

Barcelona, June 10th 2024

OTHER RELEVANT INFORMATION

FDA approves Almirall's Klisyri® (tirbanibulin) for the treatment of actinic keratosis on expanded area of face or scalp up to 100 cm²

In accordance with Securities Markets Law, Almirall S.A. ("Almirall") announces the following:

- Original FDA approval (December 2020) now extended to the use of Klisyri on larger areas of the face or scalp (up to 100 cm²) to address more extensive manifestations of actinic keratosis, driving convenience for both patients and dermatologists.
- Safety and tolerability profiles in Klisyri treatment of actinic keratosis in up to 100 cm² treatment area (4X originally approved treatment area of 25 cm²) are consistent with original pivotal trial results.
- Actinic keratosis is the most common pre-cancerous dermatological condition and the second most common diagnosis made by dermatologists in the United States with a reported prevalence of between 11% and 25%.

Almirall announces today that the U.S. Food and Drug Administration (FDA) has approved Almirall's recent supplemental New Drug Application (sNDA) to expand the use area for its drug, Klisyri, to up to 100 cm². Klisyri, a microtubule inhibitor ointment, is now approved in a 350 mg package size and is a 5-day topical field treatment for actinic keratosis (AK) of the face or scalp.

This new approval will change the previous Klisyri (tirbanibulin) dosing for surface area treatment from up to 25 cm² to up to 100 cm², allowing clinicians to treat a larger area of the face or balding scalp. The sNDA was supported by an additional Phase 3, multicenter, open-label, clinical safety study with more than 100 patients in the US. The primary endpoints of the study were to evaluate the safety and tolerability of applying tirbanibulin to a field of approximately 100 cm² on the face or balding scalp of adult AK patients. The study showed consistent results with the original pivotal trials conducted on an area of 25 cm², for both local skin reactions and treatment related adverse events (AEs).

The effectiveness of tirbanibulin in a larger treatment area was also explored, showing a percent reduction in AK lesion count in line with the one reported in the original pivotal studies.

Klisyri will be available in two package sizes, 250 mg (NDC 16110-391-05) for the treatment of up to 25 cm², and 350 mg (NDC 16110-391-55)] for up to 100 cm².

Sincerely,

Pablo Divasson del Fraile
Investor Relations Department
investors@almirall.com