



Almirall and Eloxx Pharmaceuticals Enter into Exclusive Agreement to license ZKN-013 for rare dermatological diseases

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- Almirall obtains exclusive global rights to develop and commercialize ZKN-013 for the treatment of rare dermatological and other diseases associated with nonsense mutations
- ZKN-013 is a phase I ready oral therapy designed to overcome nonsense mutations that cause a premature stop codon resulting in nonfunctional protein production for example in recessive Dystrophic Epidermolysis Bullosa (RDEB), Junctional Epidermolysis Bullosa (JEB) and familial adenomatous polyposis (FAP)

BARCELONA, Spain and WATERTOWN, Mass., March 13, 2024 (GLOBE NEWSWIRE) -- **Almirall, S.A. (BME:ALM)** and **Eloxx Pharmaceuticals, Inc. (OTC: ELOX)** announced today that the companies have entered into an **exclusive license agreement for the asset ZKN-013**. Under the agreement, Almirall obtains global rights to develop and commercialize ZKN-013, including for the use in orphan dermatological diseases. **ZKN-013** is a potentially promising oral, nonsense mutation readthrough drug, which enables the host cells to produce functional proteins which counteract the root cause of these rare dermatological and potentially other diseases.

The drug candidate is expected to shortly enter into Phase I development in healthy volunteers.

As part of this agreement, Eloxx will receive an upfront of \$3 million, and additional payments throughout the potential development phases, including regulatory and sales milestones of up to \$470 million, as well as tiered royalties based on any potential future global sales.

*"We are very excited about this agreement with Almirall to develop and distribute ZKN-013, our lead TURBO-ZM™ based molecule, as we believe it has the potential to have a significant impact on the treatment of these painful and debilitating diseases," said **Sumit Aggarwal, President and Chief Executive Officer of Eloxx**. "In addition to advancing development of ZKN-013, this agreement will allow Eloxx to remain focused on fully maximizing the potential of ELX-02 in rare kidney diseases and continue funded discovery efforts on our TURBO-ZM™ platform"*

*"This license agreement is aligned with Almirall's R&D strategy to develop novel treatments to help people with dermatological conditions, including rare diseases," said **Karl Ziegelbauer, Executive Vice President R&D and Chief Scientific Officer of Almirall**. "We look forward to progressing the development of ZKN-013 to find a potentially impactful solution for patients suffering from rare and devastating diseases caused by nonsense mutations."*

RDEB /JEB are rare skin diseases characterized by defects in the Collagen7 gene which is essential for the correct formation of the skin structure and barrier function. ZKN-013 has demonstrated robust functional preclinical activity in RDEB/JEB patient cells and in APCmin (multiple intestinal neoplasia) mice. The studies demonstrated that ZKN-013 induces the production of functional, full-length COL7 in RDEB patient cells.

ZKN-013 is also being developed for the treatment of FAP patients with nonsense mutations characterized by proliferation of colon polyps and progression to colon cancer. FAP is a rare GI disease with patients progressing to colon cancer caused by mutations in the APC gene.

ZKN-013 is Eloxx's lead TURBO-ZM based molecule. Eloxx's TURBO-ZM platform uses chemistry technology to develop novel Ribosome Modulating Agents to target the human ribosome to develop new potential therapeutics. Ribosomes form the translation machinery that generates functional proteins from genetic sequences; modulating the ribosome subunits provides a therapeutic approach to address a number of different diseases.

About Eloxx Pharmaceuticals

Eloxx Pharmaceuticals, Inc. is engaged in the science of ribosome modulation, leveraging its innovative TURBO-ZM™ chemistry technology platform in an effort to develop novel Ribosome Modulating Agents (RMAs) and its library of Eukaryotic Ribosome Selective Glycosides (ERSGs). Eloxx's lead investigational product candidate, ELX-02, is a small molecule drug candidate designed to restore production of full-length functional proteins. ELX-02 is in Phase 2 clinical development for the treatment of Alport syndrome in patients with nonsense mutations.

For more information, please visit www.eloxxpharma.com.

About Almirall

Almirall is a global pharmaceutical company dedicated to medical dermatology. We closely collaborate with leading scientists, healthcare professionals, and patients to deliver our purpose: *to transform the patients' world by helping them realize their hopes and dreams for a healthy life*. We are at the forefront of science to deliver ground-breaking, differentiated medical dermatology innovations that address patients' needs.

Almirall, founded in 1944 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM). Almirall (total revenue in 2023: €898.8 MM, 1900 employees globally) has a direct presence in 21 countries and affiliates in over 70 others.

For more information, please visit almirall.com

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Eloxx Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this press release, including without limitation, statements regarding the potential future payments and future benefits under the license agreement, achievement of key milestones under the license agreement and the expected timeline for clinical development and efficacy of ZKN-013 are forward-looking statements. Forward-looking statements can be identified by the words "aim," "may," "will," "would," "should," "expect," "explore," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," "seeks," or "continue" or the negative of these terms similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on management's current plans, estimates, assumptions and projections based on information currently available to us. Forward-looking statements are subject to known and unknown risks, uncertainties and assumptions, and actual results or outcomes may differ materially from those expressed or implied in the forward-looking statements due to various important factors, including, but not limited to: our ability, or our licensees' ability, to progress any product candidates in preclinical or clinical trials; the uncertainty of clinical trial results and the fact that positive results from preclinical studies are not always indicative of positive clinical results; the scope, rate and progress of our, and our licensees' preclinical studies and clinical trials and other research and development activities; the competition for patient enrollment from drug candidates in development;; our ability to obtain the capital necessary to fund our operations; the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; our ability to obtain financing in the future through product licensing, public or private equity or debt financing or otherwise; our ability to meet the continued listing requirements of the Nasdaq Capital Market; general business conditions, regulatory environment, competition and market for our products; and business ability and judgment of personnel, and the availability of qualified personnel and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2023, as any such factors may be updated from time to time in our other filings with the SEC, accessible on the SEC's website at www.sec.gov and the "Financials & Filings" page of our website at <https://investors.eloxxpharma.com/financials-filings>.

All forward-looking statements speak only as of the date of this press release and, except as required by applicable law, we have no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Almirall Legal warning

This document includes only summary information and is not intended to be exhaustive. The facts, figures and opinions contained in this document, in addition to the historical ones, are "forward-looking statements". These statements are based on the information currently available and the best estimates and assumptions that the Company considers reasonable. These statements involve risks and uncertainties beyond the control of the Company. Therefore, actual results may differ materially from those declared by such forward-looking statements. The Company expressly waives any obligation to revise or update any forward-looking statements, goals or estimates contained in this document to reflect any changes in the assumptions, events or circumstances on which such forward-looking statements are based, unless required by the applicable law.



Source: Eloxx Pharmaceuticals