Long-term Safety and Efficacy of Fixed-Combination Halobetasol Propionate and Tazarotene Lotion in Patients With Clinically Meaningful Improvement in Plaque Psoriasis

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OBJECTIVE

- **This post hoc analysis of two randomized phase 3 trials (NCT02462070 and NCT02462122)[1] and a 52-week open-label study (NCT02462083)[2] evaluated the efficacy and safety of halobetasol propionate (0.01%) and tazarotene (0.045%) lotion (HP/TAZ) in participants achieving ≥75% improvement in the product of investigator's global assessment and affected body surface area (IGAxBSA-75) at or before week 12**

CONCLUSIONS

- **HP/TAZ was associated with long-term skin clearance in participants who achieved clinically meaningful improvement in psoriasis lesions, as measured by IGAxBSA-75**
  - **These findings suggest that HP/TAZ promotes remission of psoriasis after treatment discontinuation**
- **Clinically meaningful improvement in psoriasis lesions was also associated with decreased signs and symptoms (itch, dryness, and burning/stinging) and posttreatment maintenance of those improvements**

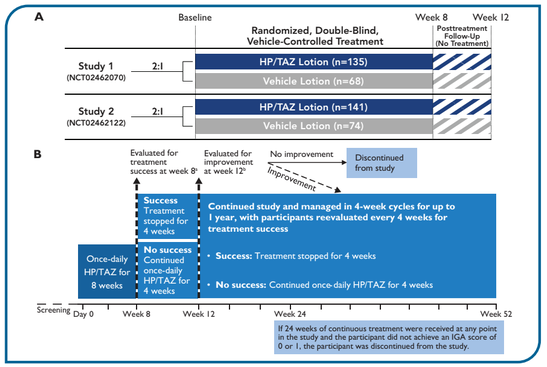
SYNOPSIS

- Fixed-combination halobetasol propionate (0.01%) and tazarotene (0.045%) lotion (HP/TAZ) is approved to treat plaque psoriasis in adults[3]
- The product of investigator's global assessment and affected body surface area (IGAxBSA) is a measure of psoriasis severity[4]
  - ≥75% reduction from baseline (IGAxBSA-75) is considered as clinically meaningful improvement in skin clearance[5]

METHODS

- In the randomized trials, participants were assigned 2:1 to either HP/TAZ once daily or vehicle lotion, with a primary endpoint of treatment success at week 8 (IGA score of clear [0] or almost clear [1]) and follow-up assessment at week 12 (Figure 1A)
- Similarly, in the open-label study, all participants received HP/TAZ once daily for 8 weeks
  - Those who achieved treatment success stopped treatment and were reevaluated monthly through 52 weeks, with retreatment as needed (any time IGA was >1)
  - Those who did not achieve treatment success at week 8 continued to apply HP/TAZ
  - Participants were allowed 24 continuous weeks of HP/TAZ if they achieved ≥1-grade improvement in IGA from baseline at week 12 (Figure 1B)
- In the randomized phase 3 trials, 276 participants were treated with HP/TAZ and 142 received vehicle, while a total of 550 participants were treated in the long-term open-label study
- Participants who achieved IGAxBSA-75 at or before week 12 in the randomized phase 3 and open-label studies of HP/TAZ were included in the analysis
- Signs and symptoms of psoriasis were evaluated at each study visit
  - 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. Designs of **(A)** pivotal phase 3 and **(B)** open-label studies 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). [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

Efficacy

Participant characteristics

- In a pooled analysis of the phase 3 trials, 140 of 276 participants (50.7%) treated with HP/TAZ and 19 of 142 participants (13.4%) who received vehicle achieved IGAxBSA-75 by week 12
- In the open-label study, 254 of 550 participants (46.2%) achieved IGAxBSA-75 by week 12
- Across all studies, prevalence of moderate-to-severe symptoms at baseline was greater in HP/TAZ-treated participants compared with those receiving vehicle (Table 1)

Table 1. Baseline Characteristics of Participants in Clinical Studies of HP/TAZ Who Achieved IGAxBSA-75 at or Before Week 12

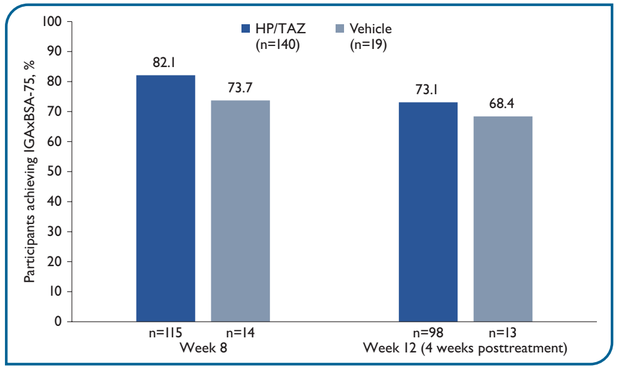
Baseline parameter	Pooled randomized trials (HP/TAZ, n=140)	Pooled randomized trials (vehicle, n=19)	Open-label study (N=254)
IGA 3	119 (85)	19 (100)	221 (87)
IGA 4	21 (15)	0	33 (13)
Mean BSA, % (SD)	5.8 (2.9)	5 (2.2)	5.5 (2.7)
Moderate-to-severe itch	62 (44.3)	3 (15.8)	118 (46.5)
Moderate-to-severe dryness	41 (29.3)	3 (15.8)	109 (42.9)
Moderate-to-severe stinging/burning	23 (16.4)	3 (15.8)	36 (14.2)

