**IMPACT OF PRIOR TREATMENT IN THE EFFICACY AND TOLERABILITY OF TIRBANIBULIN OINTMENT 1% FOR ACTINIC KERATOSIS: POOLED RESULTS FROM TWO PHASE 3 STUDIES**

**SYNOPSIS**

- Tirbanibulin was evaluated as a field treatment for actinic keratosis (AK) of face or scalp in two Phase 3, randomized, double-blind, vehicle-controlled studies (NCT03285477, NCT03285490).
- Pooled data showed complete (100%) clearance and partial (75%) clearance (PCI) rates of 49% and 72% for tirbanibulin-treated versus 16% and 8% for treatment-vehicle, respectively.
- Local skin reactions (LSR) were mostly mild-to-moderate, with the mean standard deviation (SD) maximum LSR seventy composite score being 4.4±2.2 for tirbanibulin-treated and 1.6±1.4 for vehicle-treated participants.

**OBJECTIVE**

- This post-hoc analysis of the pooled Phase 3 data assessed efficacy and tolerability according to prior AK treatment in the target area.

**METHODS**

- In the Phase 3 trials, patients with 4-8 clinically visible AK lesions in a 25 cm² area were randomized 1:1 to tirbanibulin ointment 1% or vehicle (once-daily, 5 consecutive days, self-application). The study design is shown in Figure 1.

**RESULTS**

- **Table 1. Baseline Characteristics**
  - Pooled pretreated participants were 130/353 (37%) of those randomized to tirbanibulin and 141/349 (40%) of those randomized to vehicle.
  - Of tirbanibulin-pretreated participants, 91/130 (70%) had received cryosurgery and 45/130 (35%) topicals in the same treatment area (22 in each group had both).
  - There were no major differences in the baseline characteristics between pretreated and non-pretreated participants. Baseline characteristics are shown in Table 1.

- **Figure 2. Complete and partial clearance rates of AK lesions at D57**
  - Overall pretreated (N=114; [t=130/v=141] = 1.2 ± 1.8)
  - Cryosurgery-pretreated (N=114; [t=91/v=114] = 1.4 ± 1.5)
  - Topical-pretreated (N=50; [t=39/v=39] = 1.5 ± 1.8)
  - Non-pretreated (N=220; [t=180/v=180] = 1.5 ± 1.4

**CONCLUSIONS**

- Compared to pooled Phase 3 trials, in this post-hoc analysis the efficacy of tirbanibulin in pretreated areas was similar, and there were no differences in tolerability in terms of LSR.
- Although sample sizes were limited and statistical significance was not tested, results show that tirbanibulin has a favorable safety/efficacy profile to be used either as first-line or after other treatments, and warrant further research on the most suitable treatment sequence in individuals with AK.

**ACKNOWLEDGEMENTS**

**REFERENCES**


**CONFLICTS OF INTEREST**

Tirbanibulin has been and is being developed through collaboration with biotechnological companies, laboratories, and their representatives. The authors declare no professional or educational relationships with any of the companies, biotechnology firms, or intellectual property holders.

**Figure 1. Design of Phase 3 studies**

- **Table 2. Time (months) since previous treatment**
  - No complete clearance
  - Complete clearance
  - Overall

- **Table 3. Highest mean LSR composite score from Baseline to D57**
  - Mean ± SD
  - t = 91, v = 114
  - t = 39, v = 39
  - t = 180, v = 180

- **Figure 2. Complete and partial clearance rates of AK lesions at D57**

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- **METHODS**

- **RESULTS**

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- **ACKNOWLEDGEMENTS**

- **REFERENCES**

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