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Tirbanibulin 1 % ointment: A narrative review of new data presented at the 11th World Congress of Melanoma in conjunction with 21st European Association of Dermato-Oncology Congress 2025

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ABSTRACT

Purpose: This article provides an overview of the scientific content on tirbanibulin 1 % ointment, summarizing key Phase IV results and real-life experiences with tirbanibulin shared by dermatologists across Europe.
Materials and Methods: Summary of posters, oral presentation and symposium discussions related to tirbanibulin presented at the 11th World Congress of Melanoma in conjunction with 21st European Association of Dermato Oncology (EADO) Congress held between 3rd and 5th of April 2025 in Athens, Greece.
Results: We report presented data on the efficacy/effectiveness, safety and tolerability of tirbanibulin 1 % ointment for the treatment of actinic keratosis (AK) on the face, scalp and décolleté. We also collected evidence supporting its use in AK in organ transplant recipients (OTR), solar damaged skin, pigmented AK (PAK), proliferative AK, hypertrophic AK, actinic cheilitis (AC), keratinocyte carcinoma (KC) and lentigo maligna (LM).
Conclusions: Overall, data from a Phase IV trial and real-world clinical practice suggest that tirbanibulin is an effective, safe and well-tolerated treatment for AK. Tirbanibulin may also be an option for OTR, patients with

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PAK, proliferative or hypertrophic AK, and even for conditions such as AC or KC, although the sample size is small in some of these groups and further evidence is needed.

1. Introduction

Tirbanibulin 1 % ointment is approved for the field-directed treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (AK) of face or scalp in adults, and it has been shown to be effective and safe on an area of 25 cm^2 and up to 100 cm^2 [1–3]. Tirbanibulin inhibits tubulin polymerization and, subsequently, Src kinase signaling, leading to antiproliferative and pro-apoptotic activities [4]. Unlike other topical therapies, tirbanibulin causes a lower release of cytokines, which results in limited tissue necrosis and inflammation [4,5]. Furthermore, given its mechanism of action (MoA) [4], tirbanibulin is expected to be safe and effective in organ transplant recipients (OTRs).

This manuscript presents data on the efficacy/effectiveness, safety and tolerability of tirbanibulin from a Phase IV trial and real-world clinical practice by dermatologists across Europe presented at the 11th World Congress of Melanoma in conjunction with 21st European Association of Dermato-Oncology (EADO) Congress 2025.

2. Material and methods

A systematic search for presentation of tirbanibulin was conducted within the book of abstracts on the EADO 2025 Congress homepage. A symposium, 15 posters and 1 oral presentation are summarized here.

3. Presentations at EADO Congress 2025

3.1. Symposium

In the AK symposium entitled “Actinic keratosis and beyond: patient understanding is first, lesion characterisation is key” lead by Dr. Heppt and Dr. Ardigò it was highlighted the need to use alternative measures to assess the effectiveness of AK treatments since complete clearance (CC) rate is inversely related to the number of lesions at baseline. Percent reduction in AK lesion count offers a more robust measure for this purpose [6]. On the other hand, there is no way to accurately predict which lesion will develop into cutaneous squamous cell carcinoma (SCC) or when this might occur [7]. Therefore, non-invasive imaging techniques, as line-field confocal optical coherence tomography (LC-OCT), are key for support to lesion understanding, and treatment follow-up [8].

Tirbanibulin offers a short treatment duration (5 days once daily) and mostly mild/moderate local skin reactions (LSRs), also known as local tolerability signs (LTS) [1,4], challenging the "no pain, no gain" mindset applicable with other treatments as 5-fluorouracil. No correlation between percent reduction in AK lesion count and LSRs occurrence was identified with tirbanibulin, suggesting that inflammation degree does not necessarily predict a better response [6]. Unlike other treatments, and due to its MoA, tirbanibulin does not induce a pronounced release of pro-inflammatory cytokines in keratinocytes [4]. Furthermore, tirbanibulin inhibits tubulin polymerization and disrupts microtubules, leading to cell cycle arrest and apoptosis in atypical keratinocytes, highlighting its potential as a promising therapy for advanced proliferative AKs (proliferation score system [PRO] II and III) [9]. AKs with marked basal proliferation and acantholysis should be assumed to be histological high-risk factors for the progression into invasive SCC [10]. In addition, a special clinical consideration is needed for OTRs, as AKs are more common in this population, with a 32-fold increased risk of progression to SCC [11]. Tirbanibulin showed to be effective and well-tolerated in OTRs [12,13].

