



Press Release

Barcelona,
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Almirall and Athenex announce strategic partnership for the treatment of actinic keratosis

- Almirall and Athenex have entered into a strategic partnership to develop and commercialize KX2-391 in the United States and Europe
- KX2-391 is a first-in-class topical treatment currently in Phase III development that will strengthen Almirall's actinic keratosis franchise and dermatology market leadership
- This move represents a major step for Almirall in adding to its pipeline highly innovative drugs in an area of unmet medical need and for Athenex in broadening its global reach through KX2-391
- Athenex will receive an upfront fee, development and sales milestones, and royalty payments with a scheme that will incentivize a strong partnership going forward

Almirall, S.A (ALM), a global skin-health focused pharmaceutical company, today announced an agreement with Athenex, Inc. (Nasdaq:ATNX), a global biopharmaceutical company dedicated to the discovery, development and commercialization of novel therapies for the treatment of cancer and related conditions, to further develop and commercialize KX2-391 for the treatment of actinic keratosis and other skin conditions.

Subject to the terms and conditions of the License Agreement, Athenex will grant to Almirall an exclusive license under the Athenex IP to research, develop and commercialize KX2-391 in the United States of America and European countries, including Russia.

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 precancerous condition in dermatology and it affects more than 55 million Americans. Actinic keratosis constitutes between 14-29% of dermatologist visits in the USA¹.

Under the terms of the partnership agreement, Athenex will receive an up-front fee and near-term payments of up to USD \$55 million. Athenex will also be eligible to receive launch and additional indications milestones for USD \$65 million. In addition, there will be sales performance milestones of KX2-391 estimated to be USD \$155 million. Almirall will reward Athenex with additional sales milestones, should the sales exceed the currently projected amounts. In addition, there will be tiered royalties starting at 15% based on annual net sales, with incremental increases in royalty rates with increased sales.

Athenex will be 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. Milestones encourage the joint effort of Athenex and Almirall to develop additional indications and additional formulations.

This transaction is subject to antitrust clearance by antitrust authorities.

Peter Guenter, Chief Executive Officer, Almirall, commented, "We are pleased to enter this collaboration with Athenex, a Company dedicated to the development of oncology focused products. We are very impressed by the Athenex team in their innovation and execution of drug development efforts and we look forward to partnering with them as we progress towards the development and commercialization of this promising product. KX2-391 has the potential to change the standard of care of actinic keratosis. Today, many patients with AK remain undiagnosed or untreated, therefore, we believe this product can become a game changer in the treatment of this disease. Our leadership in the field of actinic keratosis will complement the drug development expertise of Athenex. In addition, our partnership will be further strengthened by researching and developing other potential indications in the field of dermatology."

Johnson Lau, Chief Executive Officer, Athenex, stated, "Athenex is excited to partner with Almirall to further develop KX2-391 for actinic keratosis, one of our leading clinical candidates currently in the midst of Phase III registration studies. Almirall is a leader in the field of medical treatment of actinic keratosis in both Europe and USA, and also a market leader in the field of dermatology. We are very impressed by the management team of Almirall and are very confident that this partnership will create strong synergies and a platform for growth for both companies and our partnership going forward. Almirall's experience in the US and Europe will be critical to develop and commercialize this product across the territories for AK patients."

Bhushan Hardas, Executive Vice President R&D and Chief Scientific Officer of Almirall added, "By combining Athenex and Almirall drug development and regulatory expertise, and adding Almirall dermatology experience as well as our deep knowledge in actinic keratosis, we are confident that we will jointly be able to bring this exciting novel treatment opportunity for patients with actinic keratosis to both the US and EU market. KX2-391 has a short treatment duration and potentially an excellent adverse event profile compared to some of the current treatment options in actinic keratosis, with comparable efficacy."

Rudolf Kwan, Chief Medical Officer, Athenex, said, "Almirall has great scientific, regulatory and marketing experience globally in actinic keratosis, which, coupled together with our innovative drug discovery and clinical development will allow the speedy registration of this product and access for patients in the licensed territories. Our Phase II clinical trial results of KX2-391 showing excellent efficacy in the topical treatment of actinic keratosis without major toxicities will be presented in the upcoming American Academy of Dermatology meeting on February 17, 2018 in San Diego. After consultation with the FDA, we initiated our Phase III pivotal clinical trials which are progressing rapidly and meeting our aggressive timelines."

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 in 1943 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 2016 were 859.3 million euros and more than 2,000 employees are devoted to Science.

For more information, please visit <u>almirall.com</u> <u>linkedin.com/company/almirall</u>

References

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



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This document includes only summary information and does not intend to be comprehensive. Facts, figures and opinions contained herein, other than historical, are "forward-looking statements". These statements are based on currently available information and on best estimates and assumptions believed to be reasonable by the Company. These statements involve risks and uncertainties beyond the Company's control. Therefore, actual results may differ materially from those stated by such forward-looking statements. The Company expressly disclaims any obligation to review or update any forward-looking statements, targets or estimates contained in this document to reflect any change in the assumptions, events or circumstances on which such forward-looking statements are based unless so required by applicable law.

About Athenex, Inc.

Founded in 2003, Athenex, Inc. is a global clinical stage biopharmaceutical company dedicated to becoming a leader in the discovery and development of next generation drugs for the treatment of cancer. Athenex is organized around three platforms, including an Oncology Innovation Platform, a Commercial Platform and a Global Supply Chain Platform. Athenex's Oncology Innovation Platform generates clinical candidates through an extensive understanding of kinases, including novel binding sites and human absorption biology, as well as through the application of Athenex's proprietary research and selection processes in the lab. The Company's current clinical pipeline is derived from two different platform technologies Athenex calls Orascovery and Src Kinase Inhibition. The Orascovery platform is based on the novel oral P-glycoprotein pump inhibitor molecule HM30181A, through which Athenex is able to facilitate oral absorption of traditional cytotoxics, which Athenex believes may offer improved patient tolerability and efficacy as compared to IV administration of the same cytotoxics. The Orascovery platform was developed by Hanmi Pharmaceuticals and licensed exclusively to Athenex for all major worldwide territories except Korea, which is retained by Hanmi. The Src Kinase Inhibition platform refers to novel small molecule compounds that have multiple mechanisms of action, including the inhibition of the activity of Src Kinase and the inhibition of tubulin polymerization during cell division. Athenex believes the combination of these mechanisms of action provides a broader range of anti-cancer activity as compared to either mechanism of action alone. Athenex's employees worldwide are dedicated to improving the lives of cancer patients by creating more active and tolerable treatments. Athenex has offices in Buffalo and Clarence, New York; Cranford, New Jersey; Houston, Texas; Chicago, Illinois; Hong Kong; Taipei, Taiwan and multiple locations in Chongqing, China.

Forward-Looking Statement Disclaimer/Safe Harbor Statement

Except for historical information, all of the statements, expectations, and assumptions contained in this press release are forward-looking statements. Actual results might differ materially from those explicit or implicit in the forward-looking statements. Important factors that could cause actual results to differ materially include: the development stage of our primary clinical candidates and related risks involved in drug development, clinical trials, regulation, manufacturing and commercialization; our reliance on third parties, including Almirall for success in certain areas of Athenex's business; need to raise additional capital; competition; intellectual property risks; risks relating to doing business in China; and the other risk factors set forth from time to time in our SEC fillings, copies of which are available for free in the Investor Relations section of our website at http://ir.athenex.com/phoenix.zhtml?c=254495&p=irol-sec or upon request from our Investor Relations Department. We assume no obligation and do not intend to update these forward-looking statements, except as required by law.

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