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Almirall announces that both phase III trials of KX2-391 for actinic keratosis achieved primary endpoint

- **Both phase III studies met their primary endpoint of complete clearance of actinic keratosis lesions at day 57**
- **Each study achieved statistical significance ($p < 0.0001$). Statistical significance ($p < 0.001$) was also achieved for both face and scalp subgroups**
- **KX2-391 is a first-in-class topical treatment for actinic keratosis, a pre-cancerous skin condition resulting in patches of thick, scaly, or crusty skin**
- **Almirall and Athenex entered into a strategic partnership in December 2017 to develop and commercialize KX2-391 in the United States and Europe**

[Almirall, S.A \(ALM\)](#), today announced that both phase III studies of KX2-391 for actinic keratosis (AK), 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 ($p < 0.0001$)¹ on this endpoint. Statistical significance ($p < 0.001$) was also achieved for both face and scalp subgroups as well.

These double-blind, randomized, vehicle-controlled, studies were designed as pivotal phase III efficacy and safety studies to support the registration of KX2-391 (or KX-01) as field therapy for AK of the face and scalp. The studies, each conducted in 31 centers in the USA, enrolled a total of 702 patients. KX2-391 or vehicle ointment was applied once daily for 5 days. In addition to the clinical activity of KX2-391, the local skin reaction (LSR) profile was in line with the prior phase II study results reported in the annual American Academy of Dermatology (AAD), meeting in February 2018 in San Diego.

KX2-391, also known as KX-01, is a first-in-class dual Src kinase and tubulin polymerization inhibitor in phase III development as a topical medicinal product 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, the lesions have risk of progression to squamous cell carcinoma and consequently treatment by a dermatologist is recommended. Actinic keratosis is the most common pre-cancerous condition in dermatology and affects more than 55 million Americans, and accounts for between 14% and 29% of dermatologist visits in the USA².

Dr. Bhushan Hardas, Executive Vice President, Research & Development, CSO of Almirall, stated, *“As one of the leaders in the medical treatment of actinic keratosis, we were excited to see the successful results in both parallel phase III studies. We were impressed by the Athenex team’s capabilities in drug development execution. The rapid completion of recruitment in these two parallel clinical studies and the ahead of schedule analysis underscore the unmet need in actinic keratosis as well as the quality of the Athenex clinical research team. We are fully committed to this collaboration and will be helping to lead the European development and registration strategy. KX2-391 has the potential to change the standard of care for actinic keratosis and we look forward to combining our leadership capabilities in the field with the drug development expertise of Athenex with the shared goal of advancing patient care.”*

Almirall and Athenex 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 US FDA approval. Almirall will employ its expertise to support the development in Europe and also to commercialize the product in the licensed territories. Projected peak sales for KX2-391 are expected to be in excess of €250 million.

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 & future generations. Our efforts are focused on fighting against skin health diseases and helping people feel and look their best. We support healthcare professionals in its continuous improvement, bringing our innovative solutions where they are needed.

The company, founded 75 years ago and with headquarters in Barcelona, is listed on the Spanish Stock Exchange (ticker: ALM). Almirall has become a key element of value creation to society according to its commitment with its major shareholders and its decision to help others, to understand their challenges and to use Science to provide them with solutions for real life. Total revenues in 2017 were 755.8 million euros. It has more than 1,830 employees.

For more information, please visit almirall.com

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References

¹ A Phase 3, Double-Blind, Vehicle-Controlled, Randomized, Parallel Group, Multicenter, Efficacy and Safety Study of KX2-391 Ointment 1% in Adult Subjects With Actinic Keratosis on the Face or Scalp. ClinicalTrials.gov identifier (NCT number): NCT03285477. <https://clinicaltrials.gov/ct2/show/NCT03285477>

² E. Stockfleth et al. Physician perceptions and experience of current treatment in actinic keratosis. JEADV 2015, 29, 298–306