Open-Label Study of A-101, a 40% Hydrogen Peroxide Topical Solution, in Patients With Seborrheic Keratosis

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CONCLUSIONS

1. Up to 4 treatment sessions with hydrogen peroxide topical solution, 40% (w/w) were safe and well tolerated for patients with seborrheic keratoses
2. On December 14, 2017, A-101 40 became the first and only US FDA-approved topical treatment for raised seborrheic keratoses

INTRODUCTION

- Seborrheic keratoses (SKs) are common cutaneous lesions that affect an estimated 84 Americans,[1] particularly those who are middle-aged and older. While benign, these lesions are cosmetically unacceptable to many patients
- Removal of SKs is often performed for cosmetic reasons, but it may be indicated for inflamed, pruritic, or painful lesions
- Prior to December 2017, there was no US FDA–approved drug for the treatment of SKs. Ablative/destructive procedures (eg, cryotherapy, electrodessication/curettage, etc) had been available; however, their efficacy and safety have not been rigorously evaluated in well-controlled clinical trials, and they often involve burning, cutting, or freezing
- A noninvasive, well-tolerated, topical agent for the removal of SKs is an important unmet treatment need
- A proprietary, stabilized hydrogen peroxide topical solution, 40% (w/w) (A-101 40) was approved by the FDA in December 2017 for SKs that are raised[2]
- Two identical double-blind, randomized, phase 3 studies showed that, after 2 treatments per lesion, significantly more patients treated with A-101 40 completely cleared all 4 target SKs on the trunk, extremities, and face, whereas no patients treated with vehicle cleared all 4 target SKs[2]
- The main objective of the current study was to evaluate the safety of A-101 40 after completion of up to 4 treatments per lesion of 4 target SKs on the trunk, extremities, and face

MATERIALS AND METHODS

Patients and Study Design

- Multicenter, open-label study (NCT02667288)
- Eligible patients: aged ≥ 18 years with 4 eligible SKs on the trunk, extremities, and face, identified by the study investigator
- Eligible lesions were stable, typical SKs, measuring 5-15 mm in length and width, > 0-2 mm in thickness, with a Physician Lesion Assessment (PLA)™ grade of ≥ 2 (**Table 1**)[2]
  - Target SKs could not be located on the eyelid, within 5 mm of the orbital rim, inside the orbital rim, in an intertriginous area, or pedunculated
- All SKs were treated on Day 1; on Days 22, 43, and 64, any previously treated SKs with a PLA score > 0 were retreated
- Patients were followed for 84 days after the fourth treatment visit (total 148 days)
- At Day 148, the investigator assessed SKs using the validated PLA
- Safety was assessed at all visits, including end of study (Day 148)

Table 1. Validated Physician Lesion Assessment (PLA)[2] Scale

Grade	Descriptor
0	Clear: No visible SK
1	Near Clear: A visible SK with a surface appearance different from the surrounding skin (not elevated)
2	Thin: A visible SK (≤ 1 mm)
3	Thick: A visible SK (> 1 mm)

Safety Endpoints

- Treatment-emergent adverse events (TEAEs), local skin reactions (LSRs), laboratory evaluations, and vital signs
- The safety population comprised all patients who began treatment. The intent-to-treat population comprised all patients who were enrolled

RESULTS

- A total of 147 patients were enrolled and treated, and 139 patients (94.6%) completed the study
- The mean age of patients was 68 years (range, 35-94): 41% were aged ≥ 71 years, 68% were women, and 94% were Caucasian
  - Fitzpatrick skin types 1 to 6 were represented:
    - Type 1: 12 (8.2%); Type 2: 71 (48.3%); Type 3: 47 (32.0%);Type 4: 11 (7.5%); Type 5: 4 (2.7%); Type 6: 2 (1.4%)
- All patients had at least 1 target SK retreated on Days 22, 43, and 64

Safety

- TEAEs were reported for 25 (17%) patients, and all were reported as mild or moderate in intensity (**Table 2**)
  - One patient experienced a treatment-related TEAE (contact/skin irritation)
  - No patient discontinued due to a TEAE or serious adverse event (SAE)
- LSRs were predominantly mild and most commonly included transient pruritus, stinging, crusting, edema, erythema, and scaling that usually resolved by the next visit
  - The majority of SKs had no LSRs by Day 148, and the few reported LSRs were generally mild (**Table 3**; **Figure 1**)

