Akebia Therapeutics Received Interim Response from the FDA to Appeal for Vadadustat for the Treatment of Anemia due to Chronic Kidney Disease

February 21, 2023

CAMBRIDGE, Mass., Feb. 21, 2023 /PRNewswire/ -- 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 company received a second interim response from the U.S. Food and Drug Administration to its Formal Dispute Resolution Request regarding the Complete Response Letter for vadadustat received in March 2022.

Akebia received notification from the Office of New Drugs (OND), Center for Drug Evaluation and Research, that due to agency resource constraints and staffing needs the deciding authority for the appeal will now be Peter Stein, M.D., Director, OND. The appeal was originally assigned to a Senior Advisor within the OND.

Dr. Stein has indicated a need to seek internal consultation with nephrology, cardiology and liver safety experts in the Office of New Drugs to complete the review and render a decision. Dr. Stein indicated that he will do all he can to facilitate the appropriate meetings and discussions given the delay resulting from the staffing change. Akebia expects to be notified of a response to the appeal within thirty days of Dr. Stein completing the discussions and any required follow up.

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. The Company 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.

About Vadadustat
Vadadustat is an oral hypoxia-inducible factor prolyl hydroxylase inhibitor designed to mimic the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with stabilization of hypoxia-inducible factor, which can lead to increased red blood cell production and improved oxygen delivery to tissues. Vadadustat is an investigational new drug and is not approved by the U.S. Food and Drug Administration (FDA). On March 29, 2022, the FDA issued a complete response letter to Akebia's New Drug Application for vadadustat for the treatment of anemia due to chronic kidney disease (CKD). In November 2022, Akebia submitted a Formal Dispute Resolution Request focused on the favorable balance of the benefits and risks of vadadustat for the treatment of anemia due to CKD in adult patients on dialysis. Vadadustat is currently under review by the European Medicines Agency for the treatment of anemia due to CKD in adults. In Japan, vadadustat is approved as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients.

Forward Looking Statement
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 expectations on the timing of a response from the FDA with respect to its appeal. The terms "expect," "intend," "believe," "plan," "goal," "potential," "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 European Medicines Agency, with respect to regulatory filings, including the New Drug Application for vadadustat and the Formal Dispute Resolution Request for vadadustat; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat; the direct or indirect impact of the COVID-19 pandemic on regulators and Akebia's business, operations, and the markets and communities in which Akebia and its partners, collaborators, vendors and customers operate; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; early termination of any of Akebia's collaborations; and the competitive landscape for vadadustat, if approved. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, 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.

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