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Tirbanibulin Ointment 1% over a Treatment Field up to 100 cm2 in Actinic Keratosis: A Phase 3 Study

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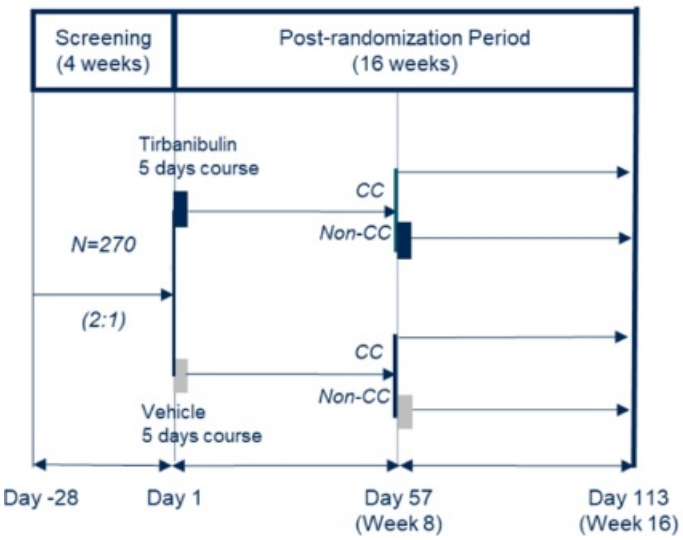
Introduction & Objectives: Actinic keratosis (AK) is a pre-cancerous skin disease resulting from the atypical proliferation of keratinocytes that may progress to invasive squamous cell carcinoma. Tirbanibulin 1% ointment is approved for treating AK on the face or scalp in Europe over a field up to 25 cm2, and in the United States over a field up to 100 cm2.

Materials & Methods: This is a Phase 3, multicentre, randomised, double-blind, vehicle-controlled, parallel-group study (EudraCT: 2023-505487-11-00) to evaluate the efficacy and safety of tirbanibulin 10 mg/g ointment applied to a treatment field (TF) larger than 25 cm2 and up to 100 cm2, containing ≥4 to ≤12 clinically typical, visible, and discrete AK lesions, in adult patients with AK on the face or the balding scalp. At baseline, eligible patients were randomized in a 2:1 ratio to either tirbanibulin 10 mg/g ointment or vehicle; the randomisation was stratified by the number of lesions at baseline (≥4 to ≤8, >8 to ≤12), treatment location (face or scalp), and country. Patients applied tirbanibulin 10 mg/g ointment or vehicle once daily for 5 days. All patients were evaluated for efficacy, safety, and tolerability at Days 8, 15, 29, and 57. Those patients who did not achieve complete clearance (CC) at Day 57 received a second 5-day course of the randomised treatment. Patients receiving a second treatment course were also evaluated for efficacy, safety, and tolerability at Days 64, 71, 85 and 113.

Results: Primary endpoint is percent change from baseline (CFB) in lesion count at Day 57. Moreover, proportion of patients with partial clearance (PC), defined as ≥75% clearance in the TF, proportion of patients with CC, defined as 100% clearance in the TF, CFB in Skindex-16, cosmetic outcome assessed by patient and by the investigator, and Treatment Satisfaction Questionnaire for Medications (TSQM-1.4) transformed score at Day 57 and, for patient who received 2 treatment courses were assessed, at Day 113 as well. Tolerability assessments include local tolerability score (0-3), maximum (max) local tolerability score, local tolerability signs (LTS) composite score (0-18), and changes in pigmentation and scarring by treatment course and visit. Safety assessments include adverse events (AEs), serious AEs, AEs of special interest, abnormalities in clinical laboratory results and vital signs. Results to be disclosed in the poster.

Conclusion: The aim of this study is to evaluate the efficacy, safety, and tolerability of tirbanibulin 10 mg/g ointment, compared to vehicle, in adult patients with AK on the face or scalp in a field larger than 25 cm2 and up to approximately 100 cm2, as well as examining the effects of up to two 5-day treatment courses.

Figure 1 Study Design



CC, complete clearance; PC, partial clearance.