# Efficacy and safety of tirbanibulin 1% ointment for the treatment of actinic keratosis under conditions close to routine clinical practice in Spain and Italy (TIRBASKIN study)

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## Introduction and Objectives

- Tirbanibulin 1% ointment is approved for the field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (AK) of face or scalp in adults.
- Efficacy and safety of tirbanibulin have been evaluated in two Phase III trials in the United States.[1]
- Tirbanibulin 1% has been shown to be effective and safe on an area of 25 $cm^2$ and even on larger areas, up to 100 $cm^2$.[1,2]
- Here, we present the efficacy and safety of tirbanibulin administered to patients with actinic keratoses under conditions close to routine clinical practice in Spain and Italy.

## Material and Methods

- TIRBASKIN is a multicenter, single-cohort, phase IV, low-interventional, clinical study conducted among adult patients with 4-8 non-hyperkeratotic non-hypertrophic AK lesions of the face or scalp in an area up to 25 $cm^2$ not previously treated in the last 6 months.
- Patients applied tirbanibulin for 5 consecutive days.
- Efficacy was assessed by the percentage of patients with complete clearance (CC), defined as a reduction of 100% of lesions within the application area, and the percentage of patients with partial clearance (PC), defined as a reduction of at least 75% in the number of lesions, at Day 57.
- Mean percentage (standard deviation [SD]) change from baseline (%CFB) in AK lesion count was measured.
- Safety was assessed by incidence and severity of adverse events and local tolerability signs (LTS) (erythema, flaking/scaling, crusting, swelling, vesiculation/pustulation and erosions/ulcerations) on a grading scale ranging from 0=absent to 3=severe.

## Results

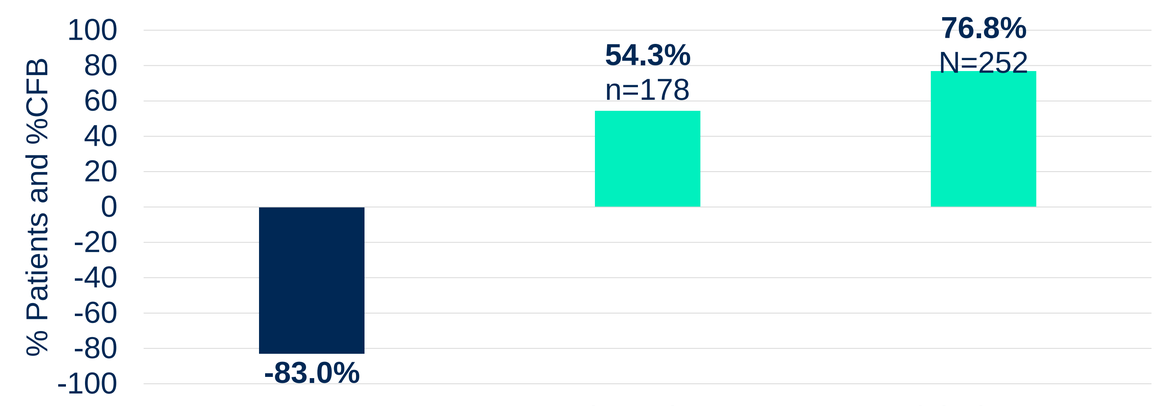
### *Patients*

- A total of 328 patients (mean age: 75 years; male: 84%; Fitzpatrick skin type II: 54%) with AK on face (47%) or scalp (53%) completed study assessments at Day 57. Baseline characteristics are shown in Gilaberte Y *et al*. EADO 2025. Poster P1-10.
- Six patients were immunosuppressed (mean age: 71.5 years; male: 83.3%; Fitzpatrick skin type II: 66.7%; renal transplant: 50%; AKs on scalp: 83.3%). Immunosuppression therapy included apremilast (1 patient), azathioprine (1 patient), brodalumab (1 patient), mychophenolate mofetil (1 patient), mycophenolate sodium (2 patients), tacrolimus (1 patient) and tacrolimus monohydrate (1 patient).

### *Efficacy*

- Mean %CFB (SD) was -83.0% (25.4).
- 54.3% of patients achieved CC and 76.8% achieved PC (**Figure 1** and **Figure 2**).
- 40% of immunosuppressed patients achieved CC and 100% achieved PC.

**Figure 1. Complete and Partial clearance at Day 57**




*Partial clearance is defined as reduction of ≥75% (includes patients with complete clearance).
CFB, change from baseline

**Figure 2. Clinical clearance at baseline, Day 8 and Day 57 with use of tirbanibulin for actinic keratoses on scalp: 72 years-old man with 6 lesions at baseline. LTS at Day 8: mild flaking/scaling. CC at Day 57.**



Baseline | Day 8 | Day 57

### *Safety*

- No new safety events were identified (**Table 1**), although percentage of patients with pruritus (27.5%) was higher than in other studies[1].
- Individual LTS scores increased to peak around Day 8 and then decreased to return to or close to baseline score by Day 57 (**Table 2**), similar to previous studies[1,2].
- Immunosuppressed patients presented similar good safety profile. LTS at Day 8 were mild or moderate erythema/redness (83.4% of patients), crusting/scabs (50% of patients) and flaking/scaling (33.4% of patients), all of them resolved on day 57. There were no severe LTS. No patient presented swelling, vesiculation/pustulation or erosions/ulcerations.

