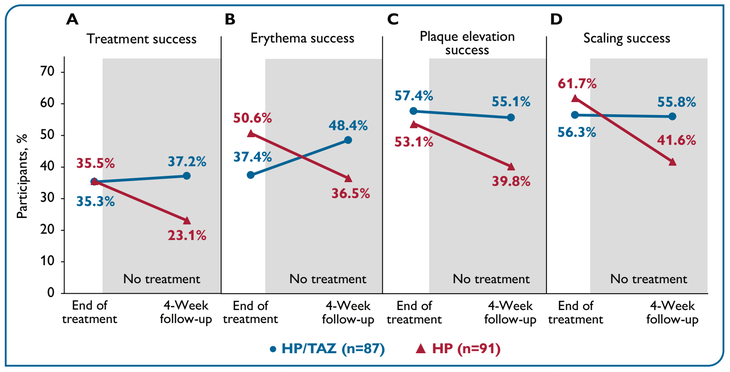
	Men with target lesions on the leg	
Parameter	**HP/TAZ (n=87)**	**HP (n=91)**
Mean IGA score	3.2	3.2
Mean erythema score	3.0	3.0
Mean plaque elevation score	3.0	3.0
Mean scaling score	3.0	3.2

IGA, erythema, plaque elevation, and scaling are graded on a 5-point scale (0=clear/none, 4=severe). HP, halobetasol propionate 0.01%; HP/TAZ, HP (0.01%) and tazarotene (0.045%) lotion; IGA, investigator's global assessment.

Efficacy outcomes

- HP/TAZ–treated participants exhibited increased rates of treatment and erythema success following treatment cessation (Figure 1A, B)
  - Treatment success: end of treatment, 35.3%; 4-week follow-up, 37.2%
  - Erythema success: end of treatment, 37.4%; 4-week follow-up, 48.4%
- Conversely, HP-treated participants exhibited decreased rates of treatment and erythema success following treatment cessation (Figure 1A, B)
  - Treatment success: end of treatment, 35.5%; 4-week follow-up, 23.1%
  - Erythema success: end of treatment, 50.6%; 4-week follow-up, 36.5%
- HP/TAZ–treated participants largely maintained rates of plaque elevation and scaling success following treatment cessation (Figure 1C, D)
  - Plaque elevation success: end of treatment, 57.4%; 4-week follow-up, 55.1%
  - Scaling success: end of treatment, 56.3%; 4-week follow-up, 55.8%
- Conversely, HP-treated participants experienced decreased rates of plaque elevation and scaling success following treatment cessation (Figure 1C, D)
  - Plaque elevation success: end of treatment, 53.1%; 4-week follow-up, 39.8%
  - Scaling success: end of treatment, 61.7%; 4-week follow-up, 41.6%

Figure 1. Participants achieving treatment, erythema, plaque elevation, and scaling success at end of treatment period (week 8) through the 4-week follow-up (week 12).

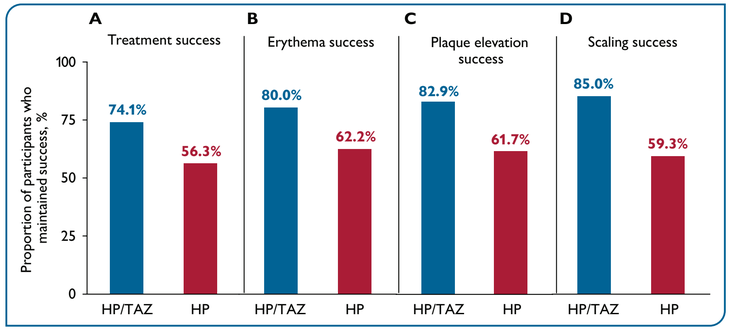


Treatment success was defined as ≥2-grade improvement in IGA score from baseline and a score of clear or almost clear. Erythema, plaque elevation, and scaling success were defined as ≥2-grade improvement from baseline for each. Gray shading denotes treatment cessation. HP, halobetasol propionate 0.01%; HP/TAZ, HP (0.01%) and tazarotene (0.045%) lotion; IGA, investigator's global assessment.

