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**Safety and tolerability of tirbanibulin for the treatment of actinic keratosis: Results from clinical trials and post-registration**

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**Introduction & Objectives:** Broadening the understanding of the safety for medications, including those employed for actinic keratosis (AK) treatment, requires information from large cohorts [1]. Comparing safety and tolerability from clinical trials vs those in clinical practice is important because of restrictive entry criteria and limitations on concomitant medications in controlled clinical trials [2].

**Materials & Methods:** Information regarding safety and tolerability of tirbanibulin 1% ointment has been obtained in (i) three phase III trials, in two tirbanibulin was applied to an area of 25 cm2 (NCT03285477, NCT03285490) [3] and in one, to an area of 100 cm2 (NCT05279131) [4] (N=458 total patients), (ii) one open phase IV multicenter, single-cohort, low-interventional study (TirbaSkin [EU2022-001251-16] [5], N=334) and (iii) two real-world/low interventional studies, KLIR (DRKS00027120) [6] (N=543) and PROAK (NCT05260073) [7] (N=300), in which tirbanibulin was applied to an area of 25 cm2. In all studies, tirbanibulin was applied once daily for 5 days according to the prescribing information.

**Results:** Combined results for 1,635 tirbanibulin-treated patients indicated that 19.6% had adverse events (AEs, all causality, application site and systemic) and 12.8% had AEs possibly related to tirbanibulin. Serious AEs were reported for 0.8% and severe AEs for 0.4%. AEs leading to drug or study discontinuation were reported for 0.4%. The most common individual AEs were pain (2.9%) and pruritus (8.3%) at the application site. Local skin reactions (LSRs) were evaluated in 1,320 patients and were generally mild-to-moderate. Erythema was reported for 89.8% (7.9% severe) of patients, flaking/scaling for 73.8% (5.4% severe), crusting for 46.4% (3.4% severe), swelling for 25.3% (0.3% severe), vesiculation/pustulation for 6.4% (0.4% severe), and erosion/ulceration for 11.1% (0.6% severe).

**Conclusion:** These combined results indicate that tirbanibulin has low occurrence for serious or severe AEs, and severe LSRs were uncommon. The safety/tolerability profile for tirbanibulin in real-world clinical practice was comparable to the one reported in clinical trials.

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