

IMPACT OF ACTINIC KERATOSIS (AK), AS MEASURED BY PATIENT-REPORTED AK SYMPTOMS, AND IMPACT ON EMOTIONS AND FUNCTIONING (USING SKINDEX-16) AMONG PATIENTS WITH AK ADMINISTERED TIRBANIBULIN IN REAL-WORLD COMMUNITY PRACTICES ACROSS THE U.S. (PROAK STUDY)

Leon Kircik, MD¹; Todd Schlesinger, MD²; April Armstrong, MD³; Brian Berman, MD, PhD⁴; Neal Bhatia, MD⁵; James Del Rosso, DO⁶; Mark Lebwohl, MD¹; Vishal A. Patel, MD⁷; Darrell Rigel, MD, MS¹; Siva Narayanan, PhD⁸; Volker Koscicelny, MD⁹ Ismail Kasujee PhD⁹

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

SYNOPSIS

Introduction: Actinic Keratosis (AK) has been shown to negatively affect emotional functioning and skin-related quality of life of patients¹. Impact of tirbanibulin treatment on the quality of life of patients with AKs is not adequately understood. The primary objective of the study was to evaluate patient-reported outcomes in terms of AK symptoms, and impact of AKs on emotions and functioning, among AK patients treated with tirbanibulin in community practices across the U.S. **Methods:** A single-arm, prospective cohort study (PROAK) was conducted among adult patients with AK of the face or scalp who were newly initiated with tirbanibulin treatment in real-world practices in the U.S., as part of usual care. Patients and clinicians completed surveys and clinical assessments at baseline, Week-8 (timeframe for main endpoints) and Week-24. Skindex-16, completed at baseline and Week-8, is a 16-item survey with 3 domains: symptoms (4 items), emotions (7 items) and functioning (5 items), with each domain score computed on a scale of 0 to 100 with higher score indicating severe impairment due to AKs. Changes from baseline in Skindex-16 scores were analyzed, as observed. **Results:** A total of 290 patients with AKs completed the study assessments at Week-8. Patient self-reported skin-texture at baseline was – dry: 39.66%, smooth: 47.59%, rough: 19.66%, bumpy: 18.62%, scaly: 35.17%, blistering/peeling: 6.55%. Baseline Skindex-16 domain scores were: symptoms: 22.30, emotions: 38.17, functioning: 14.41. At Week-8, a statistically significant (p<0.0001) decrease in scores from baseline was observed for all Skindex-16 domains, with Week-8 domain scores being symptoms: 8.15, emotions: 13.49, functioning: 4.63. **Conclusion:** Patients with AKs who used once-daily tirbanibulin treatment for 5-days reported a significant reduction in the symptoms and emotional/functional impact domains of Skindex-16, at Week-8.

Reference: 1. Br J Dermatol. 2013;168(2):277-283.

RESULTS

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 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

- 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.
 - Overall, in 77.93% and 33.79% of study patients (not mutually exclusive), AK lesions on their face and scalp respectively were treated with tirbanibulin.
 - 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 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

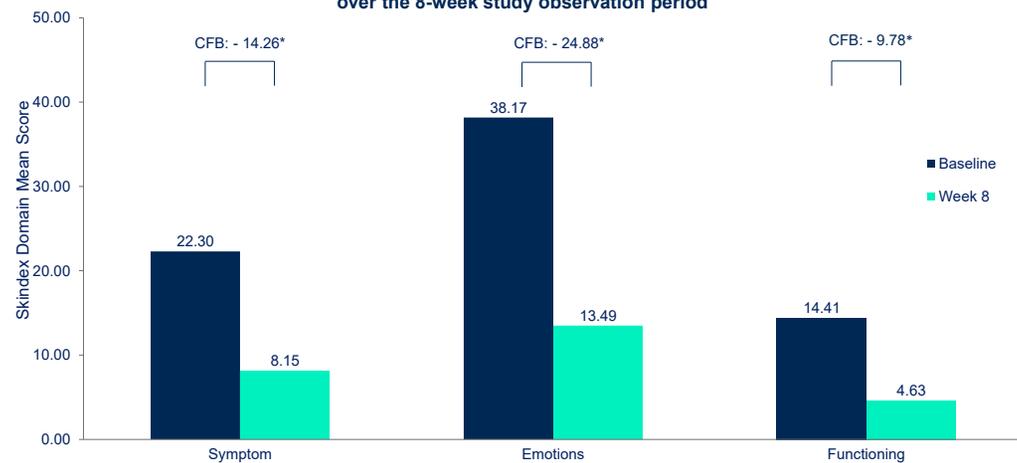
OBJECTIVE

- The primary objective of the study was to evaluate patient-reported outcomes in terms of AK symptoms, and impact of AKs on emotions and functioning, among AK patients treated with tirbanibulin in community practices across the U.S.

METHODS

- A single-arm, prospective cohort study (PROAK) 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.
 - Patients and clinicians completed surveys and clinical assessments at baseline, week-8 (timeframe for main endpoints) and week-24, concerning safety and effectiveness of tirbanibulin.
 - Skindex-16, a validated PRO instrument, was completed by patients at baseline and Week-8.
 - This 16-item survey has 3 domains, namely, symptom domain (4 items), emotions domain (7 items) and functioning domain (5 items).
 - All items are scored on a seven-point adjectival response scale, with a potential score of 0 (never bothered) to 6 (always bothered).
 - Each domain score is individually computed on a scale of 0 to 100 with higher score indicating severe impairment due to AKs.
- Changes from baseline in Skindex-16 domain scores at week-8 were analyzed, as observed.

Figure 1: Mean Skindex-16 domain scores significantly decreased over the 8-week study observation period



N= 290; one & four patients had missing data at baseline for Symptom & Emotions domain respectively; one patient had missing data at week-8 for Emotions domain. CFB: Change from baseline to Week-12. *P <0.0001

CONCLUSIONS

- Within the study cohort of adult patients with AKs administered once-daily tirbanibulin treatment for 5-days as part of usual care, a significant reduction in AK burden was observed, as indicated by the improvement in AK symptoms and emotional/functional impact (using Skindex-16), 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.