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

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SYNOPSIS

- Psoriasis is an immune-mediated disease that is often chronic with frequent remissions and exacerbations[1,2]
- Topical corticosteroids are the mainstay of treatment, though long-term safety remains a concern, limiting use[3,4]
- Adherence to topical therapy by patients with psoriasis is also generally poor, but may improve with simple regimens and once-daily therapy[5,6]
- A topical treatment for psoriasis that provides maintenance of efficacy after stopping treatment may be beneficial for patients, though data on maintenance of efficacy posttreatment are sparse

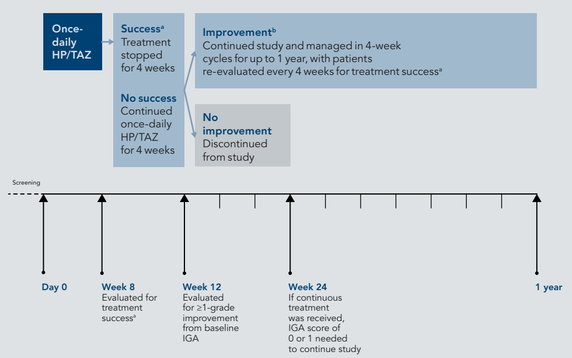
OBJECTIVE

- To investigate the maintenance of effect posttreatment following once-daily application of halobetasol propionate 0.01%/tazarotene 0.045% (HP/TAZ) lotion in patients with moderate-to-severe psoriasis

METHODS

- This was a 1-year multicenter, open-label study (NCT02462083) in patients ≥18 years of age with moderate-to-severe plaque psoriasis
  - An Investigator's Global Assessment (IGA) score of 3 or 4 (5-point scale; 0=clear and 4=severe) and Body Surface Area (BSA) of 3-12% were needed to enroll in the study
- Participants were treated with HP/TAZ lotion once-daily for 8 weeks and intermittently as needed in 4-week intervals (**Figure 1**)
  - At Week 8, treatment was stopped for participants that achieved treatment success, defined as IGA score of 0 or 1 ('clear' or 'almost clear'); participants who did not reach treatment success were treated for 4 additional weeks
  - All participants were re-evaluated at Week 12
  - Those demonstrating ≥1-grade improvement from baseline IGA continued the study and were subsequently managed in 4-week cycles (eg, treated with HP/TAZ lotion once-daily if they had not achieved treatment success or receiving no treatment until the next evaluation if they had achieved treatment success)
- Maximum continuous exposure was 24 weeks; at Week 24, if continuous treatment was received, participants needed an IGA score of 0 or 1 to continue in the study
- In this study, CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (L'Oreal, NY) were provided as needed for optimal moisturization/cleaning of the skin

FIGURE 1. Open-Label Study Design

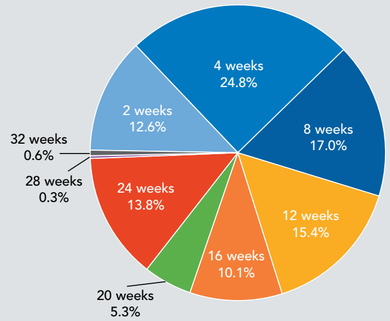


Maximum continuous exposure was 24 weeks.
[a]Treatment success defined as score of 0 or 1 on IGA.
[b]Improvement defined as ≥1-grade improvement from baseline IGA.
HP/TAZ, halobetasol propionate 0.01%/tazarotene 0.045%; IGA, Investigator's Global Assessment.

RESULTS

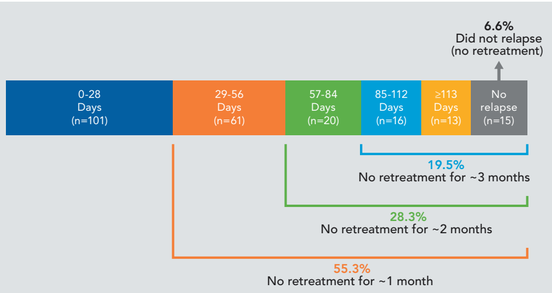
- A total of 555 participants were treated with HP/TAZ; 550 had post-baseline safety data
- Mean age was 51.9 years, 65.6% were male, and 86.0% were white; mean BSA at baseline was 5.6%
- Overall, 318 participants (57.8%) achieved treatment success at some point during the study; the majority (54.4%, n=173) achieved treatment success within the first 8 weeks (**Figure 2**; blue sections)
- In many participants, treatment success was rapid, being achieved within the first 2 and 4 weeks in 12.6% and 37.4% of those who achieved treatment success, respectively (**Figure 2**)
- Of 226 participants who stopped therapy after achieving treatment success, 55.3% did not require retreatment for at least 29 days and 6.6% did not require any retreatment (**Figure 3**)

FIGURE 2. Time to First Treatment Success[a] With HP/TAZ (n=318)



[a]Treatment success defined as score of 0 or 1 on IGA; blue sections show treatment success achieved within the first 8 weeks.
HP/TAZ, halobetasol propionate 0.01%/tazarotene 0.045%; IGA, Investigator's Global Assessment.

