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Clearance of actinic keratosis with tirbanibulin: Comparing results from controlled trials with real-world/low interventional clinical studies

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Introduction & Objectives: Randomized controlled trials (RCTs) are known to provide information about the efficacy of treatments under highly controlled conditions and in carefully selected homogeneous patient groups [1,2]. It is important to examine how efficacy achieved in such trials compares with that obtained in a broader spectrum of patients in real-world clinical practice.

Materials & Methods: Efficacy of tirbanibulin 1% ointment in the treatment of actinic keratosis (AK) has been evaluated in three phase III clinical trials; two [NCT03285477, NCT03285490] [3] in which tirbanibulin was applied to an area of 25 cm2 and one to an area of 100 cm2 [NCT05279131] [4] (N=458 total patients). Tirbanibulin efficacy has also been assessed in an open-label phase IV trial (TirbaSkin [EU2022-001251-16] [5], N=334) and two real-world studies (KLIR [DRKS00027120] [6] N=543, and PROAK [7] [NCT05260073] N=300). These phase IV studies were low-interventional and in all of them tirbanibulin was applied to an area up to 25 cm2 once daily for 5 days according to prescribing information. Complete and partial clearance were defined as clearance of 100% and ≥75% to <100% of lesions, respectively.

Results: Combined results from two phase III studies (N=353 patients, 25 cm2 application) reported a clearance ≥75% in 72.2% of patients. Combined results from real-world/low interventional studies PROAK, KLIR (assessed in SmPC time window), and TirbaSkin (N=1,123 patients) showed a clearance ≥75% in 66.1%. Reported percent reduction in AK lesions from three phase III trials (N=458) was 78.4% and from two post-registration studies (TirbaSkin and KLIR, N=832) was 74.4%.

Conclusion: These results indicate that clearance rates and reductions in AK lesion counts achieved with tirbanibulin in RCTs approximated results achieved in an open-label phase IV study and in real-world clinical practice.

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