INVESTIGATOR GLOBAL ASSESSMENT (IGA) OF ACTINIC KERATOSIS (AK) AMONG PATIENTS ADMINISTERED TIRBANIBULIN IN REAL-WORLD COMMUNITY PRACTICES ACROSS THE U.S., AND CLINICIAN LIKELIHOOD TO CONSIDER TIRBANIBULIN AGAIN FOR FUTURE AK TREATMENTS (PROAK STUDY)

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SYNOPSIS

Introduction: Actinic Keratosis (AK) are epidermal lesions with potential to progress to squamous cell carcinomas if left untreated.[1] AKs have also been shown to negatively affect emotional functioning and skin-related quality of life of patients.[2] The primary objective of the analysis was to evaluate IGA success at Week-8, and clinician-reported likelihood to consider tirbanibulin again for future treatments, among patients with AKs administered 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 tirbanibulin treatment in real-world community 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. Clinicians assessed AK responses using an IGA on a five-point adjectival response scale of 0 (completely cleared), 1 (partially cleared), 2 (moderately cleared), 3 (minimally cleared) and 4 (not cleared). IGA success was defined as achieving an IGA score of 0 or 1 at Week-8. Clinicians also reported their likelihood to reuse tirbanibulin treatment for their patients, as a surrogate measure of satisfaction with the treatment. **Results:** A total of 290 AK patients completed the study assessments at Week-8. At Week-8, proportion of patients with completely/partially cleared AK (approximately 75-100% clearance of AK lesions in the treated area, IGA 1/0) was 73.79%; moderately cleared (IGA 2) was 17.24%, and minimally cleared/not cleared (IGA 3/4) was 8.97%. Correspondingly, IGA success in this cohort of patients treated with tirbanibulin was 73.79%. Proportion of patients for whom clinicians noted that they would 'somewhat or very likely' consider tirbanibulin treatment again, if need arises, was 85.17%, with 7.59% reporting a neutral response, and 7.24% reporting 'somewhat or very unlikely' to consider treatment with tirbanibulin again. **Conclusion:** The majority of patients with AKs using tirbanibulin experienced IGA success at Week-8, and a majority of clinicians reported their desire to consider tirbanibulin again to treat AK lesions for their patients.

References: 1. J Drugs Dermatol. 2021;20(8):888-893; 2. Br J Dermatol. 2013;168(2):277-283.

OBJECTIVE

- The primary objective of the analysis was to evaluate IGA success at Week-8, and clinician-reported likelihood to consider tirbanibulin again for future treatments, among patients with AKs administered 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.
  - At week-8, clinicians assessed AK responses (compared to baseline) using an IGA on a five-point adjectival response scale, as follows:
    - 0 (completely cleared), 1 (partially cleared), 2 (moderately cleared), 3 (minimally cleared) and 4 (not cleared).
    - IGA success was defined as achieving an IGA score of 0 or 1 at week-8.
  - At week-8, Clinicians reported their likelihood to consider tirbanibulin again (for each of their patients) if need arises in the future, on a five-point adjectival response scale, as follows:
    - 1 (very unlikely), 2(somewhat unlikely), 3 (neutral), 4 (somewhat likely), 5 (very likely).
- IGA, IGA success, and clinician-reported 'likelihood to consider tirbanibulin again' were analyzed 'as observed', using week-8 data.

RESULTS

- 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.

Figure 1: Majority of patients who were administered tirbanibulin at baseline achieved IGA success at week-8

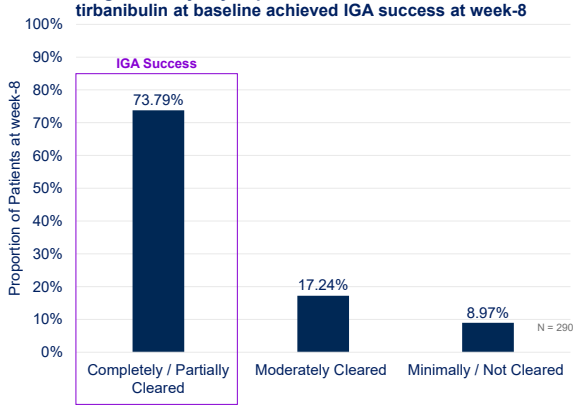

Figure 2: For majority of patients, clinicians reported their desire to consider tirbanibulin again

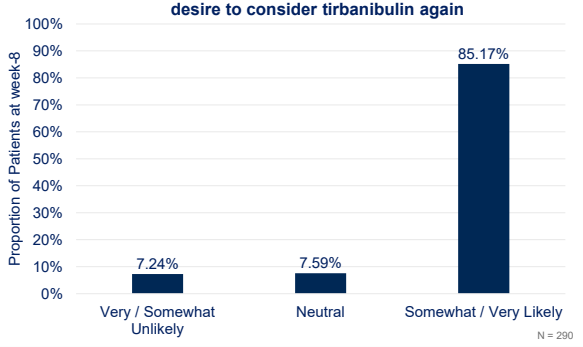

Table 1: Baseline Patient Characteristics

		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

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

- Within the study cohort of adult patients with AKs administered once-daily tirbanibulin treatment for 5-days as part of usual care, a majority of patients (73.79%) with AKs experienced IGA success at Week-8.
- For majority of patients (85.17%), clinicians reported their desire to consider tirbanibulin again to treat AK lesions, if need arises.
- The demonstrated effectiveness and the safe and tolerable profile of once-daily tirbanibulin treatment, and the associated clinician willingness to reconsider tirbanibulin treatment for their patients in the future, highlights the benefits associated with this novel therapeutic option for optimal management of AKs.

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