Remittance of disease

- For all outcomes, a greater proportion of participants receiving HP/TAZ versus HP achieved remittance of disease (ie, achieved success at end of treatment and maintained success status at the 4-week follow-up; Figure 2A-D)
  - HP/TAZ remittance of disease rates: range, 74.1%-85.0%
  - HP remittance of disease rates: range, 56.3%-62.2%

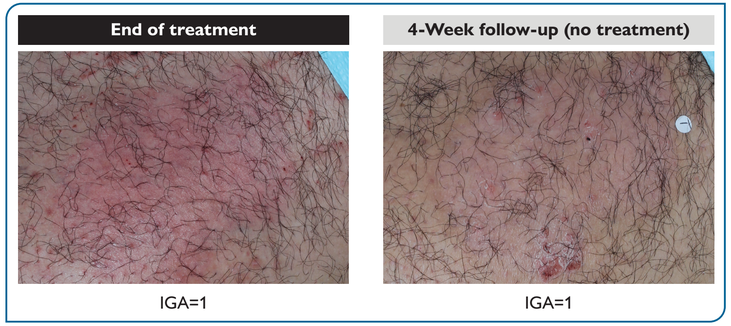
Figure 2. Proportion of participants who achieved treatment, erythema, plaque elevation, or scaling success at week 8 and maintained success status at week 12.



Treatment success was defined as ≥2-grade improvement in IGA score from baseline and a score of clear or almost clear. Erythema, plaque elevation, and scaling success were defined as ≥2-grade improvement from baseline for each. HP, halobetasol propionate 0.01%; HP/TAZ, HP (0.01%) and tazarotene (0.045%) lotion; IGA, investigator's global assessment.

- Figure 3 shows a representative target lesion treated with HP/TAZ and demonstrates remittance of disease observed in this analysis
  - This participant achieved IGA 1 (almost clear) at the end of the 8-week treatment period and maintained IGA 1 at the 4-week follow-up

Figure 3. Remittance of disease in a representative HP/TAZ–treated plaque in a male participant with psoriasis on the leg (ie, a region with body hair).



Participant consent was obtained for use of all photographs. HP/TAZ, halobetasol propionate (0.01%) and tazarotene (0.045%) lotion; IGA, investigator's global assessment.

Safety

- Through 8 weeks of treatment, 42 and 19 treatment-emergent adverse events (TEAE) were reported by participants receiving HP/TAZ and HP, respectively
- Contact dermatitis (n=11; 12.9%) was the most reported TEAE for HP/TAZ–treated participants; nasopharyngitis (n=3; 3.3%) was the most reported TEAE for HP-treated participants
- No new safety signals were reported

Disclosures: GH is or has been an investigator for Athenex, BMS, Boehringer Ingelheim, Bond Avillion, Celgene, Eli Lilly, Janssen, MC2, Novartis, PellePharm, Pfizer, and UCB; and a consultant, advisor, or speaker for AbbVie, Boehringer Ingelheim, Dermtech, Eli Lilly, Incyte, Janssen, LEO, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharmaceutical, and UCB. **EL** has served as an investigator, speaker, consultant, or advisory board member for AbbVie, Aclaris Therapeutics, AlfaSigma, Allergan, Almirall, Arcutis Biotherapeutics, AstraZeneca, Athenix, Biofrontera, Biopelle, BioPharmX, Biorasi, Brickell Biotech, Bristol-Myers Squibb, Cassiopea S.p.A, Castle Biosciences, Celgene, Cellceutix, ChemoCentryx, Concert Pharma, Cutanea, Dermavant Sciences, Dermira, Dermtech, Dow, Dr. Reddy's Laboratories, Eli Lilly, Endo Pharma, EPI Health, Evelo, Gage Development Company, Galderma Laboratories, Galderma, Hovione, Incyte, Janssen, Johnson & Johnson, Kadmon Corporation, La Roche-Posay, LEO Pharma, MedImmune, Menlo Therapeutics, Mindera, Moleculin, Neothetics, Nielsen Holdings N.V., Novartis, Ortho Dermatologics (a division of Bausch Health Companies Inc), Pierre Fabre, Pfizer, Promius Pharma, Sanofi, Sebacia, Sienna Labs, SkinCeuticals, Sol-Gel Technologies, Sun Pharmaceutical, Symatese, Timber Pharma, UCB, Valeant Pharmaceuticals North America, and Vyne Therapeutics. **LSG** has served as an investigator, advisor, and/or speaker for Almirall, Galderma, Novartis, Ortho Dermatologics (a division of Bausch Health Companies Inc), Sol-Gel Technologies, Sun Pharmaceutical Industries, and Vyne Therapeutics. **AJ** is an employee of Bausch Health Companies Inc.

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