All values are n (%) except for mean BSA. BSA, body surface area; HP/TAZ, halobetasol propionate (0.01%) and tazarotene (0.045%) lotion; IGA, investigator's global assessment; IGAxBSA-75, ≥75% improvement in product of IGA and BSA; SD, standard deviation.

IGAxBSA-75

- In the randomized trials, a numerically greater proportion of participants receiving HP/TAZ achieved IGAxBSA-75 versus those receiving vehicle at week 8 and week 12 (4 weeks posttreatment; Figure 2)
- In the open-label study, 63.3% of participants who achieved IGAxBSA-75 by week 12 maintained IGAxBSA-75 at week 52

Figure 2. Proportion of participants achieving IGAxBSA-75 at week 8 and week 12 (4 weeks posttreatment) in the randomized phase 3 trials of HP/TAZ.

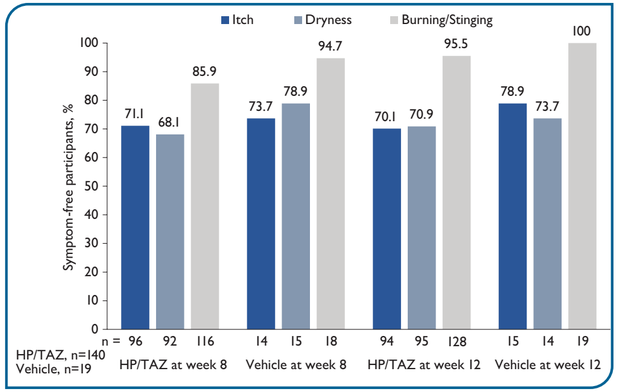


BSA, body surface area; HP/TAZ, halobetasol propionate (0.01%) and tazarotene (0.045%) lotion; IGA, investigator's global assessment; IGAxBSA-75, ≥75% improvement in product of IGA and BSA.

Signs and symptoms of psoriasis

- In the phase 3 randomized trials, most participants receiving HP/TAZ or vehicle who achieved IGAxBSA-75 at or before week 12 also reported no itch (71.1% vs 73.7%), dryness (68.1% vs 78.9%), or burning/stinging (85.9% vs 94.7%) at week 8, with similar results at week 12 (4 weeks posttreatment; Figure 3)

Figure 3. Proportion of participants achieving IGAxBSA-75 at or before week 12 who were free of itch, dryness, and burning/stinging at week 8 and week 12 (4 weeks posttreatment) in the randomized phase 3 trials of HP/TAZ.



BSA, body surface area; HP/TAZ, halobetasol propionate (0.01%) and tazarotene (0.045%) lotion; IGA, investigator's global assessment; IGAxBSA-75, ≥75% improvement in product of IGA and BSA.

- In the open-label study of HP/TAZ, the proportion of participants with moderate-to-severe itch, dryness, and stinging/burning decreased at week 52 from baseline (Table 2)

Table 2. Change in Moderate-to-Severe Signs/Symptoms of Psoriasis in the Open-label Study of HP/TAZ

Sign/Symptom	Participants with sign/symptom at week 52, n (%)	Mean change from baseline	SD
Itch	10 (10.2)	-0.70	1.09
Dryness	6 (6.1)	-0.70	0.90
Stinging/Burning	4 (4.1)	-0.20	0.68

HP/TAZ, halobetasol propionate (0.01%) and tazarotene (0.045%) lotion; SD, standard deviation.

Safety

- Across all studies, rates of skin atrophy, striae, telangiectasias, and folliculitis were low
- At week 12 in the randomized phase 3 trials, only 1 participant (0.7%) in the HP/TAZ group experienced skin atrophy, and all other reactions were absent
- In the open-label study, rates of these skin reactions were absent in all participants at week 52

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References: 1. Stein Gold et al. *J Am Acad Dermatol.* 2018;79:287-293. **2.** Lebwohl et al. *J Eur Acad Dermatol Venereol.* 2021;35:1152-1160. **3.** Duobrii [package insert]. Bausch Health US, LLC; 2019. **4.** Gottlieb et al. *Dermatology.* 2019;235:348-354. **5.** Blauvelt et al. *J Drugs Dermatol.* 2019;18:297-299.

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