3.2. Poster and oral presentations

3.2.1. Tirbanibulin for AK

Phase IV TIRBASKIN study (EudraCT No. 2022–001251–16), conducted in Spain and Italy, evaluated efficacy and safety of tirbanibulin [14,15] and satisfaction with treatment [16] (Treatment Satisfaction Questionnaire for Medication [TSQM]-9, TSQM-1.4 and Expert Panel Questionnaire [EPQ] [17]) in adult patients with 4–8 AK lesions on the face or scalp in an area $\leq$ 25 cm^2 not previously treated in the last 6 months. A total of 328 patients completed study assessments at day 57. Percent (%) reduction in AK lesions or lesion clearance rate was 83.0 %. 54.3 % of patients achieved CC (100 % lesions reduction) and 76.8 % partial clearance (PC; $\geq$75 % lesion reduction). Considering patients achieving CC, 174 (97.8 %) presented mainly mild/moderate LTS. In addition, patients reported high levels of satisfaction with tirbanibulin for the 3 domains of TSQM-9 (convenience of use score: 82.8, global satisfaction score: 76.9, effectiveness score: 73.6). According to TSQM-1.4, side effects interfered minimally/not at all on mental function (100 %) or on physical health (98 %). Physicians and patients reported high levels of satisfaction with the improvement in overall skin appearance (96.3 % and 92.5 %), how skin looked (92.3 % and 89.3 %) and skin texture (91.7 % and 88.8 %) after tirbanibulin and both reported likelihood of considering tirbanibulin again (87.1 % and 86.3 %), if needed. In conclusion, CC was not associated with bothersome LTS, and most patients who achieved CC experienced absent or mild/moderate LTS. These results reaffirm tirbanibulin’s well balanced profile in terms of efficacy, safety/tolerability and patient satisfaction.

Similarly, in a series of 27 patients with AK presented by Luque Varela P et al. [18], treated with tirbanibulin once daily for 5 consecutive days, 74 % of patients achieved CC and 100 % PC. Redness in the treated area was the most common reported side effect. No patient interrupted treatment due to side effects. Patient satisfaction was high, and all patients stated they would undergo the treatment again if necessary. Tirbanibulin was a good treatment option for AK with an easy posology, low rate of local side effects and good level of efficacy.

In addition, Vera F et al. [19] conducted an analysis of 12 participants from the TIRBASKIN study using LC-OCT to assess tirbanibulin efficacy in improving epidermal structure and keratinocyte nuclei abnormalities in AK lesions on the face and scalp. Additionally, they evaluated tirbanibulin’s potential effect on the surrounding subclinical cancerization field. Tirbanibulin significantly improved structural and cellular abnormalities in AK lesions and cancerization field. This was evidenced by reductions in viable epidermal thickness and keratinocyte atypia, suggesting normalization of the epidermal architecture and a decrease in dysplastic features. Increases in keratinocyte surface density and average compactness indicated enhanced cellular organization and cohesion. In the cancerization field, a progressive decrease in stratum corneum thickness was observed potentially reflecting subclinical improvements in the skin.

Kuchner M et al. [20] presented the case of a patient with high-risk AK with a PRO III treated with tirbanibulin once daily for 5 days. Images with LC-OCT were taken before the treatment, at day 15 post-treatment and after 10 weeks to evaluate tirbanibulin effect on the basal proliferation. LC-OCT imaging revealed a complete response to tirbanibulin, with a significant reduction in basal proliferation at day 15. Follow-up at 10 weeks showed continued improvement, with no signs of basal proliferation in the treated lesion. Tirbanibulin demonstrated efficacy in treating high-risk, proliferative AKs, as indicated by the complete remission in LC-OCT imaging.

A single-center, prospective study from Morelló Vicente A et al. [13] was conducted to evaluate LSRs and pain levels in solid OTRs

undergoing treatment with tirbanibulin for AK. Pain was evaluated using a numeric pain scale from 0 (no pain) to 10 (highest pain). Thirty-nine patients (men: 94.9 %) with 4–8 AK lesions were included. All had been under immunosuppressive therapy for at least 1 year. All participants completed the 5-day treatment regimen, and only 9 patients reported pain, being the highest score 4/10 in 1 patient. Erythema and scaling were the most common LSRs, occurring in 100 % and 87.2 % of patients, respectively. No severe AEs were reported.

