Patient- and clinician-reported outcomes of tirbanibulin 1% in the treatment of actinic keratosis on the face and scalp (PROAK study)

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Synopsis

- Actinic Keratosis (AK) has been shown to negatively affect emotional and social functioning and skin-related quality of life of patients.[1]

Objective

- The objective of this analysis was to evaluate clinician- and patient-reported outcomes (ClinRO; PRO) for tirbanibulin treatment satisfaction and effectiveness among patients administered tirbanibulin in routine clinical practice across the U.S.

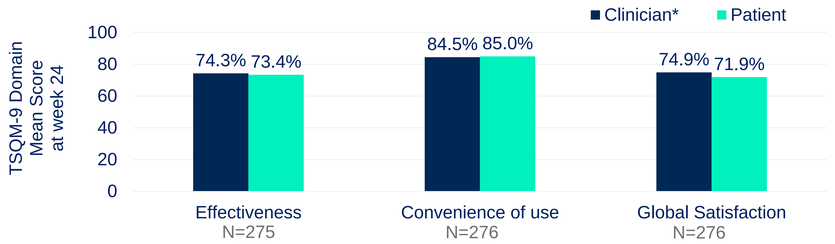
Methods

- A single-arm, multicenter, prospective cohort study (PROAK: NCT05260073) was conducted in adult patients with AKs on 25 cm^2 on the face or scalp and treated with once-daily tirbanibulin 1% ointment (5 consecutive days course) as part of usual care.
- Patients and clinicians completed surveys and clinical assessments at baseline, Week-8, and Week-24.
- ClinRO and PRO comprised:
  - **Treatment Satisfaction Questionnaire for Medication (TSQM-9)** (with 3 domains: treatment effectiveness, convenience of use, and global satisfaction with treatment)
  - **Expert Panel Questionnaire (EPQ)** (assessing overall skin appearance, satisfaction with improvement in “skin texture” and “how skin looks”, and likelihood to consider tirbanibulin again).
- Clinicians assessed AK responses using **Investigator's Global Assessment (IGA)** and patient’s **skin photodamage severity scale**. IGA success was defined as achieving IGA score of 0-1 (≥75% AK lesions clearance).
- Data at Week-8 was already published.[1] Here we present the results at Week-24.

Results

- A total of 278 patients completed study assessments at Week-24 (mean age: 66.3 years; 68.6% males; Fitzpatrick skin type II: 71.4%).
- At Week-24, clinicians and patients reported similar, high levels of tirbanibulin treatment satisfaction for the 3 domains of TSQM-9 (**Figure 1**).
- At Week-24, clinicians and patients reported a high levels of satisfaction with tirbanibulin treatment to improve ‘how skin looks’ and ‘skin texture’ (**Figure 2**), and high likelihood for considering tirbanibulin treatment in the future (**Figure 3**).
- At Week-24, 83.6% of clinicians and 78.5% of patients rated overall skin appearance after tirbanibulin treatment to be mostly somewhat/much improved.
- At Week-24, the proportion of patients with completely/partially cleared AK (IGA 0/1) was 71.9% (**Figure 4**), like that obtained at Week-8 (73.8%).[1]
- Moderate/severe skin photodamage improved from 76.9% patients at baseline to 42.1% of patients at week-24. The reduction of skin photodamage severity at week-24 measured by changes from baseline was statistically significant (p<0.0001).

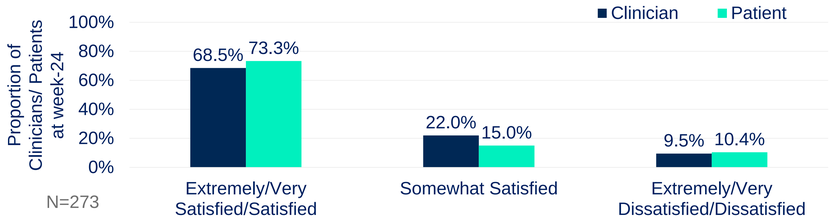
Figure 1. Satisfaction across the key tirbanibulin treatment attributes, at week-24



*adapted from patient-version of TSQM-9

Figure 2. Satisfaction rating for improvement in “how skin looks” and “skin texture”

