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Patient-Reported Outcomes for Tirbanibulin Effectiveness and Safety in Actinic Keratosis in Real-world Settings: PROAK Study Protocol

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Acknowledgments: This study is supported by Almirall, LLC. Medical writing, editorial assistance, and graphical support for this poster were provided under the direction of the authors by MedThink SciCom and funded by Almirall, LLC.

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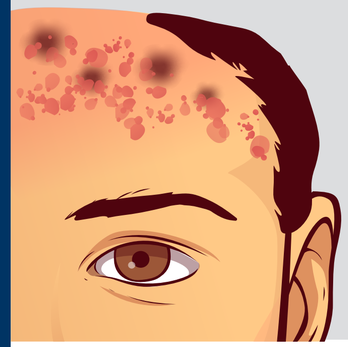
Disclosures: BB has served as an investigator, speaker, advisory board member, or consultant for Aclaris, Almirall, AiViva Biopharma, Biofrontera, Evommune, Ferndale Laboratories, Inc, Galderma Laboratories, L.P., GlaxoSmithKline, Leo Pharma, Mediwound, Mino Labs, Miragen, NOVAN, Novartis Pharmaceuticals Corp., Pierre Fabre, PHD Biosciences, Pulse Biosciences, Sensus, Sirnaomics. **AA** served as a research investigator and/or scientific advisor to AbbVie, BI, BMS, EPI, Incyte, Leo, UCB, Janssen, Lilly, Novartis, Ortho Dermatologics, Sun, Dermavant, Dermira, Sanofi, Regeneron, and Pfizer. **ML** receives research funding from Abbvie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Dermavant Sciences, Eli Lilly, Incyte, Janssen Research & Development, LLC, Ortho Dermatologics, Regeneron, and UCB, Inc., and is a consultant for Aditum Bio, Almirall, AltruBio Inc., AnaptysBio, Arcutis, Inc., Aristea Therapeutics, Arrive Technologies, Avotres Therapeutics, BiomX, Boehringer-Ingelheim, Bristol-Myers Squibb, Cara Therapeutics, Castle Biosciences, Corrona, Dermavant Sciences, Dr. Reddy's Laboratories, Evelo Biosciences, Evommune, Inc., Facilitation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Helsinn Therapeutics, Hexima Ltd., LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Seanergy, and Verrica. **AG** was the Head of R&D and Medical Affairs at Almirall, US. **NB** has been an investigator for Sun Pharma., J&J, Amgen, Arcutis, BMS, Atacama Therapeutics, Abbvie, UCB, MC2 Therapeutics, Foamix, Sanofi/Regeneron, Dermira, Brickell Biotech, Soligenix, Sol-Gel Tech., Pfizer, Menlo Therapeutics, DUSA Pharma, LEO Pharma US; **NB** has also been a consultant for: Ferndale Laboratories, Biofrontera AG, Almirall, Sun Pharmaceutical Industries, La Roche-Posay, Mayne Pharma Group, Ortho Derm., Sanofi/Regeneron, ISDIN, Galderma Laboratories, Vyome Therapeutics Limited, EPI Health, Dermavant Sciences, DermTech Inc, Sonoma Pharm, Castle Biosciences; he has also been paid on the Advisory Board for Dr. Reddy's. **VAP** has received honoraria from Regeneron and Almirall; has served as a consultant for PhD Biosciences and Jounce Therapeutics; and has served as a speaker for Regeneron and Sanofi. **DR** has no disclosures to provide. **JDR** has served as a research investigator, consultant/advisor, or speaker for AbbVie, Aclaris, Almirall, Amgen (Celgene), AnaptysBio, Arcutis, Athenex, Bausch (Ortho Dermatology), Biofrontera, BioPharmX, Biorasi, Blue Creek, Botanix, Brickell, Bristol Myers Squibb, Cara Therapeutics, Cassiopea, Dermata, Dermavant, Encore, EPI Health, Ferndale, Galderma, Genentech, Incyte, Jem Health, LEO Pharma, La Roche-Posay, Lilly (Dermira), MC2, NOVAN, Pfizer, Ralexar, Regeneron, Sanofi-Genzyme, Sente, Solgel, Sonoma (Intraderm) Sun Pharma, UCB, Verrica, and VYNE (Foamix/Menlo). **TS** reports receiving grant/research funding from AbbVie, Aclaris, Allergan, Anterios, AOBiome, Arcutis Premier Research, Astellas Pharma US, Inc, Athenex, Biofrontera, Biorasi, Boehringer Ingelheim, Brickell Biotech, Bristol-Myers Squibb, Cara Therapeutics, Castle BioScience, Celgene, Centocor Ortho Biotech (Now Janssen Biotech), ChemoCentryx, Coherus Biosciences, Concert Pharmaceutical, Corrona, Cutanea Life Sciences, Dermavant, Dermira, DT Pharmacy & DT Collagen (Melasma), EPI Health, Galderma (Nestle), Janssen Pharmaceuticals, Inc, Kiniksa, Leo, Lilly, Merz, Nestle Skin Health, Nimbus, Novartis, Pfizer, Processa, Pulse Biosciences, Regeneron, Sanofi Genzyme, Sisaf, and Trevi; has received honoraria from AbbVie, Allergen, Almirall, Biofrontera AG, Bristol-Myers Squibb, Castle BioScience, EPI Health, Foundation for Research and Education in Dermatology (FRED), Galderma (Nestle), Merz, Novartis, Regeneron, and Sun Pharma; and has served as a speaker, advisory board member, or consultant for AbbVie, Allergan, Almirall, Amgen, Biofrontera AG, Bristol-Meyers Squibb, Castle BioScience, Celgene, CMS Aesthetics DCME, DUSA Sun Pharma, EPI Health, Foundation for Research and Education in Dermatology (FRED), Genentech, Greenway Therapeutix, Kintor, Merz, Nextphase, Novartis, Pharmatecture, Prolacta Biosciences, Pulse Biosciences, Regeneron, Remedy, Inc, Sanofi Genzyme, Sun Pharma, UCB, and Verrica; has received consulting fees from Lilly, Ortho Dermatologics, Pierre Fabre, Plasmed, Regeneron, and Skinceuticals/L'Oreal; has been involved in the CME Program for MED Learning Group; has been involved with OncLive SSC Insights Filming/Stacy Jaffe for MJH Associates; and owns stock in Remedy, Inc. **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; Qustrix; 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. **RS** is an employee of Almirall, US. **IK** is an employee of Almirall, Spain.



