CLINICIAN SATISFACTION WITH TIRBANIBULIN TREATMENT'S ABILITY TO IMPROVE 'HOW SKIN LOOKS' AND 'SKIN TEXTURE' IN THE TREATED AREA, AMONG PATIENTS WITH ACTINIC KERATOSIS TREATED WITH TIRBANIBULIN IN COMMUNITY PRACTICES ACROSS THE U.S (PROAK STUDY)

Todd Schlesinger, MD[1]; Leon Kircik, MD[2]; April Armstrong, MD[3]; Brian Berman, MD, PhD[4]; Neal Bhatia, MD[5]; James Del Rosso, MD[6]; Mark Lebwohl, MD[2]; Vishal A. Patel, MD[7]; Darrell Rigel, MD, MS[2]; Siva Narayanan, PhD[8]; Volker Koscielny, MD[9] Ismail Kasujee PhD[9]

[1]Clinical Research Center of the Carolinas, Charleston, SC, USA; [2]Mount Sinai Icahn School of Medicine, New York, NY, USA; [3]Keck School of Medicine, University of Southern California, Los Angeles, CA, USA; [4]University of Miami Miller School of Medicine, Miami, FL, USA; [5]Therapeutics Clinical Research, San Diego, CA, USA; [6]JDR Dermatology Research/Thomas Dermatology, Las Vegas, NV, USA; [7]George Washington School of Medicine and Health Sciences, Washington, DC, USA; [8]Avant Health LLC, Bethesda, MD, USA; [9]Almirall SA, Barcelona, Spain

BACKGROUND

- Timely, effective treatment of actinic keratoses (AKs) is important because there is no reliable way to predict which of these hyperkeratotic lesions on chronically sun-exposed skin will become cancerous.[1,2]
- AKs impact quality of life because they often occur in visible areas, primarily sun-exposed areas such as the face, scalp, and arms.[1,3,4] Patients have reported that the appearance of their AKs affects emotional and social functioning.[5]
- Considering the chronic nature of AKs, long-term achievement of treatment outcomes is important and depends on patient and clinician perceptions of the benefits and risks of treatment.[6]
- Tirbanibulin is a synthetic, first-in-class, potent anti-proliferative agent that inhibits tubulin polymerization and disrupts Src kinase signaling that are upregulated in AK and iSCC.[7] Two double-blind, vehicle-controlled, randomized Ph-3 studies, as well as supportive data from the Ph-2a study, demonstrated use of tirbanibulin ointment 1% for 5 days was safe and efficacious in the clearance of AKs.[8,9]
- Assessing clinician reported outcomes, incl. treatment effectiveness, associated with 8-week treatment course of tirbanibulin among patients with AKs in real-world setting is important to inform HCPs and Payers to aid their clinical and reimbursement decisions, respectively.

OBJECTIVE

- The objective of this analysis was to evaluate clinician satisfaction with tirbanibulin treatment's ability to improve 'how skin looks' and 'skin texture' in the treated area, among patients with Actinic Keratosis (AK) treated with tirbanibulin in community practices across the U.S.

METHODS

- A single-arm, prospective cohort study (PROAK: NCT05260073) was conducted among adult patients with AKs on the face or scalp who were newly initiated with once-daily tirbanibulin treatment (5-day course) in real-world community practices in the U.S, as part of usual care.
- A total of 300 subjects were enrolled from 32 community practices across the U.S.
  - Clinicians completed surveys and clinical assessments at baseline and Week-8 over patient's skin appearance.
  - At Week-8, clinicians reported sastifaction with the ability of tirbanibulin to 'improve how skin looks' and 'improve skin texture' for patient's skin in the tirbanibulin-treated area (compared to baseline) were individually assessed for each patient on a seven-point adjectival response scale of 1 (extremely dissatisfied) – 7 (extremely satisfied).
    - These clinician reported outcomes were analyzed descriptively using data from Week-8, for all study patients with available data, as observed.

