

Almirall's Klisyri® (tirbanibulin) receives strong recommendation in American Academy of Dermatology AK guideline update

- The AAD's update to the guideline on the management of actinic keratosis includes a "strong recommendation" designation in the topical field therapy category.

[MALVERN, PA]: Almirall, LLC, a global biopharmaceutical company focused on skin health, announced its microtubule inhibitor ointment, KLISYRI® (tirbanibulin), a topical field treatment for actinic keratosis (AK) of the face and scalp, received a strong recommendation designation in the AAD's American Academy of Dermatology's Focused Update to the Guidelines of Care for the Management of Actinic Keratosis.¹

According to the newly-updated AAD AK treatment guidelines, the strong recommendation for KLISYRI® comes with a high certainty of evidence in the topical treatment of AK. KLISYRI® is the only topical AK treatment agent with this distinction.¹

The AAD guidelines play a critical role in advancing care in dermatology and providing clinicians with unbiased and objective guidance in the selection of appropriate agents, based on best available clinical evidence.

*"The recent changes to the AK treatment guidelines are particularly significant for both healthcare providers and patients," says **Pablo Alvarez, President and GM at Almirall US**. "For clinicians, the revised guidelines further validate the strong clinical benefits of KLISYRI® and reinforce the strong clinical outcomes seen with KLISYRI® in clinical trials."*

The AAD's strong recommendation was supported by clinical outcomes that suggest the benefits of treating with KLISYRI® clearly outweigh the clinical risks based on the following critical and important outcome criteria¹:

Critical:

- Mean reduction in AK lesion counts from baseline to assessment
- Participant complete clearance (100%)
- Participant partial clearance ($\geq 75\%$)
- Investigator global improvement index
- Participant global improvement index
- Withdrawals due to adverse events

*“The new guidelines are based on a systematic review that identified two phase III randomized, double-blinded parallel-group placebo-controlled trials, including 702 adult participants,” says **Brian Berman, MD, PhD, Professor Emeritus of Dermatology at the University of Miami Miller School of Medicine.** “KLISYRI® met key clinical criteria required for its inclusion with 49% of KLISYRI patients achieving complete clearance (100%) of lesions (9% for vehicle) and no patients withdrew from clinical trials due to adverse events.”²*

Please [click here](#) for the executive summary of the updated guidelines.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Ophthalmic Adverse Reactions

KLISYRI may cause eye irritation. Avoid transfer of the drug into the eyes and to the periocular area during and after application. Wash hands immediately after application. If accidental exposure occurs, instruct patient to flush eyes with water and seek medical care as soon as possible.

Local Skin Reactions

Local skin reactions, including severe reactions (erythema, flaking/scaling, crusting, swelling, vesiculation/pustulation and erosion/ulceration) in the treated area can occur after topical application of KLISYRI. Avoid use until skin is healed from any previous drug, procedure, or surgical treatment. Occlusion after topical application of KLISYRI is more likely to result in irritation.

ADVERSE REACTIONS

The most common adverse reactions (incidence $\geq 2\%$) were local skin reactions, application site pruritus, and application site pain.

Please see Full Prescribing Information at <https://www.klisyrihcp.com/>.

About KLISYRI®: KLISYRI® tirbanibulin ointment is a novel microtubule inhibitor indicated for the topical treatment of actinic keratosis (AK) on 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.³ [Click here to view full Prescribing Information.](#)

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.⁴ The reported prevalence of AK is between 11% and 25%.⁵

About Almirall

Almirall is a global biopharmaceutical company focused on skin health. We collaborate with scientists and healthcare professionals to address patient's needs through science to improve their lives. Our Noble Purpose is at the core of our work: "Transform the patients' world by helping them realize their hopes and dreams for a healthy life." We invest in differentiated and ground-breaking medical dermatology products to bring our innovative solutions to patients in need.

The company, founded in 1943 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM). Throughout its 79-year history, Almirall has retained a strong focus on the needs of patients. Currently, Almirall has a direct presence in 21 countries and strategic agreements in over 70, with about 1,800 employees. Total revenues in 2021 were 836.5 million euros.

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

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References:

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3. KLISYRI [package insert]. Malvern, PA: Almirall, LLC, 2021
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