INTRODUCTION

- Actinic keratosis (AK) lesions occur primarily on visible, sun-exposed areas such as the face and scalp and may negatively affect health-related quality of life (HRQoL)
- Common treatments are also associated with severe local skin reactions (LSRs)[1,2] that may further impact HRQoL and treatment adherence[2-5]
- Therefore, it is vital to consider patient experiences and preferences when weighing treatment options
- Tirbanibulin demonstrated safety and efficacy in treating AK in phase 3 clinical trials[6]
- In 2021, a consensus meeting generated an AK-specific expert panel questionnaire (EPQ), which includes questions about skin appearance, LSRs, and treatment satisfaction, to complement the validated Skindex-16 and treatment satisfaction questionnaire for medicine (TSQM-9) tools
- Here we describe the protocol for the Patient-Reported Outcomes for Actinic Keratosis (PROAK) study

OBJECTIVE

- To assess the impact of tirbanibulin on patient-reported outcomes for patients with AK in real-world settings

CONCLUSIONS

- The real-world PROAK study will gather insights into patient experiences with tirbanibulin as a treatment for AK using validated health-related PRO measures and a recently developed EPQ
- This new EPQ was developed to capture disease-specific patient perspectives and meaningful outcomes to patients that may not be fully reflected in existing questionnaires

DESIGN

- This a prospective cohort study enrolling 300 participants ≥18 years with AK on the face or scalp treated with tirbanibulin 1% ointment from 50 community practices across the United States (Figure 1)

Patient inclusion criteria

- Diagnosed with AK of the face and scalp
- Has clinically typical, visible, and discrete AK lesions
- Considered as a potential candidate for tirbanibulin treatment to manage their AK
- Male or female, aged 18 years and above at the time of initiation of treatment with tirbanibulin
- Willing to avoid excessive sun or UV exposure and/or use relevant sunscreen protection and protective clothing during the study duration
- Able to read and write English
- Provide consent to participate in the study

Key exclusion criteria

- Patients with any dermatological condition of the face or scalp that could interfere with the clinical evaluations
- Hypertrophic AK lesions, open wounds, or suspected skin cancers within close proximity of the treatment area

