Long-Term Management of Moderate-to-Severe Plaque Psoriasis: Maintenance of Treatment Success Following Cessation of Fixed Combination Halobetasol Propionate 0.01% and Tazarotene 0.045% (HP/TAZ) Lotion in Patients with Baseline Body Surface Area of 6-12%

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SYNOPSIS

- Psoriasis is a chronic, immune-mediated disease that can have exacerbations and remissions[1]
- Topical therapy is the mainstay of treatment for patients with localized psoriasis[2]; however, long-term continuous use of topical corticosteroids is not recommended due to the potential for local adverse events[1]
- Though applying topicals to large areas in more severe disease may not be practical for patients with very high affected body surface area (BSA), there is limited data on the efficacy of topical treatments in more localized severe plaque psoriasis
- Data from phase 3 clinical trials have shown 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) over 8 weeks in participants with localized moderate-to-severe plaque psoriasis[3,4]

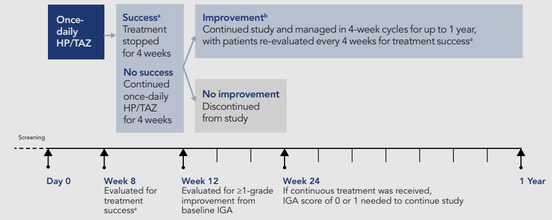
OBJECTIVE

- To investigate long-term maintenance of treatment effect following cessation of once-daily HP/TAZ lotion in a subgroup of participants with higher levels of affected BSA (6–12%)

METHODS

- This was a 1-year multicenter, open-label study (NCT02462083) in participants aged ≥18 years with moderate-to-severe plaque psoriasis
  - Investigator's Global Assessment (IGA) score of 3 or 4 and an affected BSA of 3–12% were required for study enrollment
  - In this study, CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (L'Oreal, NY) were provided as needed for optimal moisturization/cleaning of the skin
- Participants were treated with HP/TAZ lotion once-daily for 8 weeks and intermittently in 4-week intervals for a maximum continuous exposure of 24 weeks (**Figure 1**)
  - At week 8, participants who achieved treatment success stopped treatment; those who did not achieve treatment success were treated for 4 additional weeks
  - All participants were re-evaluated at week 12; those demonstrating ≥1-grade improvement in baseline IGA continued the study and were subsequently managed in 4-week cycles
    - If they had not achieved treatment success, they were treated once daily with HP/TAZ lotion
    - If they had achieved treatment success, they received no treatment until the next evaluation
- A post hoc analysis was conducted to investigate maintenance of effect with HP/TAZ lotion in a subgroup of participants with higher baseline BSA (6–12%); results from the overall study population (BSA 3–12%) were included for comparison

FIGURE 1. Open-Label Study Design

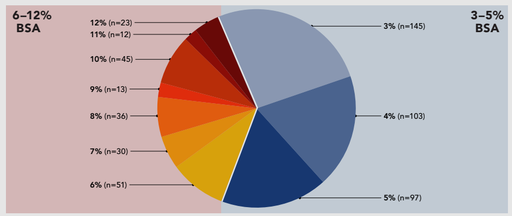


Maximum continuous exposure was 24 weeks.
[a]Treatment success defined as score of 0 or 1 on IGA (clear or almost clear).
[b]Improvement defined as ≥1-grade improvement from baseline IGA.
HP/TAZ, halobetasol propionate 0.01%/tazarotene 0.045%; IGA, Investigator's Global Assessment.

RESULTS

- A total of 555 participants were included in the study, of which 210 (37.8%) had baseline BSA levels of 6–12% (**Figure 2**)

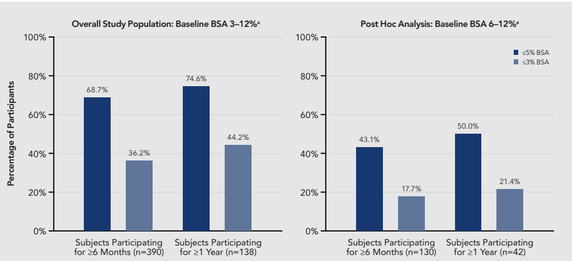
FIGURE 2. Baseline BSA in Participants Treated with HP/TAZ (N=555)



BSA, body surface area; HP/TAZ, halobetasol propionate 0.01%/tazarotene 0.045%.