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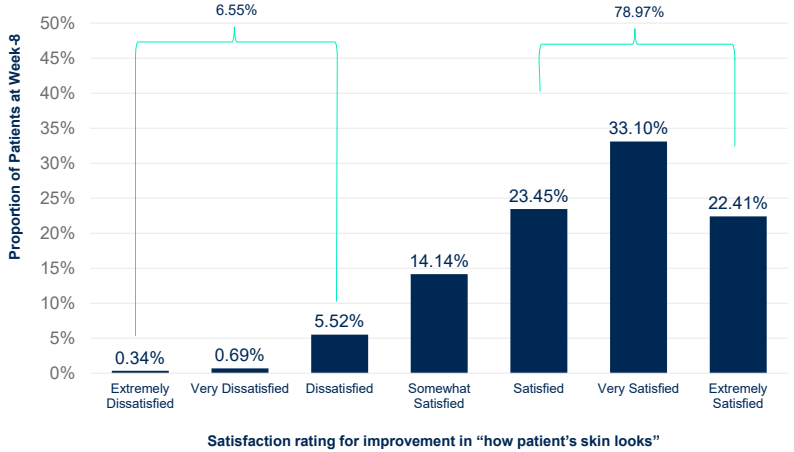
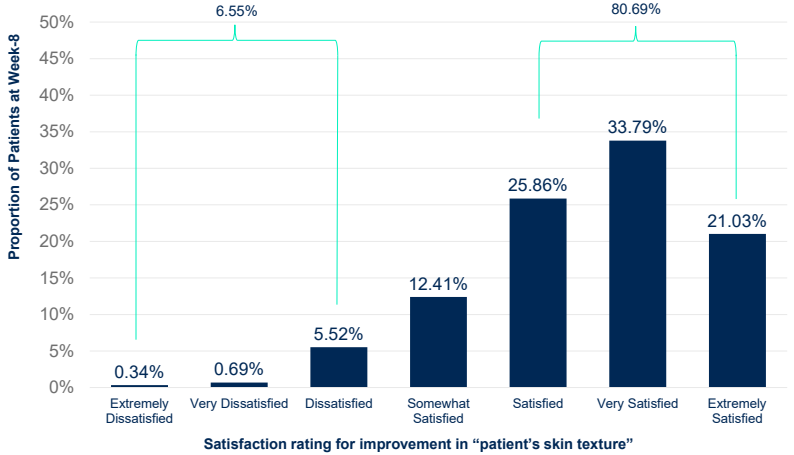
RESULTS

Figure 1: For overwhelming majority of patients, clinicians were satisfied with tirbanibulin's ability to improve "how skin looks" for their patients after the 8-week treatment course.



N=290. For 1 patient (0.34%), clinician reported 'don't know.'

Figure 2: For overwhelming majority of patients, clinicians were satisfied with tirbanibulin's ability to improve skin texture for their patients after the 8-week treatment course.



N=290. For 1 patient (0.34%), clinician reported 'don't know.'

- PROAK study (NCT05260073) was initiated in 2022, with more than 75% of the study patients treated with tirbanibulin between April and August of 2022.
- Out of 300 enrolled patients, a total of 290 patients with AKs completed the study assessments at Week-8, and hence included in the analyses.
- All patients (100%) completed their 5-day once-daily treatment course.
- Ten patients were not included in the week-8 analyses: 1 patient had missing data, and 9 patients were discontinued from the study due to patient voluntary withdrawal of consent or lost to follow-up.
- No discontinuations were related to adverse drug reactions (ADRs), and there were no Serious ADRs reported at week-8.

Table 1: Baseline Patient Characteristics

		N=290
Age, mean years [min, max]		66.30 [30.00, 90.00]
Gender, %	Female	31.38
	Male	68.62
Primary health insurance, %	Private Health Insurance	41.72
	Medicaid	3.10
	Medicare	53.79
	Uninsured	1.38
History of skin cancer, %		61.72
Fitzpatrick skin type, %	Type I	7.59
	Type II	71.38
	Type III	18.62
	Type IV	1.38
	Type V	1.03
Baseline patient self-reported skin-texture, %	Dry	39.66
	Smooth	47.59
	Rough	19.66
	Bumpy	18.62
	Scaly	35.17
	Blistering	0.34
	Peeling	6.21
Baseline severity of skin photodamage in AK affected area, %	Absent	1.03
	Mild	21.38
	Moderate	56.55
	Severe	20.34

Table 2: Site Characteristics (N=32)

Current workplace: Private, office-based practice, %	100
Total number of board-certified dermatologists in the clinic/practice, Mean	3.53
Number of patients with AKs managed by the clinic in a given month, Mean	136.34
Number of years practicing dermatology, Mean	15.66

CONCLUSIONS

- For a vast majority of patients with AKs administered once-daily tirbanibulin treatment for 5-days, clinicians reported satisfaction with tirbanibulin's ability to improve 'how skin looks' or 'skin texture' in the tirbanibulin-treated area, at Week-8.
- The demonstrated effectiveness and the safe and tolerable profile of once-daily tirbanibulin treatment highlights the benefits associated with this novel therapeutic option in routine community practice settings, for optimal management of AKs.