Safety and Efficacy of a Fixed Combination Halobetasol Propionate 0.01%/Tazarotene 0.045% (HP/TAZ) Lotion in the Treatment of Females With Moderate-to-Severe Plaque Psoriasis

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SYNOPSIS

- Psoriasis is a chronic, immune-mediated disease that can have frequent exacerbations and remissions[1]
- Disease characteristics and optimal treatment strategies for psoriasis may differ between males and females[2]
- Females may have an increased burden of disease compared with males, as they have been shown to have higher levels of stress, stigmatization, and loneliness due to psoriasis[3]
- 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; Duobrii® Ortho Dermatologics, Bridgewater, NJ) in patients with moderate-to-severe localized plaque psoriasis[4,5]

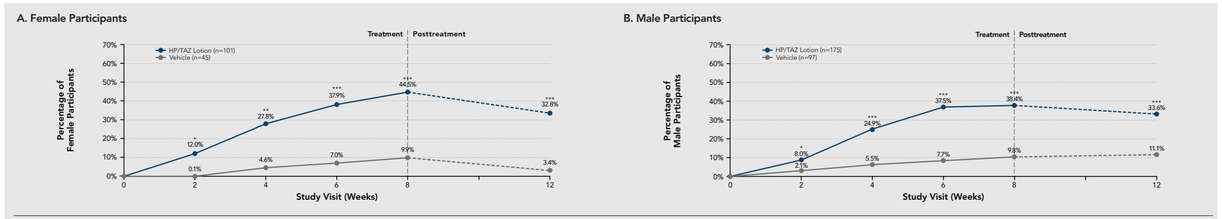
OBJECTIVE

- To evaluate efficacy and safety of HP/TAZ lotion in female and male patients with moderate-to-severe plaque psoriasis

METHODS

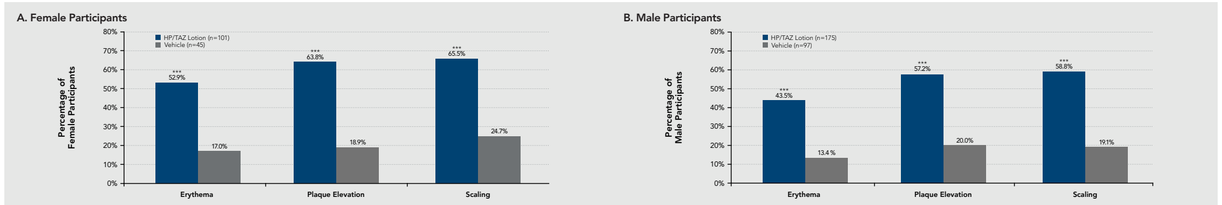
- In two phase 3, multicenter, double-blind studies, participants were randomized (2:1) to receive HP/TAZ or vehicle lotion once-daily for 8 weeks, with a 4-week posttreatment follow-up[4,5]
  - At baseline, patients were required to have an Investigator Global Assessment (IGA) score of 3 or 4 (5-point 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 the 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

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



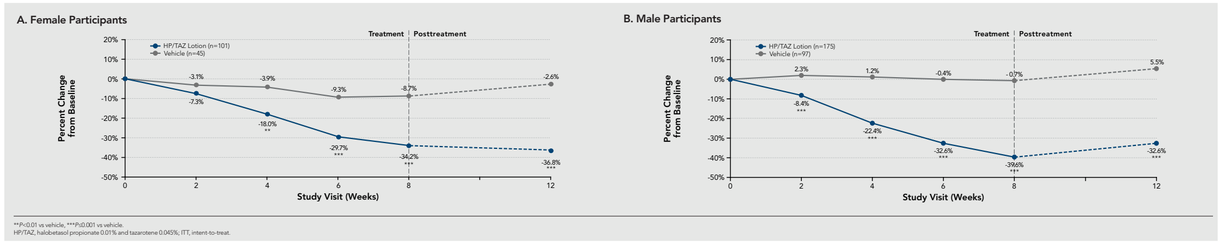
*P<0.05 vs vehicle, **P<0.01 vs vehicle, ***P<0.001 vs vehicle.
[a]Treatment success is defined as a ≥2-grade improvement from baseline in IGA score and a score of 'clear' or 'almost clear' (0 or 1)
HP/TAZ, halobetasol propionate 0.01% and tazarotene 0.045%; IGA, Investigator Global Assessment; ITT, intent-to-treat.

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/TAZ, halobetasol propionate 0.01% and tazarotene 0.045%; ITT, intent-to-treat.

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/TAZ, halobetasol propionate 0.01% and tazarotene 0.045%; ITT, intent-to-treat.

RESULTS

- The analysis population included 146 female participants (HP/TAZ lotion, n=101; vehicle, n=45) and 272 male participants (HP/TAZ lotion, n=175; vehicle, n=97)

Efficacy

- At week 8, the percentage of female and male participants with treatment success was significantly greater in the HP/TAZ group than the vehicle group; significant differences were observed by week 2 and maintained posttreatment (**Figure 1**)
- Significantly more HP/TAZ-treated female and male participants achieved a ≥2-grade improvement in erythema, plaque elevation, and scaling at week 8 compared with the vehicle group (**Figure 2**)
- Females and males treated with HP/TAZ lotion had a significantly greater reduction from baseline in affected BSA at week 8 versus the vehicle group, with significant differences observed as early as week 4 for females and week 2 for males; significant differences were sustained posttreatment for both females and males (**Figure 3**)

Safety

- The most frequently reported treatment-related TEAEs in the female HP/TAZ group were contact dermatitis, pruritis, and application site pain (all 4.0%); pruritis was the most common TEAE deemed related to vehicle treatment (7.0%)
- For males in the HP/TAZ group, the most frequently reported treatment-related TEAE was contact dermatitis (7.6%); in the vehicle group, no TEAEs deemed related to treatment occurred in >1 male

CONCLUSIONS

- Halobetasol propionate 0.01% and tazarotene 0.045% lotion was associated with significant 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

REFERENCES

1. Nestle FO, et al. *N Engl J Med*. 2009;361(5):496-509.
2. Hotard RS, et al. *J Am Acad Dermatol*. 2000;42(4):620-623.
3. Gottlieb AB, et al. *Int J Womens Dermatol*. 2019;5(3):141-150.
4. Stein Gold L, et al. *J Am Acad Dermatol*. 2018;79(2):287-293.
5. Sugarman JL, et al. *J Drugs Dermatol*. 2018;17(8):855-861.

AUTHOR DISCLOSURES

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