Long-Term Management of Moderate-to-Severe Plaque Psoriasis: Maintenance of Treatment Success Following Cessation of Halobetasol Proipionate 0.01%/Tazarotene 0.045% Lotion

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*Bausch Health US, LLC is an affiliate of Bausch Health Companies Inc. Ortho Dermatologics is a subdivision of Bausch Health US, LLC.

SYNOPSIS

Psoriasis is a chronic, inflammatory skin disorder characterized by abnormal differentiation/hyperproliferation of keratinocytes, infiltration of immune cells in the dermis and epidermis, and increased capillary density.

A fixed combination halobetasol propionate 0.01%/tazarotene 0.045% (HP/TAZ) lotion (Dydrozol®, Ortho Dermatologics) was developed to address unmet needs in the topical treatment of psoriasis (see inset).

Topical corticosteroids—such as HP—are the mainstay of treatment, though long-term safety remains a concern, limiting use.

The topical retinoid TAZ has demonstrated efficacy by modulating major causes of psoriasis and maintaining therapeutic effect, though TAZ may induce cutaneous irritation.

Treating psoriasis by combining HP with TAZ may enhance efficacy, reduce side effects of both HP and TAZ, and sustain treatment response posttreatment.

OBJECTIVE

To investigate maintenance of effect posttreatment following once-daily application of HP/TAZ lotion in patients with moderate-to-severe psoriasis who achieved clear skin

METHODS

This was a 1-year, multicenter, open-label study (NCT032462083) in participants ≥18 years of age with moderate-to-severe plaque psoriasis (Investigator’s Global Assessment [IGA] score of 3 or 4 and affected body surface area [BSA]) of 3–12%)

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 who achieved treatment success (IGA score of clear [0] or almost clear [1]); all other participants were treated for an additional 4 weeks.

All participants were re-evaluated at week 12 for improvement; maximum continuous exposure was 24 weeks.

In this study, CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (50mL) were provided as needed for optimal moisturization/cleaning of the skin.

A post hoc analysis evaluated maintenance of effect in participants who were enrolled ≥8 weeks and who achieved an IGA score of 0 (clear) during the study

RESULTS

A total of 555 participants in this study were treated with HP/TAZ and 550 had post-baseline safety data

- Mean age was 51.9 years, 65.6% were male, and 86.0% were white.
- At baseline, 86.5% had an IGA score of 3 (moderate) and 13.5% had IGA of 4 (severe); mean BSA was 5.5%.
- Overall, 318 participants (57.8%) achieved treatment success at some point during the study; 54.9% of those did so within the first 8 weeks.

Participants Achieving Clear

Fifty-six participants were enrolled in the study for at least 8 weeks and achieved an IGA score of 0 (clear) ≥1 visit.

Of these participants, 28.6% did not require any HP/TAZ treatment after first achievement of clear, 53.4% did not require retreatment for ≥8 days, 62.5% for ≥57 days, and 83.9% for ≥29 days (Figure 2).

FIGURE 1. Open-Label Study Design

FIGURE 2. Time to Retreatment with HP/TAZ After First Achievement of Clear On or After Week 8 (n=56–)

CONCLUSIONS

- In this 1-year, open-label study of HP/TAZ, 53.6% of participants who achieved clear skin (IGA score of 0) did not require retreatment for more than 12 weeks.
- Results are notable given a limitation of the study design, in which participants were required to stop using HP/TAZ lotion at the time of first treatment success (achievement of clear or almost clear).
- This may have reduced the total number of participants who could have achieved clear skin with continued HP/TAZ treatment, potentially also reducing the duration of time to retreatment.
- These data indicate a long maintenance of therapeutic effect with HP 0.01%/TAZ 0.045% lotion in participants who achieved clear skin, likely due to the role of TAZ in sustaining efficacy posttreatment (see inset).

REFERENCES


WHY TAZAROTENE + HALOBETASOL?

- Tazarotene is a retinoid sparing that is rapidly metabolized to tazarotenic acid, which binds with high affinity to ligand-dependent transcription factors RARα (enriched in the skin) and RARβ.
- Tazarotene modulates pathogenic factors of psoriasis, thereby appearing to restore skin to a more quiescent, preclinical status (figure).
- This “normalization” of keratinocytes may be the basis of the relatively long remission after tazarotene treatment.

Tazarotene mechanism of action in psoriasis

Fixed-combination HP 0.01%/TAZ 0.045% lotion formulation

- Innovative topical coemulsion technology formulation allows for uniform distribution of active ingredients in a lower-dose formulation (figure).
- Vehicle lotion formulation is non-greasy and provides enhanced barrier to the skin.
- Application of HP/TAZ lotion results in higher permeation efficiency of the active ingredients compared with application of higher-dose HP or TAZ creams (alone or layered)

ACKNOWLEDGEMENTS: Medical writing support was provided by Prestige Medical Communications Group (Chicago, IL) with financial support from Ortho Dermatologics; Ortho Dermatologics is a division of Bausch Health US, LLC. Presented at: Fall Clinical 2020; October 29- November 1, 2020; Virtual.