Safety of Hydrogen Peroxide Topical Solution, 40% (w/w) in Patients With Skin of Color and Seborrheic Keratoses: Pooled Analysis of Two Phase 3, Randomized, Double-Blind, Vehicle-Controlled, Parallel-Group Studies

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CONCLUSIONS

1. Treatment with HP40 was safe and well tolerated in patients with skin of color and SKs on the face, extremities, and trunk
2. Incidences of both investigator- and patient-reported LSRs were similar between groups and most were mild
3. At the final study visit, no LSRs were severe, and all except crusting and hyperpigmentation were mild

SYNOPSIS

- Seborrheic keratoses (SKs) are benign yet aesthetically bothersome cutaneous lesions found mainly on the trunk, head, and neck[1]
- Hydrogen peroxide topical solution 40% (w/w) (HP40) is the first topical treatment approved by the US Food and Drug Administration for adults with raised SKs[2,3]
  - Limited information is currently available regarding HP40 treatment in patients with skin of color
- Two randomized, double-blind, vehicle-controlled, parallel-group Phase 3 studies were conducted to investigate the safety and efficacy of HP40 compared with vehicle for the treatment of SKs
  - At visit 1 of both trials, investigators determined the Fitzpatrick Skin Type of all eligible study patients

OBJECTIVE

- We conducted a post hoc, pooled analysis of data from the two Phase 3 pivotal clinical trials to evaluate the safety and tolerability of HP40 treatment in patients with skin of color, defined as having Fitzpatrick Skin Types ≥IV

MATERIALS AND METHODS

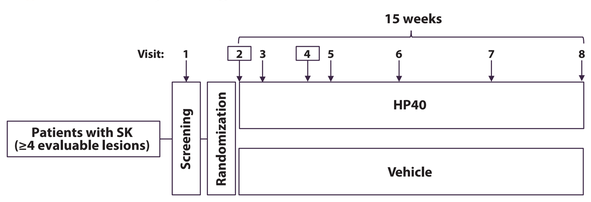
Patients

- This was a pooled, post hoc analysis of data from two Phase 3, multicenter, randomized, double-blind, vehicle-controlled studies (NCT02667236, NCT02667275)
- Eligible patients were required to be ≥18 years of age and have 4 target SKs (≥1 on the face and ≥1 on the trunk or extremities)
  - For the current analysis, patients were also required to have a Fitzpatrick Skin Type of IV, V, or VI

Study Design

- Both studies were vehicle-controlled and had a parallel-group design (**Figure 1**)
  - Patients were randomized to receive HP40 or vehicle
  - Treatments were administered at visit 2 (all patients) and visit 4 (if the Physician Lesion Assessment™ [PLA] grade was >0)
    - Details of the validated PLA tool are summarized in **Table 1**
  - The PLA was performed at visits 1, 2, 4, 6, 7, and 8
- Safety was assessed at all visits

Figure 1. Study Design



Boxed visits: treatment administered.
HP40, hydrogen peroxide topical solution 40% (w/w); SK, seborrheic keratosis.

Table 1. PLA Scoring

Grade	Description
0	Clear: no visible SK leison
1	Near clear: a visible SK lesion with a surface appearance different from the surrounding skin (not elevated)
2	Thin: a visible SK lesion (thickness ≤1 mm)
3	Thick: a visible SK lesion (thickness >1 mm)

PLA, Physician Lesion Assessment; SK, seborrheic keratosis.

Safety Endpoints

- Safety assessments included treatment-related treatment-emergent adverse events (TEAEs) and local skin reactions (LSRs), which were evaluated by patients and clinical trial investigators
  - At visits 2 and 4, patients rated LSRs at 10 minutes posttreatment, and investigators rated LSRs at 20 minutes posttreatment

RESULTS

Patient Characteristics

- A total of 97 patients with Fitzpatrick Skin Types of IV, V, or VI were included in the pooled analysis (HP40, n=39; vehicle, n=58)
- Baseline demographics were similar between the HP40 and vehicle treatment groups (**Table 2**)