A. “How skin looks”



B. “Skin texture”

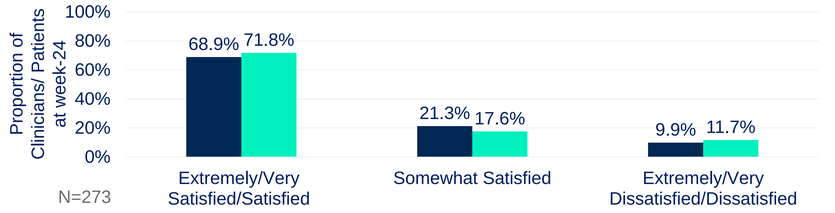


Figure 3. Likelihood to consider tirbanibulin to treat AK lesions in future

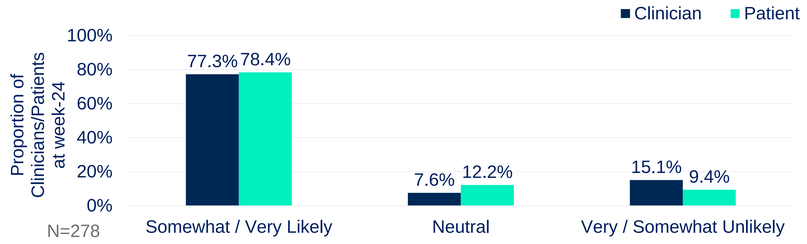
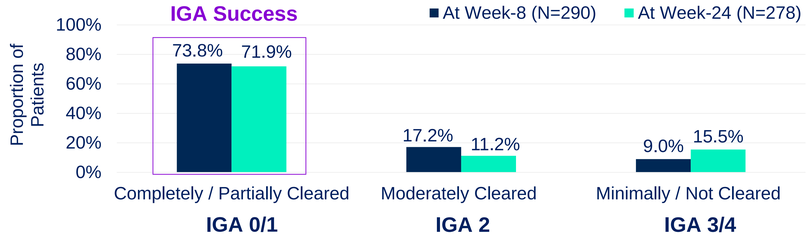


Figure 4. Clinician-reported overall improvement in Actinic Keratosis



Conclusion

- **In real world, AK lesion clearance ≥75% (effectiveness) was stable over time (same in Week-8 [73.8% patients] and Week-24 [71.9% patients]).**
- **ClinROs and PROs demonstrated high satisfaction with once-daily tirbanibulin treatment for 5 consecutive days at Week-24, and both clinicians and patients reported a desire to consider tirbanibulin treatment in the future.**

