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Almirall announces EMA acceptance for filing of Marketing Authorization Application (MAA) for tirbanibulin in actinic keratosis

- Approval in Europe is anticipated during the first half of 2021
- Tirbanibulin met the primary endpoint of complete clearance of actinic keratosis lesions at day 57 in the two Phase III studies conducted
- Actinic keratosis is a common skin condition that is induced through ultra-violet light damage and can become cancerous

Almirall, S.A. (ALM) today announced that the **European Medicines Agency's (EMA)** has accepted the filing of the Marketing Authorization Application (MAA) for tirbanibulin, also known as ALM14789, for the treatment of actinic keratosis.

Actinic keratosis is a common skin condition that is induced through ultra-violet light damage, resulting in patches of thick, scaly, or crusty skin. Left untreated, there is a risk that the lesions can progress to squamous cell carcinoma and therefore, should be treated by a dermatologist.

“If approved by the EMA, tirbanibulin could be an important step towards significantly improved treatment of actinic keratosis both in Europe, as it has the potential to provide a marked improvement of the quality of life for patients suffering from this disease. Almirall’s commitment to unmet needs in dermatology, in partnership with Athenex’s expertise in drug development in this space, will significantly transform the approach towards this disease”, commented Volker Koscielny, MD, Chief Medical Officer of Almirall.

EMA filing is based on the analysis of two **Phase III studies (KX01-AK-003 and KX01-AK-004)** that evaluated the efficacy and safety of tirbanibulin ointment 1% (10 mg/g) in adults with actinic keratosis on the face or scalp. Tirbanibulin met the primary endpoint of complete clearance of actinic keratosis lesions at day 57 within the face or scalp treatment areas, each study achieving statistical significance ($p < 0.0001$) on this endpoint.

Almirall and Athenex, Inc. (NASDAQ: ATNX) entered into a **strategic partnership in December 2017 to further develop and commercialize KX2-391 for the treatment of actinic keratosis and other skin conditions** in the United States and Europe, including Russia. Athenex is responsible for conducting all preclinical and clinical studies up to first FDA approval. Almirall will employ its expertise to support the development in Europe and also to commercialize the product in the licensed territories. It is estimated that peak sales of tirbanibulin will be in excess of €250 million.

About KX01-AK-003 / KX01-AK-004 Phase III studies

The two double-blind, vehicle-controlled, randomized, parallel group, multicenter, Phase III studies (KX01-AK-003 and KX01-AK-004) evaluated the efficacy and safety of KX2-391 ointment 1% (10 mg/g) in adults with actinic keratosis on the face or scalp.

The studies enrolled a total of 702 patients across 62 sites in the US. Tirbanibulin ointment 1%(10 mg/g) or vehicle (randomized 1:1) was self-administered to 25 cm² of the face or scalp encompassing 4-8 typical AK lesions, once daily for 5 consecutive days.

Both Phase III studies, KX01-AK-003 and KX01-AK-004, achieved their primary endpoint, which was defined as 100% clearance of the AK lesions at Day 57 within the face or scalp treatment areas, each study achieving statistical significance (p<0.0001) on this endpoint. Complete Clearance was observed in 44% and 54% of the patients for tirbanibulin respectively while it was 5% and 13% for vehicle treated groups.

About Actinic Keratosis

Actinic keratosis is a common skin condition that is induced through ultra-violet light damage, resulting in patches of thick, scaly, or crusty skin. Left untreated, there is a risk that the lesions can progress to squamous cell carcinoma and therefore, should be treated by a dermatologist. Actinic keratosis is the most common pre-cancerous condition in dermatology and it affects more than 55 million Americans. Actinic keratosis constitutes between 14-29% of dermatologist visits in the USA¹.

About Almirall

Almirall is a leading skin-health focused global pharmaceutical company that partners with healthcare professionals, applying science to provide medical solutions to patients and future generations. Our efforts are focused on fighting skin health diseases and helping people feel better. We support healthcare professionals in their continuous improvements, providing our innovative solutions where they are needed.

The company was founded over 75 years ago and has its headquarters in Barcelona. It is listed on the Spanish Stock Exchange (ticker: ALM). Almirall has become a key source of value creation for society thanks to its commitment to its principal shareholders and its decision to help others by understanding their challenges and using science to provide solutions for real life. Total Revenues in 2019 were more than 900 million euros. Almirall has c. 1,800 employees.

For more information, please visit [almirall.com](https://www.almirall.com)

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1. E. Stockfleth *et al.* Physician perceptions and experience of current treatment in actinic keratosis. *JEADV* 2015, 29, 298–306