In addition, ESTIMATE is a prospective, observational study from Zavattaro E et al. [12] aiming to evaluate tirbanibulin efficacy and safety in 40 OTRs (men: 75 %) with AKs on the face or scalp, previously submitted to different organ transplantation (kidney: 87.5 %; liver: 5.0 %; combined kidney-liver: 5.0 %; heart: 2.5 %). Clinical evaluation was conducted by 3 expert dermatologists at baseline, at days 8 and 60. At baseline, mean Actinic Keratosis Area and Severity Index (AKASI) was 2.6, and mean number of AKs was 6.7. Change from baseline at day 60 in AKASI was 70.7 %, and in lesion count reduction 70.1 %. At day 60, 52.5 % of patients reached PC, and 42.5 % obtained CC. At day 8, mean LSR score was 4 (range 1–9). In both studies, tirbanibulin demonstrated a favorable safety/tolerability profile in solid OTRs, as in immunocompetent patients. Moreover, the short treatment duration promotes better adherence, which is crucial for this population, due to the high AK rate caused by immunosuppression.

In an ambispective cohort study from Clavijo Herrera J et al. [21] conducted to describe differences in treatment outcomes with tirbanibulin between classic AK (CAK) and pigmented AK (PAK) based on sex, phototype, anatomical location, and prior treatments, 50 patients were treated with tirbanibulin. 48 % of patients had PAK, being more frequent in women (66.7 %). Overall, 90 % of patients responded to tirbanibulin (CAK: 84.6 %; PAK: 95.8 %) (Fig. 1). Tirbanibulin showed to be highly effective for both CAK and PAK. Treatment response was better in women, patient with phototype II and facial locations, particularly in PAK.

Furthermore, a prospective, non-randomized real-life study from Moyano Almagro B et al. [22] was conducted to assess the effectiveness and tolerability of tirbanibulin for the treatment of AKs and surrounding solar-damaged skin (field therapy). One hundred patients (men: 79 %) were included. Half (52 %) of them achieved CC, and > 70 % PC. Tirbanibulin showed a good tolerability profile, with no discontinuations due to AEs, and a high level of patient satisfaction. This study confirmed the effectiveness and safety of tirbanibulin for AKs and surrounding solar-damaged skin, including anti-aging effects on both skin texture and lightening, and solar lentigos.

Bearzi E et al. [23] presented the case of a patient with > 10-year history of multiple skin cancers, including 2 SCC and 5 basal cell carcinoma (BCC) treated successfully with surgery, with numerous AKs on her face and décolleté, which were treated with 2 sessions of daylight photodynamic therapy with poor response. Tirbanibulin was used to treat both the face and décolleté, covering an area of approximately 70 cm^2. Photographs of the décolleté were taken before treatment, at days 5 and 30. Images at day 5 showed a pronounced erythema (rated 2; scale: 0–4), including areas that did not exhibit clinically evident AK before treatment. Patient reported mild soreness (rated 1) on day 5, which she found tolerable. By day 30, erythema was barely perceptible (rated 1), with minimal scaling (rated 1). Improvement in AK was clinically noticeable, and the patient expressed satisfaction with the results (rated 3; scale: 0–4). Tirbanibulin was a safe and effective option for AK on the décolleté, with no significant side effects. Its ability to induce erythema in subclinical lesions supports its role in treating cancerization fields.

Finally, a retrospective, single-centre study from Li Pomi F et al. [24,25] including 51 typical, visible, discrete, indolent hypertrophic AK lesions in 32 consecutive patients was conducted to explore tirbanibulin effectiveness in managing hypertrophic AKs. No mechanical pre-treatment or prior application of keratolytic agents was performed. Clinical and dermoscopic pictures of hypertrophic AK lesion were recorded at baseline (T0), and after 8 weeks (T1) to evaluate its efficacy (Fig. 2). At T1, CC was observed in 54.9 % of lesions, and 19.6 % did not respond to treatment. Regarding tirbanibulin tolerability, 69.8 % of patients developed LSRs, of which 54.5 % were classified as moderate, and 45.5 % as mild. No patient discontinued treatment due to LSRs. This study suggests the effectiveness and safety of tirbanibulin for treating hypertrophic AKs.

3.2.2. *Tirbanibulin beyond AK*

Hobelsberger S et al. [26] presented a series of 20 patients (men: 50 %) with actinic cheilitis (AC) diagnosed with OCT and/or histopathology who were treated with tirbanibulin. Imaging with OCT was performed on day 1 to diagnose AC and on day 56 to assess healing. Patient's self-assessment score, Dermatology Life Quality Index (DLQI) and LSR score were analyzed at each visit to assess potential side effects. At day 56, 60 % of patients showed complete remission and 40 % partial remission. In the OCT examination on day 56, a significant reduction of the hyperreflective entry signal ($p = 0.002$), stratum corneum thickness