Assessments

- The primary endpoint is patient-reported outcomes at week 8 assessed by Skindex-16, with additional endpoints described in Figure 2
- Recognizing the need for an AK-specific patient-reported outcome (PRO) instrument, the EPQ (Figure 3) was developed during a consensus advisory board held in 2021; after discussion of proposed questions, revisions were made and consensus on all items was reached by all 9 advisers
- LSRs will be documented by clinicians and, in a subset of sites, will be photographed and have severity graded by clinicians; this subset of patients will also be asked to record a 1- to 3-minute audio narrating their experience with treatment
- Tirbanibulin safety and tolerability will be monitored throughout the study

Figure 1. PROAK study design. AK, actinic keratosis; EPQ, expert panel questionnaire; PRO, patient-reported outcome.

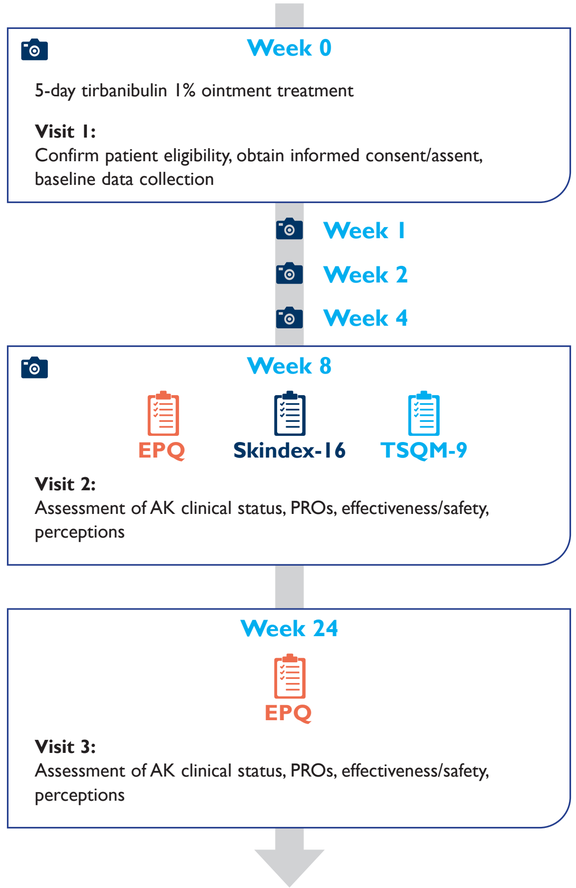


Figure 2. Comparison of questionnaires used to assess outcomes.

Skindex-16
Number of items: 16
6-point scale (never bothered to always bothered)
- Signs and symptoms (itching, burning, hurting, irritation, persistence/recurrence, appearance)
- Emotional impact (worry about condition, frustration, embarrassment, being annoyed, feeling depressed)
- Impact on interactions with others, desire to be with people, showing affection, daily activities, work or other activities

TSQM-9
Number of items: 9
7-point scale (extremely dissatisfied to extremely satisfied) or 5-point (not at all confident to extremely confident) scales
- Prevent/treat condition and relieve symptoms
- Time to treatment effect
- Convenience and ease of use
- Treatment satisfaction
- Confidence in benefits of treatment

TSQM, treatment satisfaction questionnaire for medicine.

Figure 3. Actinic keratosis–specific questionnaire.

EPQ
Number of items: 11
Consensus reached by 9/9 advisers

Patient-reported	
1. Overall appearance	(5-pt scale: much worse to much improved)
2. Satisfaction with improvement in appearance	(7-pt scale: extremely dissatisfied to extremely satisfied)
3. Satisfaction with improvement in texture	
4. Satisfaction with duration of skin reactions	(5-pt scale: much shorter to much longer)
5. Severity of skin reactions compared to previous treatment	(5-pt scale: much better with tirbanibulin to much worse with tirbanibulin
6. Impact on daily activities compared to previous treatment	
7. Convenience and ease of use	
8. Overall satisfaction	
9. Likelihood of retreating with tirbanibulin	(5-pt scale: very unlikely to very likely)
Clinician-reported	
10. Overall improvement in AK	(5-pt scale: not cleared to completely cleared)
11. Severity of photodamage in treated area	(4-pt scale: absent to severe)

AK, actinic keratosis; EPQ, expert panel questionnaire.