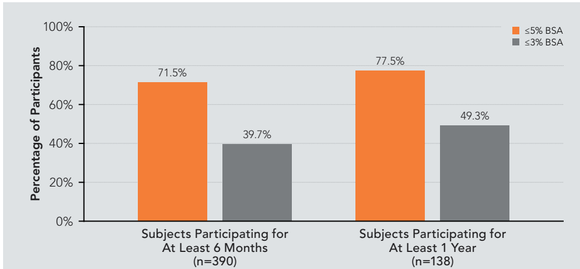
FIGURE 3. Time to Retreatment with HP/TAZ (n=226[a])



[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).
HP/TAZ, halobetasol propionate 0.01%/tazarotene 0.045%; IGA, Investigator's Global Assessment.

- For individuals participating for at least 1 year, 77.5% maintained a BSA level of ≤5% and 49.3% maintained a BSA level of ≤3% during the study (**Figure 4**)

FIGURE 4. Maintained Body Surface Area (BSA) From Week 8 to End of Study With HP/TAZ



HP/TAZ, halobetasol propionate 0.01%/tazarotene 0.045%.

CONCLUSIONS

- A novel lotion formulation of halobetasol propionate 0.01%/tazarotene 0.045% (HP/TAZ) demonstrated rapid and sustained treatment success in participants with moderate-to-severe psoriasis when followed for 1 year, with more than half of participants not requiring retreatment for at least one month
- These data are consistent with those reported in an earlier study of HP/TAZ lotion, where 55% of participants who were treatment successes remained so at the end of the 4-week posttreatment follow-up

REFERENCES

1. Nestle FO, et al. *N Engl J Med.* 2009;361(5):496-509.
2. Cohen SN, et al. *Clin Exp Dermatol.* 2012;37 Suppl 1:13-8.
3. Kim WB, et al. *Can Fam Physician.* 2017;63(4):278-285.
4. Uva L, et al. *Int J Endocrinol.* 2012;2012:561018.
5. Svendsen, MT, et al. *J Dermatolog Treat.* 2019:1-10.
6. Belinchon I, et al. *Patient Prefer Adherence.* 2016;10:2357-2367.

AUTHOR DISCLOSURES

Dr. Linda Stein Gold is an investigator/consultant or speaker for Ortho Dermatologics, LEO, Dermavant, Incyte, Novartis, AbbVie, and Lilly.
Dr. Mark Lebwohl is an employee of Mount Sinai and receives research funds from: AbbVie, Amgen, Arcutis, AstraZeneca, Boehringer Ingelheim, Celgene, Clinuvel, Eli Lilly, Incyte, Janssen Research & Development, LLC, Kadmon Corp., LLC, Leo Pharmaceuticals, Medimmune, Novartis, Ortho Dermatologics, Pfizer, Sciderm, UCB, Inc., and ViDac. Dr. Lebwohl is also a consultant for Allergan, Almirall, Arcutis, Inc., Avotres Therapeutics, BirchBioMed Inc., Boehringer-Ingelheim, Bristol-Myers Squibb, Cara Therapeutics, Castle Biosciences, Corrona, Dermavant Sciences, Foundation for Research and Education in Dermatology, Incyzme Pharma, LEO Pharma, Meiji Seika Pharma, Menlo, Mitsubishi, Neuroderm, Pfizer, Promius/Dr. Reddy's Laboratories, Theravance, and Verrica. Dr. Neal Bhatia has received honoraria from Ferndale Laboratories, Inc., Promius Pharma, LLC, Novartis, Allergan, Biofrontera AG, IntraDerm Pharmaceuticals, Almirall, Sun Pharmaceutical Industries, La Roche-Posay, Mayne Pharma Group, Ortho Dermatologics, Pierre Fabre Dermo-Cosmétique US, ISDIN, Galderma Laboratories, Skinfix, Inc., and grants/research funding from Aclaris Therapeutics, Inc., Asana Biosciences, LLC, Crown Laboratories, Inc., LEO Pharma US, DUSA Pharmaceuticals, Inc., Menlo Therapeutics, Par Pharmaceutical, Pfizer Inc., Perrigo Company, Realm Therapeutics, Sienna Biopharmaceuticals, Sol-Gel technologies, Soligenix, Inc., Strata Skin Sciences, Vidac Pharma, Brickell Biotech, Inc., Dermira, Glenmark Generics Inc., Sanofi/Regeneron, Actavis, BioPharmX, Foamix, Cutanea Life Sciences, MC2 Therapeutics, UCB, AbbVie, Atacama Therapeutics, Naked Biome Inc., Kiniksa Pharmaceuticals, Ltd., BMS, Dr. Reddy, and Vyome (Pending).
Dr. Lin is an employee of Ortho Dermatologics. Dr. Pillai is an employee of Bausch Health Americas.

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