# Safety and Efficacy of A-101 Hydrogen Peroxide Topical Solution 40% in Adults With Seborrheic Keratosis: Results From the Phase 3, Randomized, Double-Blind, Vehicle-Controlled Study

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## Introduction

- Seborrheic keratoses (SK) is a common cutaneous lesion that affects more than 83 million Americans, particularly those who are middle-aged and older. While benign, these lesions are often cosmetically distressing to many patients.
- Malignancy concerns following the appearance of lesions act as a primary driver for a patient to seek medical advice.
- Removal of SKs is often performed for cosmetic reasons, but it may be indicated for unmet needs.

## Materials and Methods

- **Patients and Study Design**
  - The purpose of this study (A-101-SEBK-301; NCT02667236) was to evaluate the safety and efficacy of A-101 40% versus its matching vehicle for the treatment of SK.
  - A-101 is a patented topical formulation based on a high concentration of hydrogen peroxide (40% w/w) for asymptomatic SK.
- **Study Design**
  - A total of 450 patients were enrolled—220 of 223 and 226 of 227 patients randomized to A-101 and vehicle, respectively, completed the study.
- **Endpoints**
  - Primary efficacy endpoint: percent of patients with complete clearance (PLA 0) of all 4 SKs at 106 days after first treatment.
  - Secondary endpoint: percent of patients with complete clearance (PLA 0) in at least 3 of 4 SKs.
  - Exploration endpoint: mean per-patient percent of SKs judged Clear/Near Clear (PLA 1-3).

## Results

- **Demographics**
  - Demographic characteristics were similar across all treatment groups.
- **Mean age of patients was 69 years (range, 42–90). 59% of subjects were women, and 97.8% (440) were Caucasian.
- **Safety**
  - Local skin reactions were predominantly mild and had generally resolved by Day 106.
- **Efficacy**
  - Mean per-patient percent of SKs achieving Clear/Near Clear (PLA 1-3) was observed in the A-101 arm (48% vs 10% at Day 106) (Table 2).

## Conclusions

- **A-101 (hydrogen peroxide) topical solution, 40% (w/w) is safe, effective, and well-tolerated treatment for seborrheic keratoses (Figure 3).**
- **For SKs on the face and cosmetically sensitive locations, A-101 was highly effective, with very low occurrence of hypopigmentation and/or scarring.**

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