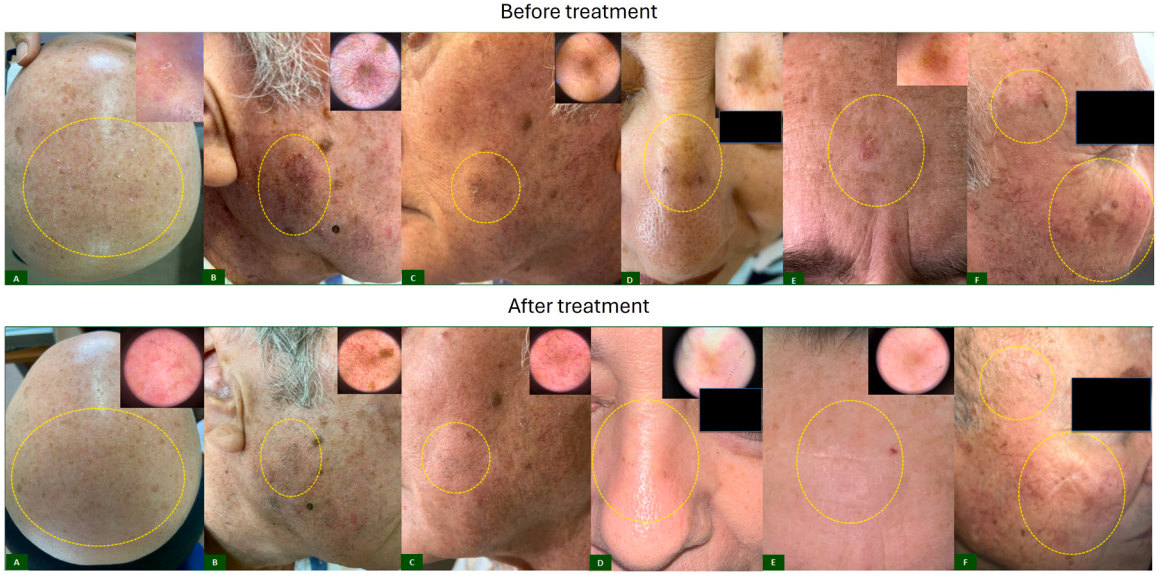

Fig. 1. Patients with PAK before and after treatment with tirbanibulin. PAK: Pigmented actinic keratosis. Image from Clavijo Herrera J et al. [21].

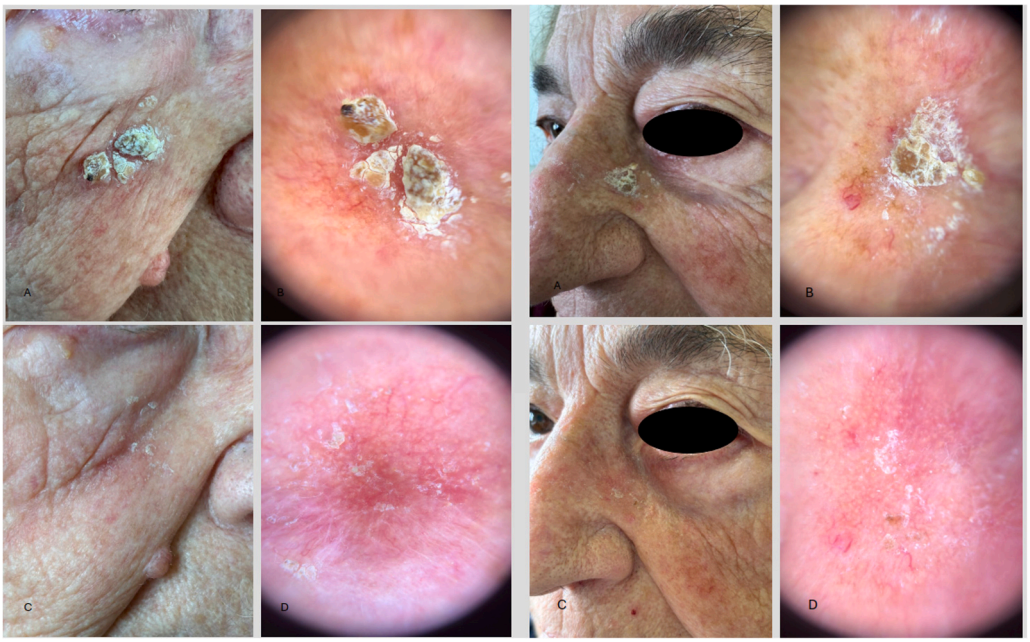

Fig. 2. Clinical and dermoscopic pictures of patients with hypertrophic AK at baseline and after 8 weeks. AK: actinic keratosis. Image from Li Pomi F et al. [25].

