Akebia Therapeutics Announces Positive Opinion of European Medicines Agency for XOANACYL®, an Oral Therapy for Chronic Kidney Disease Licensed to Averoa

April 3, 2025

CAMBRIDGE, Mass., April 03, 2025 (GLOBE NEWSWIRE) -- Akebia Therapeutics®, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending the European Commission (EC) to approve XOANACYL® (Ferric Citrate as Coordination Complex) for the treatment of concomitant elevated serum phosphorous and iron deficiency in adult patients with chronic kidney disease (CKD).

Averoa, a renal-focused biopharmaceutical company, licensed the rights to develop and commercialize ferric citrate from Akebia in the European Economic Area and certain countries in Europe and the Middle East. Averoa recently announced the positive opinion from CHMP here: https://averoa-pharma.org/wp-content/uploads/2025/04/20250402-AVA1014-Positive-opinion-EN-VF-2.04.2025.pdf.

“We congratulate our partner Averoa on a positive step toward securing EMA approval for XOANACYL, and we will continue to support their efforts to deliver a treatment for complications of kidney disease to patients in Europe,” said John P. Butler, Chief Executive Officer of Akebia.

The EC will review the CHMP recommendation, and a final decision is expected in approximately two months.

About Akebia Therapeutics
Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease. Akebia was founded in 2007 and is headquartered in Cambridge, Massachusetts. For more information, please visit our website at www.akebia.com, which does not form a part of this release.

Forward-Looking Statements

Statements in this press release regarding Akebia Therapeutics, Inc.'s ("Akebia's") strategy, plans, prospects, expectations, beliefs, intentions and goals are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, and include, but are not limited to, statements regarding: Akebia’s statements regarding Averoa’s ability to secure EMA approval for XOANACYL; Akebia’s plans to support efforts to deliver a treatment for complications of kidney disease to patients in Europe; and Akebia’s expectations on the timing of a final decision from the EC. The terms "intend," "believe," "plan," "goal," "potential," "anticipate, "estimate," "expect," "future," "will," "continue," derivatives of these words, and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results, performance or experience may differ materially from those expressed or implied by any forward-looking statement as a result of various risks, uncertainties and other factors, including, but not limited to, risks associated with: decisions made by health authorities, such as the FDA and the EMA, with respect to regulatory filings and other interactions; the results of preclinical and clinical research; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; and early termination of any of Akebia's collaborations. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Annual Report on Form 10-K for the year ended December 31, 2024, and other filings that Akebia may make with the U.S. Securities and Exchange Commission in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and, except as required by law, Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

Akebia Therapeutics® is a registered trademark of Akebia Therapeutics, Inc.

Akebia Therapeutics Contact
Mercedes Carrasco
mcarrasco@akebia.com

Source: Akebia Therapeutics, Inc.