Press Release

For media and investors only
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FDA approves Almirall's Klisyri® (tirbanibulin) for the treatment of actinic keratosis on expanded area of face or scalp up to 100 cm^2

- **Original FDA approval (December 2020) now extended to the use of Klisyri on larger areas of the face or scalp (up to 100 cm^2) 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 cm^2 treatment area (4X originally approved treatment area of 25 cm^2) 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%[2-3]**

[MALVERN, PA. June 10, 2024]: Almirall, a global pharmaceutical company dedicated to medical dermatology, announced 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 cm^2. 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.

"The FDA's approval of the use of Klisyri for actinic keratosis on an extended surface of the face or scalp is a significant step forward for both patients and treating dermatologists. With patients experiencing AK over larger surface areas, dermatologists are looking for ways to treat the entire affected area to help prevent further lesion progression," says **Karl Ziegelbauer, Chief Scientific Officer at Almirall.**

This new approval will change the previous Klisyri (tirbanibulin) dosing for surface area treatment from up to 25 cm^2 to up to 100 cm^2, 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 cm^2 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 cm^2, 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.

"With this new FDA approval, clinicians can now treat up to four times the surface area, allowing increased flexibility to provide treatment of actinic keratoses and achieve effective results with a good safety and tolerability profile for more patients," says **Neal Bhatia, MD,** from San Diego, CA, who served as the principal investigator for the larger treatment area pivotal study.

Klisyri will be available in two package sizes, 250 mg (NDC 16110-391-05) for the treatment of up to 25 cm^2, and 350 mg (NDC 16110-391-55)] for up to 100 cm^2.

About Klisyri: Klisyri tirbanibulin ointment, 1% is a microtubule inhibitor indicated for the topical field treatment of actinic keratosis (AK) of the face or scalp. Klisyri has a demonstrated efficacy and safety profile, and a convenient 5-day application period, which is the shortest of any topical treatment for AK.[1]

About Actinic Keratosis: Actinic keratosis 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. 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 all lesions should be treated by a dermatologist. Actinic keratosis is the most common pre-cancerous dermatological condition. AK is the second most common diagnosis made by dermatologists in the United States.[2] The reported prevalence of AK is between 11% and 25%.[3]

About Almirall

Almirall is a global pharmaceutical 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 are at the forefront of science to deliver ground-breaking, differentiated medical dermatology innovations that address patients´ needs.

Almirall, founded in 1944 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM, total revenue in 2023: €898.8 MM, 1900 employees globally). Almirall products help to improve the lives of patient every day and are available in over 100 countries.

For more information, please visit https://www.almirall.us/

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