- At week 8, BSA ≤5% was achieved by 79% of the overall study population (baseline BSA 3–12%) and 50% of participants with baseline BSA 6–12%
- This reduction in BSA was maintained in those who participated in the study for at least 1 year (**Figure 3**)

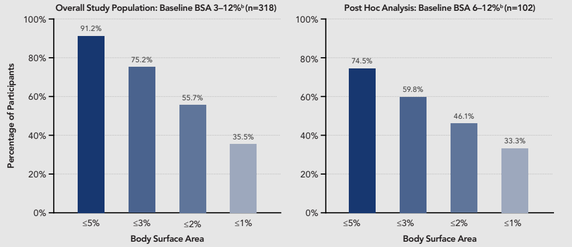
FIGURE 3. Maintenance of ≤5% or ≤3% Affected BSA From Week 8 to End of Study (Safety Population)



[a]Only BSA records considered as occurring on treatment were used in assessing if the percent BSA was maintained.
BSA, body surface area; HP/TAZ, halobetasol propionate 0.01%/tazarotene 0.045%.

- Of the participants who achieved treatment success during the study (IGA score of clear or almost clear), approximately one-third had BSA ≤1% at treatment success, regardless of BSA severity at baseline (**Figure 4**)

FIGURE 4. Body Surface Area at Treatment Success[a] (Safety Population)



[a]Treatment success defined as score of 0 or 1 on IGA (clear or almost clear).
[b]BSA assessments at the Treatment Success visit were included. All BSA assessments included regardless of whether they were on treatment or not.
BSA, body surface area; HP/TAZ, halobetasol propionate 0.01%/tazarotene 0.045%; IGA, Investigator's Global Assessment.

- In those participants who stopped HP/TAZ therapy after achieving treatment success, maintenance of therapeutic benefit is demonstrated by the extended time to retreatment (**Table 1**)

TABLE 1. Time to Retreatment With HP/TAZ Lotion (Safety Population)

Percentage of participants	Overall Study Population: Baseline BSA 3–12% (n=226[a])	Post Hoc Analysis: Baseline BSA 6–12% (n=70[a])
No retreatment (did not relapse)	6.6%	5.7%
No retreatment for ≥85 days	19.5%	12.9%
No retreatment for ≥57 days	28.3%	21.4%
No retreatment for ≥29 days	55.3%	44.3%

[a]Participants still enrolled post 8 weeks in the study and who stopped therapy after achieving treatment success (defined as a score of 0 or 1 on IGA).
BSA, body surface area; HP/TAZ, halobetasol propionate 0.01%/tazarotene 0.045%; IGA, Investigator's Global Assessment.

CONLUSIONS

- In participants with moderate-to-severe psoriasis and a baseline BSA of 6–12%, HP 0.01%/TAZ 0.045% lotion provided rapid and sustained treatment success, with nearly 45% of participants followed for 1 year not requiring retreatment for ≥1 month

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AUTHOR DISCLOSURES

Linda Stein Gold has served as investigator/consultant or speaker for Ortho Dermatologics, LEO, Dermavant, Incyte, Novartis, AbbVie, and Lilly. Jonathan S Weiss is a consultant, speaker, advisor, and/or researcher for Abbvie, Ortho Dermatologics, Jansen Biotech, Dermira, Almirall, Brickell Biotech, DermTech, Scynexis. Lawrence Green has served as consultant, speaker, and/or investigator for Arcutis, Abbvie, Amgen, Celgene, Dermavant, Jannsen, Lilly, MC2, Novartis, OrthoDerm, Sienna, SunPharma, UCB. Leon Kircik has acted as an investigator, advisor, speaker, and consultant for Ortho Dermatologics. Lauren Miller is speaker for Lilly, Novartis, Amgen, and Pfizer. Abby Jacobson is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company. Susan Harris is an employee of Bausch Health US, LLC and may hold stock and/or stock options in its parent company.

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