Long-term Outcomes of Fixed-Combination Halobetasol Propionate and Tazarotene Lotion Stratified by Baseline Signs and Symptoms of Psoriasis

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OBJECTIVE

- **In this post hoc analysis of a 52-week open-label study (NCT02462083),[1] we assessed the efficacy and safety of once-daily halobetasol propionate (0.01%) and tazarotene (0.045%) lotion (HP/TAZ) in 550 participants with psoriasis stratified by baseline signs and symptoms of disease**

CONCLUSIONS

- **Long-term use of HP/TAZ was generally associated with treatment success regardless of baseline symptom severity, and no new safety signals emerged over 52 weeks**
- **Participants with mild baseline symptoms were less likely to experience local skin reactions postbaseline compared with participants with more severe baseline symptoms**
- **Evaluation of patients' baseline itch, dryness, and stinging/burning may help predict outcomes of HP/TAZ treatment**
- **Clinicians can use this information to counsel patients regarding treatment expectations when initiating HP/TAZ**

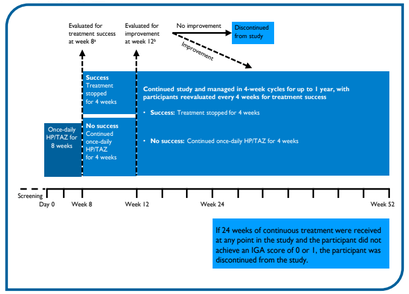
SYNOPSIS

- Topical psoriasis treatments may be used as monotherapy for mild disease or as adjunct therapy for more severe disease[2]
- Fixed-combination halobetasol propionate (0.01%) and tazarotene (0.045%) lotion (HP/TAZ) is approved for treatment of plaque psoriasis in adults[3]
- Given that patients' experiences with psoriasis differ greatly, further consideration and assessment of the utility of HP/TAZ in patients with varying symptom severity is warranted

METHODS

- All participants received once-daily HP/TAZ for 8 weeks (Figure 1)
- At week 8, participants who achieved the primary endpoint of treatment success (defined as investigator's global assessment [IGA] of clear [0] or almost clear [1]) stopped HP/TAZ and were reevaluated every 4 weeks and retreated as needed through 52 weeks. Those who did not achieve treatment success at week 8 continued HP/TAZ
- Participants were allowed 24 continuous weeks of HP/TAZ treatment if they achieved ≥1-grade improvement in IGA from baseline at week 12, with monthly reevaluation for achievement of IGA 0/1
- In this post hoc analysis, 550 participants were stratified by baseline severity of itch, dryness, and stinging/burning (none to mild vs moderate to severe)
  - Itch and stinging/burning were scored on a scale from 0 (none) to 3 (severe) as reported by the participant in the past 24 hours
  - Dryness was scored on a scale from 0 (none) to 3 (severe) as assessed by the investigator

Figure 1. Design of the long-term open-label study of HP/TAZ.



HP/TAZ, halobetasol propionate (0.01%) and tazarotene (0.045%) lotion; IGA, investigator's global assessment. [a]Treatment success defined as IGA score of clear (0) or almost clear (1) and ≥2-grade improvement from baseline IGA. [b]Improvement defined as ≥1-grade improvement from baseline IGA; those demonstrating improvement continued the study and were subsequently managed in 4-week cycles (ie, treated with once-daily HP/TAZ if they did not achieve treatment success or received no treatment until the next evaluation if they achieved treatment success). Maximum continuous exposure was 24 weeks.

RESULTS

Participant population

- Baseline characteristics are shown in Table 1

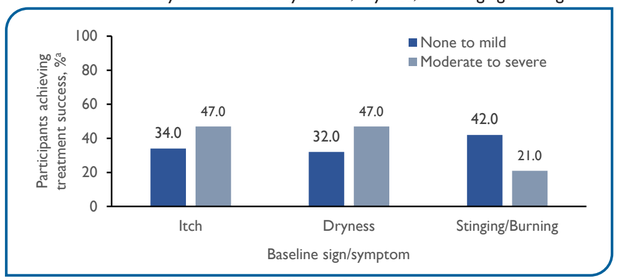
Table 1. Participants Stratified by Baseline Severity of Signs/Symptoms

	Participants, n (%)	
Sign/Symptom	**None to mild**	**Moderate to severe**
Itch	278 (50.5)	272 (49.5)
Dryness	289 (52.5)	261 (47.5)
Stinging/Burning	466 (84.7)	84 (15.3)