**Table 1. Summary of patients with Adverse Events**

| | Safety population (N=334) |
|---|---|
| **TEAE** | 153 (45.8) |
| **Serious TEAE** | 0 (0) |
| **TEAE of special interest*** | 3 (0.9) |
| **TEAE suspected related to treatment** | 129 (38.6) |
| **TEAE leading to treatment discontinuation**** | 3 (0.9) |

TEAE, treatment emergent adverse event.
*3 patients experienced BCC outside treatment area. **TEAEs leading to treatment discontinuation were: diarrhea (N=1), nausea (N=1), vomiting (N=1), burning sensation (N=1), fatigue (N=1), and headache (N=2).

**Table 2. Local tolerability signs at Day 8 after tirbanibulin treatment**

| | Safety Population N=334 |
|---|---|
| **Erythema/redness, n (%)** | |
| 0 - Absent | 83 (25.62) |
| 1 - Mild | 191 (58.95) |
| 2 - Moderate | 43 (13.27) |
| 3 - Severe | 7 (2.16) |
| **Flaking/Scaling, n (%)** | |
| 0 - Absent | 210 (64.81) |
| 1 - Mild | 91 (28.09) |
| 2 - Moderate | 21 (6.48) |
| 3 - Severe | 2 (0.62) |
| **Crusting/scabs, n (%)** | |
| 0 - Absent | 262 (80.86) |
| 1 - Mild | 50 (15.43) |
| 2 - Moderate | 11 (3.40) |
| 3 - Severe | 1 (0.31) |
| **Swelling, n (%)** | |
| 0 - Absent | 277 (85.49) |
| 1 - Mild | 37 (11.42) |
| 2 - Moderate | 10 (3.09) |
| 3 - Severe | 0 |
| **Vesiculation/Pustulation, n (%)** | |
| 0 - Absent | 321 (99.07) |
| 1 - Mild | 2 (0.62) |
| 2 - Moderate | 1 (0.31) |
| 3 - Severe | 0 |
| **Erosions/ulcerations, n (%)** | |
| 0 - Absent | 314 (96.91) |
| 1 - Mild | 6 (1.85) |
| 2 - Moderate | 4 (1.23) |
| 3 - Severe | 0 |

## Conclusions

- Tirbanibulin 1% ointment was effective, safe, and well tolerated in AK patients similar to previous studies[1].
- Although in a limited sample size, immunosuppressed patients (N=6) in this study can benefit from tirbanibulin with comparable efficacy/safety and tolerability to immunocompetent population.

## References

1. Blauvelt A et al. *New Engl J Med* 2021;384:512-20. 2. Bathia N et al. *JAAD Int* 2024;17:6-14.

## Potential or actual conflicts of interest

This study was funded by Almirall SA. **YG** has provided scientific advice, participated in medical meetings and sponsored training courses and has participated as principal investigator or collaborated in clinical research trials for Abbvie, Almirall, Leo, Cantabria Labs, Galderma, Isdin, Lilly, Pfizer, Rilastil, La Roche Posay and Sanofi. **OY** received consulting honoraria from Almirall, Leo Pharma, Isispharma, BMS, Bioderma-NAOS and Novartis; Speakers' Bureau/Advisory Board honoraria from Almirall, Leo Pharma, Isdin, Isispharma, BMS, MSD, and Kiowa Kirin. **JC** received research grants from Castle Biosciences, Regeneron; Lectures honoraria from Sanofi, Almirall, Abbvie, Regeneron, Sun Pharma; Payment for expert testimony from Sanofi, Regeneron, Almirall; Support for attending meetings from Pfyzer, Almirall, Lilly; Advisory board from Almirall, Sanofi, Regeneron, Kyowa, Roche, InflaRx. **CRG** has participated as investigator in clinical research trials for Galderma, Biofrontera, Leo Pharma, Almirall, Pierre Frabre, Roche; and he has provided advice, scientific meetings and training courses for Galderma, Biofrontera, Leo Pharma, Almirall, Pierre Frabre, Roche. Cantabria LABS and Sun Pharma. **AC** has no conflicts of interests to declare. **FP**, **AL**, **VC**, and **BK** are Almirall employees. **MR** received honoraria for advisory board from Abbvie, Lilly, Sanofi, Novartis, ConvaTec.