References

[1]Schlesinger T et al. Skin. 2023;7(3):771-787

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Conflicts of interest

TS: consulting honoraria from Abbvie, Allergan, Almirall, Arcutis, Biofrontera, BMS, Castle Bioscience, CMS Aesthetics DCME, EPI Health, Foundation for Research and Education in Dermatology, Galderma, Genentech, Kintor, Lilly, Merz, Nextphase, Novartis, Ortho Dermatologics, Pharmatecture, Pierre Fabre, Plasmed, Prolacta Bioscience, Pulse Biosciences, Regeneron, Skinceuticals/L'Oreal, RBC Consultants, Sun Pharma, UCB, and Verrica. Grant/Research funding from Abbvie, Aclaris, Allergan, Amgen, Anterios, AO Biome, Arcutis Premier Research, ASLAN, Astellas Pharma US, Athenex, Biofrontera, Biorasi, Boehringer Ingelheim, Brickell Biotech, BMS, Cara Therapeutics, Castle Bioscience, Celgene, Chemocentryx, Coherus Bioscience, Concert Pharmaceutical, Corrona, Cutanea Life Sciences, Dermavant, Dermira, DT Pharmacy & DT Collagen, EPI Health, Galderma, Janssen, Kiniksa, Leo, Lilly, Merz, Nestle, Nimbus, Novartis, Pfizer, Processa, Pulse Biosciences, Regeneron, Sanofi Genzyme, Sisaf, Trevi, and Verrica. Speakers' Bureau/Advisory Board honoraria from Abbvie, Almirall, Amgen, Arcutis, Bioderma, BMS Biofrontera, Celgene, DUSA/Sun Pharma, EPI Health, Leo, Lilly, Regeneron, Remedly, Sanofi Genzyme, and Sun Pharma. Owns stock from Amgen, BMS, Lilly, and Remedly. **JDR**: researcher, consultant, and speaker for Almirall. **VAP**: speakers bureau for Regeneron, advisory board/consultant for Regeneron, Almirall, PhD Biosciences, Castle Biosciences, and shareholder for Science 37, Avestra. **LK**: has served as an investigator, speaker, advisory board member, or consultant for Abbott Laboratories, Aclaris, Inc, Allergan, Inc, Almirall, Anacor Pharmaceuticals, Inc, Assos Pharma, Astellas Pharma US, Inc, Asubio Pharma Co, Ltd, Berlex Laboratories (Bayer Healthcare Pharmaceuticals), Biogen-Idec, Inc, Biolife, Biopelle, Boehringer Ingelheim, Breckinridge Pharma, Celgene Corporation, Centocor, Inc, Colbar, CollaGenex, Combinatrix, Connetics Corporation, Coria, Dermik Laboratories, Dermira, Inc, Dow Pharmaceutical Sciences, Inc, Dusa Pharmaceuticals, Inc, Eli Lilly & Co, Embil Pharmaceutical Co, Ltd, EOS, Ferndale Laboratories, Inc, Galderma Laboratories, LP, Genentech, Inc, GlaxoSmithKline, PLC, Health Point Ltd, Idera, Inc, Innocutis Medical, LLC, Innovail, Intendis, Inc, Johnson & Johnson, Laboratory Skin Care, Inc, Leo Pharmaceuticals, Inc, L'Oreal SA, 3M, Maruho Co, Ltd, Medical International Technologies, Medicis Pharmaceutical Corp, Merck & Co, Inc, Merz, Nano Bio Corporation, Novartis Pharmaceutical Corporation, Noven Pharmaceuticals, Inc, Nucryst Pharmaceuticals Corporation, Obagi Medical Products, Inc, Onset, Ortho Dermatologics, OrthoNeutrogena, PediaPharma, Inc, Promius Pharma, LLC, PharmaDerm, Pfizer, Inc, PuraCap, QLT, Inc, Quatrix, Quinnova, Serono (Merck-Serono International SA), SkinMedica, Inc, Stiefel Laboratories, Inc, Sun Pharmaceutical Industries, Ltd, Taro, TolerRx, Inc, Triax, UCB, Inc, Valeant Pharmaceuticals North America LLC, Warner-Chilcott, XenoPort, Inc, and ZAGE. **AA**: served as a research investigator and/or scientific adviser to AbbVie, BI, BMS, EPI, Incyte, LEO, UCB, Janssen, Lilly, Novartis, Ortho Dermatologics, Sun, Dermavant, Dermira, Sanofi, Regeneron, and Pfizer. **BB**: consulting honoraria from Almirall, Biofrontera, BMS, Pfizer, Evommune, Aiviva, Sirnaomics, Pulse, Mediwound, BPGBio, Lemonex and Minolabs. **NB**: consulting honoraria from and investigator for Almirall, Biofrontera, Leo, Ortho, and Sun Pharma. **ML**: research funds from: Abbvie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Cara therapeutics, Dermavant Sciences, Eli Lilly, Incyte, Janssen Research & Development, LLC, Ortho Dermatologics, Regeneron, and UCB, Inc.Consultant for Aditum Bio, Almirall, AltruBio Inc., AnaptysBio, Arcutis, Inc., Aristea Therapeutics, Avotres Therapeutics, Brickell Biotech, Boehringer-Ingelheim, Bristol-Myers Squibb, Cara Therapeutics, Castle Biosciences, Celltrion, Corevitas, Dermavant Sciences, Dr. Reddy, EPI, Evommune, Inc., Facilitatation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Galderma, Helsinn, Incyte, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Seanergy, Strata, Trevi, and Verrica. **DR**: has served as a consultant for Almirall, Castle BioSciences, DermTech, and SciBase. **SN**: consulting honararia or research funding from Almirall, Biogen, Johnson and Johnson, Sarepta Therapeutics, SeaGen, and Takeda. **VK** and **IK**: Almirall employees.