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Relating patient-reported treatment satisfaction and clinical outcomes in post-registration studies of tirbanibulin for actinic keratosis

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Introduction & Objectives: Expert guidance on the treatment of AKs acknowledges the importance of patient satisfaction and its impact on adherence to therapy [1-3]. However, there is little information relating physicians' evaluations of actinic keratosis (AK) treatment success with patient-reported outcomes (PROs).

Materials & Methods: Clinician assessments of complete (100%) and partial ($\geq 75\%$ to $< 100\%$) clearance of lesions and PROs were collected in two post-registration studies of tirbanibulin in patients with AK on the face or scalp. PROAK (NCT05260073) [4] was a single-arm multicenter, prospective cohort study that included adult patients (N=278 evaluable) with AK on the face or scalp treated with tirbanibulin in community practices in the United States as part of usual care. TirbaSkin (EU2022-001251-16) was an open phase IV multicenter, single-cohort, low-interventional clinical trial of tirbanibulin in adult patients (N=328 evaluable) with AK on the face or scalp from Spain or Italy [5]. In both PROAK and TirbaSkin, patients applied tirbanibulin once daily for 5 days to an area of up to 25 cm² according to instructions in the prescribing information. Patients also completed the Treatment Satisfaction Questionnaire for Medication-9 (TSQM-9) at 8 weeks.

Results: Results from the two studies were combined (N=606 evaluable) for the current analysis. $\geq 75\%$ of clearance was achieved in 75.1% of patients. Pooled TSQM-9 scores for Effectiveness, Convenience, and Global Satisfaction domains at week 8 (score range = 0-100) were 74.9, 83.9, and 78.8, respectively.

Conclusion: Results from this combined analysis of results from PROAK and TirbaSkin indicated that the high AK clearance rate achieved with tirbanibulin was associated with corresponding high scores for all domains of the TSQM-9.

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