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Press Release

Almirall receives positive CHMP opinion for Klisyri® (tirbanibulin) to treat actinic keratosis across larger skin areas

- **The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending a label extension for tirbanibulin to treat up to four times the surface area[1] on the face and scalp; European Commission approval is expected in approximately 60 days.**
- **This represents an important step forward for people living with actinic keratosis (AK) in Europe, enabling dermatologists to treat larger fields of cancerisation with tirbanibulin to better meet real-world needs.**
- **The positive opinion is supported by the TirbAKare phase III study, which shows clinically and statistically significant efficacy, with a consistent safety profile and local tolerability, in treatment areas up to 100 cm².**

BARCELONA, Spain. November 18th, 2026 – Almirall S.A. (BME: ALM), a global biopharmaceutical company dedicated to medical dermatology, announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending the regulatory approval of an extension of indication for Klisyri® (tirbanibulin 10 mg/g ointment). The label extension expands the treatment field to up to four times the surface area[2] of the face or scalp in adults. This represents an important step forward in the management of AK in Europe, allowing dermatologists to treat larger fields of cancerization while offering patients the same short 5-day topical treatment regimen, consistent efficacy and favourable tolerability established in the original pivotal trials.

"We are delighted to receive the positive CHMP recommendation for this label extension. Actinic keratosis rarely occurs as isolated lesions, and dermatologists in Europe need effective therapeutic options to treat larger affected skin areas. Expanding the treatment area up to 100 cm² would provide physicians with greater clinical flexibility to address widespread field cancerisation. The short 5-day duration of treatment, combined with proven efficacy and a favourable safety and tolerability profile, reinforces tirbanibulin as an important therapeutic option for AK in the EU," said **Dr Karl Ziegelbauer, Chief Scientific Officer at Almirall.**

AK is a chronic skin disease and one of the most common diagnoses in dermatology practices in Europe, with an estimated prevalence of around 14%[3]. As lesions may progress to invasive squamous cell carcinoma (SCC), ongoing management is important. Short, convenient and well-tolerated treatments are particularly relevant, helping to reduce the treatment burden for patients and supporting adherence[4] to ongoing disease management[5].

In June 2024, the U.S. Food and Drug Administration (FDA) approved Almirall's supplemental New Drug Application (sNDA) to expand its use up to 100cm² in the United States[6]. Today's positive CHMP opinion represents a major milestone in bringing this expanded field treatment to healthcare professionals and patients across Europe, aligned with the most recent European AK guidelines[7]. The positive opinion is supported by the TirbAKare phase III study, which shows clinically and statistically significant percent reduction in AK lesions, with a consistent safety profile and local tolerability, for tirbanibulin in treatment areas up to 100 cm².[8]

"In daily clinical practice, patients frequently present with actinic keratosis across broader areas of sun-damaged skin. Extending the treatment field up to 100 cm² fits the real-world patient needs, providing dermatologists with the flexibility

Press Release

to treat up to four times the surface area, compared to the current approved SmPC (up to 25cm²), with a convenient 5-day regimen, while maintaining a consistent and reliable safety and tolerability profile up to 1 year follow up," says **Prof. Dr. Julia Welzel, Director of the Department of Dermatology and Allergology, University Hospital Augsburg, Germany**.

The European Commission (EC) will now review the recommendation of the CHMP to deliver its final decision on the label update. The final approval of this label extension is expected in approximately 60 days. The decision is applicable in all European Union member states, as well as Iceland, Liechtenstein, and Norway.

About Klisyri® (tirbanibulin)

Klisyri® (tirbanibulin 10 mg/g ointment) is a topical field treatment for actinic keratosis (AK) of the face or scalp. Klisyri has demonstrated a well-balanced efficacy, safety and tolerability profile with the shortest 5-day treatment regimen among topical therapies for AK[9].

About the TirbAKare study

The CHMP positive opinion is based on clinical data from the TirbAKare study, a phase III, multicentre, randomised, 16-week, double-blind, vehicle-controlled study followed by a follow-up period of 32 weeks. 280 patients with 4-12 AK lesions in a field of >25 cm² and ≤100 cm² were randomised 2:1 to tirbanibulin or vehicle (5-day course). Patients not achieving complete clearance (CC) on Week 8 (W8) could receive a second course as per protocol. Primary efficacy endpoint was percent reduction in AK lesion count from baseline to W8. Tirbanibulin demonstrated a statistically significant percent reduction in AK lesions vs. vehicle from baseline at W8. The study showed results consistent with the original pivotal trials conducted on a 25 cm² area, both for local skin reactions (LSRs) and treatment-related adverse events. Clinical efficacy across the expanded 100 cm² field was also consistent with observations from the original pivotal trials.

About Actinic Keratosis (AK)

Actinic keratosis (AK) or solar keratosis is a chronic and precancerous skin disease that occurs primarily in areas that have been exposed to ultraviolet (UV) radiation for a long period of time and is one of the most common pre-cancerous dermatological conditions[10,11]. It is usually found on the face, ears, lips, bald scalp, forearms, the posterior part of the hands, and lower legs. It is not possible to predict which AK lesions will develop into squamous cell carcinoma so ongoing management of the field is important.

About Almirall

Almirall is a global biopharmaceutical company dedicated to medical dermatology. We closely collaborate with leading scientists, healthcare professionals, and patients to deliver our purpose: *to transform the patients' world by helping them realize their hopes and dreams for a healthy life*. We advance the scientific understanding of skin diseases to develop innovative and differentiated treatments and solutions that address patients' needs. Our clinical development portfolio includes four ongoing proof-of-concept (PoC)/Phase II studies and two further PoC studies planned across key areas of medical dermatology.

Almirall, founded in 1944 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM, total revenue in 2025: €1114.5 MM, over 2.100 employees globally). Almirall products help to improve the lives of patients every day and are available in over 100 countries.

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Press Release

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[1] Current approved SmPC is up to 25cm^2

[2] Op. cit 1

[3] George CD, *et al. Br J Dermatol*. 2024;190:465–476.

[4] Zakria D, *et al. Cutane Med*. 2023;7:752–763: "Higher complexity, longer duration, and adverse effects negatively impact adherence to AK treatments".

[5] Lo A, Lovell KK, Greenzaid JD, Oscherwitz ME, Feldman SR. *Adherence to treatment in dermatology: Literature review*. *JEADV Clin Pract*. 2024; 3: 401–418. https://doi.org/10.1002/jvc2.379

[6] Klisyri prescribing information US 91e45814-07a0-83f0-b1a4-73a81d8b9720

[7] Kandolf L, *et al. J Eur Acad Dermatol Venereol*. 2024;38(6):1024–1047.

[8] Study Details | NCT06135415 | A Study to Evaluate the Efficacy and Safety of Tirbanibulin Ointment in Adult Participants With Actinic Keratosis | ClinicalTrials.gov

[9] Klisyri, INN-tirbanibulin

[10] DuBois J, Jones T, Lee M, et al. **43735 Safety and Tolerability of a single 5-day Treatment Cycle of Tirbanibulin Ointment 1% in Large Field (100cm2): A phase I Trial in patients with Actinic Keratosis.** Journal of the American Academy of Dermatology, 89AB220.

[11] Bhatia N, Lain E, Jarell A, et al. **Safety and tolerability of tirbanibulin ointment 1% treatment on 100 cm^2 of the face or scalp in patients with actinic keratosis: A phase 3 study.** JAAD International, 2024; 17, 6-14