Press release

Barcelona (Spain)
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Almirall announces FDA acceptance for filing of the U.S. New Drug Application (NDA) for tirbanibulin in actinic keratosis

- **The FDA's acceptance for filing of the NDA follows the acceptance of the filing for tirbanibulin in Europe by the EMA, announced on March 3rd**
- **Tirbanibulin met the primary endpoint of complete clearance of actinic keratosis lesions at day 57 in the two Phase III studies conducted**

Almirall, S.A. (ALM) announced today that the **U.S. Food and Drug Administration (FDA)** has completed its filing review and determined that the **New Drug Application (NDA)** for tirbanibulin, also known as ALM14789[1], for the treatment of actinic keratosis (AK), is sufficiently complete to permit a substantive review. Additionally, the FDA has communicated that they are not currently planning on holding an advisory committee to discuss the application.

"The FDA's acceptance for filing of the NDA of tirbanibulin, following the acceptance for filing by the EMA, demonstrates a significant step towards its approval both in the US and Europe. Tirbanibulin has the potential to provide a significant improvement of the quality of life of the patients suffering from actinic keratosis. We are looking forward to continuing to work to prepare for the potential commercial launch of tirbanibulin for AK in the U.S. and Europe. We are pleased that our partnership with Athenex continues to be very positive", **commented Volker Koscielny, MD, Chief Medical Officer of Almirall.**

"We are delighted by the FDA's acceptance for filing of the NDA for tirbanibulin ointment, which was submitted in late December 2019," said **Dr. Rudolf Kwan, Chief Medical Officer of Athenex**. "Tirbanibulin is the first compound to come out of Athenex's discovery program. It marks an important step towards bringing this valuable treatment option to AK patients and we look forward to working with the FDA during the review process towards potential approval".

The FDA 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% 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 achieved 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.

[1] Also known as KX2-391

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 cm^2 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 USA[1].

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

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