Table 2. Patient Characteristics

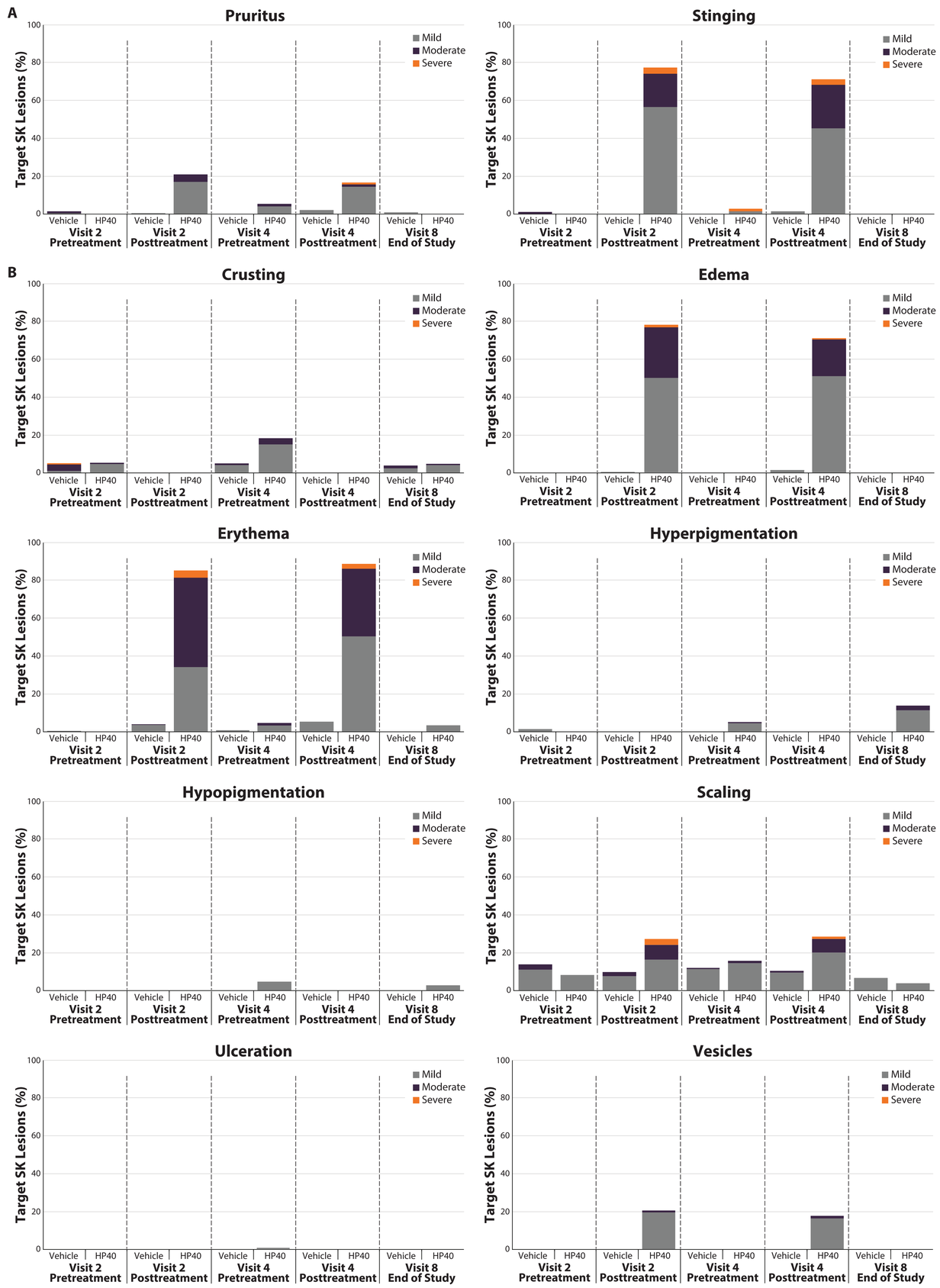
Characteristic	Vehicle (n=58)	HP40 (n=39)
Age, y		
Mean ± SD	67.4 ± 9.02	67.2 ± 9.64
Age group, y		
18–55	3 (5.2)	3 (7.7)
56–70	35 (60.3)	21 (53.8)
≥71	20 (34.5)	15 (38.5)
Gender		
Female	28 (48.3)	20 (51.3)
Race		
White	48 (82.8)	32 (82.1)
African American	4 (6.9)	4 (10.3)
Asian	6 (10.3)	2 (5.1)
Other	0	1 (2.6)
Ethnicity		
Hispanic or Latino	4 (6.9)	8 (20.5)
Not Hispanic or Latino	44 (75.9)	24 (61.5)
Missing data	10 (17.2)	7 (17.9)
Fitzpatrick Skin Type		
I–III	0	0
IV	52 (89.7)	34 (87.2)
V	5 (8.6)	5 (12.8)
VI	1 (1.7)	0

Data are reported as n (%) unless stated otherwise.

Safety

- Treatment-related TEAEs
  - In the pooled analysis, 1 (2.6%) patient treated with HP40 experienced a treatment-related TEAE of a postprocedural complication
  - No treatment-related TEAEs were observed in the vehicle group
- Investigator- and patient-reported LSRs (**Figure 2**)
  - By visit 8 (day 106, end of study), no HP40-treated patients reported an LSR of pruritus or stinging and no investigator observed atrophy, edema, erosion, scarring, ulceration, or vesicles
  - Most investigator-observed LSRs among HP40-treated target lesions at visit 8 were mild (crusting, 3.8%; erythema, 3.2%; hyperpigmentation, 11.5%; hypopigmentation, 2.6%; scaling, 3.8%)
    - Investigators reported moderate crusting for 1 target lesion (0.6%) and moderate hyperpigmentation for 4 target lesions (2.6%)
  - No severe LSRs were reported at visit 8

Figure 2. Frequencies of LSRs That Occurred During Treatment Visits or End of Study by Visit, Intensity, and Treatment: (A) Patient-Reported LSRs; (B) Investigator-Reported LSRs



HP40, hydrogen peroxide topical solution 40% (w/w); LSR, local skin reaction.

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DISCLOSURES

CH has conducted clinical trials for and participates in advisory boards for Aclaris Therapeutics, Inc. ET has conducted clinical trials for Aclaris Therapeutics. TMJ is an investigator for Aclaris Therapeutics. MB is a statistical consultant to Aclaris and owns stock in that company. JS and SDS are employees of Aclaris Therapeutics and may own stock/stock options in that company.

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