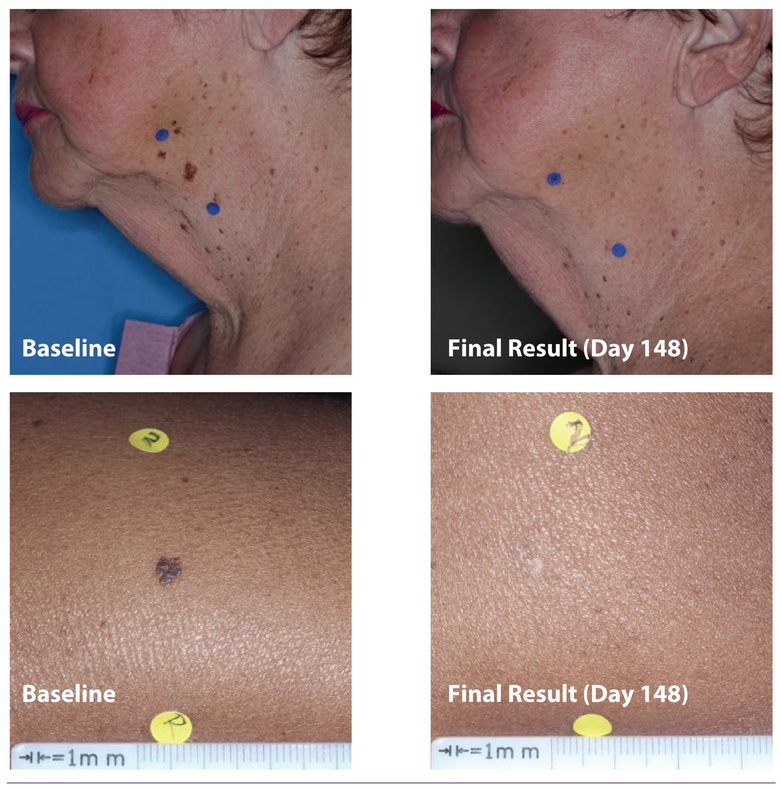
Table 2. Overview of TEAEs (Safety Population)

	(N = 147)
Number of AEs reported	32
Patients with TEAEs, n (%)	25 (17.0)
Number of SAEs reported	0
Patients with SAEs, n (%)	0
Patients with TEAEs by severity, n (%)	
Mild	17 (11.6)
Moderate	8 (5.4)
Severe	0
Patients who discontinued the study due to TEAEs/SAEs, n (%)	0
Patients with treatment-related TEAEs, n (%)	1 (0.7)

Table 3. Percent of Treated SKs With LSRs

	Mild	Moderate	Severe	No Reaction
Scaling	32%	2%	< 1%	66%
Hyperpigmentation	11%	3%	0%	86%
Crusting	11%	3%	< 1%	86%
Erythema	8%	< 1%	0%	92%
Hypopigmentation	6%	1%	0%	93%
Pruritus	1%	0%	0%	99%
Scarring	< 1%	< 1%	0%	99%
Atrophy	0%	0%	0%	100%
Edema	0%	0%	0%	100%
Stinging	0%	0%	0%	100%
Erosion	0%	0%	0%	100%
Ulceration	0%	0%	0%	100%
Vesicles/bullae	0%	0%	0%	100%

Figure 1. Patient Photos of SKs Before and After A-101 40 Treatment



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2. Baumann LS, et al. *J Am Acad Dermatol*. 2018; epub ahead of print. doi: 10.1016/j.jaad.2018.05.044.

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Disclosures

Valerie D. Callender, Ellen H. Frankel, Jonathan S. Weiss, and William P. Werschler are investigators for Aclaris Therapeutics, Inc. Christopher Powala and Stuart D. Shanler are employees of Aclaris Therapeutics, Inc. Brian B. Beger and Esther Estes are former employees of Aclaris Therapeutics, Inc.

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