($p < 0.001$), stratum corneum disruption ($p = 0.004$), erosions ($p < 0.001$), increased epidermal thickness ($p < 0.001$), irregular epidermal layering ($p = 0.004$) and subepidermal dark areas ($p = 0.001$) were observed. At D7, 50 % of patients experienced mild LSRs, 45 % moderate, and 5 % severe. There were no severe or systemic AEs. There were no treatment discontinuations. DLQI improved significantly from baseline to follow-up (6 vs. 3, $p = 0.032$). Out of the patients with incomplete remission, Hobelsberger et al. performed surgery of the hyperkeratotic area in 2 patients. One patient was diagnosed with Bowen's disease and another one with early invasive SCC. Both patients had received a punch biopsy before treatment that was false negative and had been diagnosed with AC. Tirbanibulin reduced the AC area, resulting in a smaller defect size rather than a complete vermilionectomy for both patients. Tirbanibulin may be an effective and well-tolerated option for AC treatment although further investigation including long-term follow-up is needed.

Another study from Gualdi G et al. [27] assessed whether pre-treatment with tirbanibulin improved surgical outcomes and reduced the KC lesions before removal. Sixty patients scheduled for KC surgery presenting AK lesions within the cancerization field and/or severe photodamage were treated with tirbanibulin on a 25 cm^2 area containing the KC lesion. Only those who completed treatment at least 6 weeks before surgery were included. Treated areas were clinically and instrumentally evaluated before treatment, and at day 30. After surgery, the percentage of involved margins was lower in the study group than in the control group (SCC: 3.7 vs 15.8 [$t > 0.05$]; BCC: 3.3 vs 8.9 [$t < 0.05$]). Furthermore, mean diameter of the target lesion decreased after pre-treatment with tirbanibulin for both SCC and BCC ($p < 0.05$). Side effects were mainly mild (33.3 %). Data suggests that pre-treatment with tirbanibulin could help in the management of surgical patients affected by KC.

In addition, a study from Morgan HJ et al. [28] aimed to determine whether individuals with AK with koilocytes were at greater or lesser risk of developing KC and whether their biological basis supported the identification of specific therapeutic targets. Histology samples were analyzed for HPV8, and the patient records were reviewed for KC in the subsequent 10 years. HPV8-associated AK, cell lines and mouse models were interrogated for expression of Src family kinases. *In vitro* and *in vivo* biological effects of Src inhibition were determined using small interference ribonucleic acid (siRNA) and tirbanibulin. Sixty-one patients without a history of antecedent KC were divided into those with ($n = 31$) and without HPV8. HPV8-associated AK patients had a greater risk of KC (Hazard Ratio 5.5, 95 % CI 2.3–12.9, $p < 0.001$), invasive SCC (Odds Ratio [OR] 11.6) and BCC (OR 3.5), and included all 9 patients with multiple KC. AK, due to HPV8, demonstrated elevated expression of phosphorylated Src kinase. Presence of koilocytes within AK alongside clinical risk factors can define those at high risk of subsequent KC. Src kinase inhibition in AKs with koilocytes with tirbanibulin may be an effective strategy to prevent subsequent KC.

Finally, Agostini A et al. [29] presented the case of an 85-year-old woman with lentigo maligna (LM), confirmed by histological diagnosis via incisional biopsy. Patient declined surgical excision or radiotherapy and was initiated on imiquimod, with limited benefit. Subsequently, tirbanibulin was administered for 10 consecutive days. During treatment, mild-to-moderate local inflammation was observed, characterized by erythema, edema, pruritus, and burning at the application site. One month after treatment, a complete clinical and dermoscopic lesion resolution was noted. At 1-year follow-up, lesion remained completely resolved. Treating LM can often be challenging due to its location, which may complicate radical surgical excision. Tirbanibulin could be considered as a therapeutic option for this condition.

4. Conclusion

Overall, these data suggest that tirbanibulin is an effective, safe and well-tolerated treatment for AK. Tirbanibulin may also be an option for OTR, patients with PAK, proliferative or hypertrophic AK, and even for conditions such as AC or KC, although further evidence is needed.

CRediT authorship contribution statement

Iris Zalaudek: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Paolo Broganelli:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Paola Savoia:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation,

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Authors' contributions

All authors contributed equally, therefore they are listed alphabetically: symposium authors first, followed by presentations authors.

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BM: has provided scientific advice, medical meetings and as principal investigator or collaborated in clinical research trials for Almirall, Abbvie, Novartis, Isdin.

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