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 A topical corticosteroid for patients 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 plaque psoriasis.

METHODS
This was a 3-year multicenter, open-label study (NCT02442083) in patients ≥18 years of age with moderate-to-severe plaque psoriasis.

• An Investigator’s Global Assessment (IGA) score of 0 or 1 (clear and minimal disease) for ≥80% of the body surface area (BSA) and no new psoriasis plaques for ≥24 weeks.

Participants were treated with HP/TAZ lotion once-daily for 8 weeks and intermittently as needed for up to 1 year, with patients who had not achieved treatment success or receiving no treatment until the next evaluation (Figure 4).

In many participants, treatment success was rapid, being achieved within the first 2 and 4 weeks of treatment (Figure 2). Overall, 318 participants (57.8%) achieved treatment success at some point during the study; the majority (54.4%, n=172) 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 31.4% of those who achieved treatment success, respectively (Figure 2).

In this study, CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (L’Oreal, NY) were provided as needed for optimal moisturizing/cleansing of the skin.

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%.

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• Over 8 weeks, 192 participants (34.9%) achieved treatment success.

• Overall, 318 participants (57.8%) achieved treatment success at some point during the study, the majority (54.4%, n=172) achieved treatment success within the first 8 weeks (Figure 2, blue sections).

• In participants who achieved treatment success, 62% were achieved within the first 4 weeks (Figure 2).

• Of 550 participants who stopped therapy after achieving treatment success, 55.3% did not require retreatment for at least 29 days and 6.5% did not require any retreatment (Figure 3).

FIGURE 1. Open-Label Study Design

FIGURE 2. Time to First Treatment Success With HP/TAZ (n=550)

FIGURE 3. Time to Retreatment With HP/TAZ (n=226)

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

REFERENCES

AUTHOR DISCLOSURES
Dr. Gold 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 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

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 plaque 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 75% of participants who were treatment successes remained so at the end of the 4-week posttreatment follow-up.