Efficacy

- At week 52, a greater proportion of participants with none-to-mild baseline signs/symptoms had treatment success (IGA 0 or 1) compared with participants with moderate-to-severe baseline signs/symptoms (Figure 2)

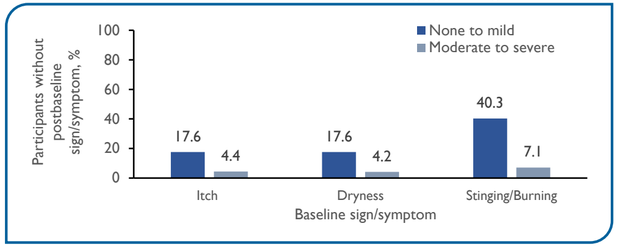
Figure 2. Treatment success at week 52 among participants treated with HP/TAZ stratified by baseline severity of itch, dryness, and stinging/burning.



HP/TAZ, halobetasol propionate (0.01%) and tazarotene (0.045%) lotion; IGA, investigator's global assessment. [a]Treatment success defined as IGA of clear (0) or almost clear (1).

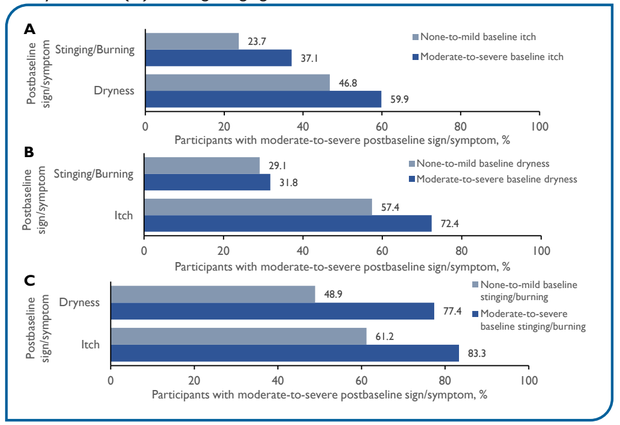
- Participants with none-to-mild signs/symptoms at baseline were more likely to experience no signs/symptoms at any time point postbaseline relative to participants with moderate-to-severe signs/symptoms at baseline (Figure 3)

Figure 3. Participants without signs/symptoms at any time point postbaseline stratified by baseline severity of itch, dryness, and stinging/burning.



- Participants with moderate-to-severe itch (Figure 4A), dryness (Figure 4B), or burning/stinging (Figure 4C) at baseline were more likely to experience moderate-to-severe postbaseline local skin reactions

Figure 4. Of the participants who experienced moderate-to-severe postbaseline signs/symptoms stratified by baseline severity of **(A)** itch, **(B)** dryness, and **(C)** burning/stinging.



Safety

- Rates of adverse events (AEs) were similar across groups and discontinuations due to AEs were low (range, 5.6%-8.3% across baseline subgroups), similar to what was seen in the overall population[1]
- Application site dermatitis was the most common treatment-emergent AE across groups (Table 2)

Table 2. Treatment-Emergent Adverse Events Stratified by Baseline Severity of Signs/Symptoms

	Participants, n (%)					
Application site TEAE	**None-to-mild baseline itch**	**Moderate-to-severe baseline itch**	**None-to-mild baseline dryness**	**Moderate-to-severe baseline dryness**	**None-to-mild baseline stinging/burning**	**Moderate-to-severe baseline stinging/burning**
Dermatitis	34 (12.2)	25 (9.2)	38 (13.1)	21 (8.0)	50 (10.7)	9 (10.7)
Pruritis	12 (4.3)	21 (7.7)	16 (5.5)	17 (6.5)	27 (5.8)	6 (7.1)
Pain	9 (3.2)	20 (7.4)	14 (4.8)	15 (5.7)	24 (5.2)	5 (6.0)
Irritation	8 (2.9)	6 (2.2)	10 (3.5)	4 (1.5)	13 (2.8)	1 (1.2)
Erosion	7 (2.5)	5 (1.8)	9 (3.1)	3 (1.1)	10 (2.1)	2 (2.4)
Erythema	4 (1.4)	4 (1.5)	6 (2.1)	2 (0.8)	7 (1.5)	1 (1.2)
Atrophy	0	4 (1.5)	1 (0.3)	3 (1.1)	2 (0.4)	2 (2.4)

TEAE, treatment-emergent adverse event.

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References: 1. Lebwohl et al. *J Eur Acad Dermatol Venereol*. 2021;35:1152-1160. **2.** Elmets et al. *J Am Acad Dermatol*. 2021;84:432-470. **3.** Duobrii [package insert]. Bausch Health US, LLC; 2019.