Akebia Receives FDA Acceptance of Resubmission to NDA of Vadadustat for the Treatment of Anemia due to Chronic Kidney Disease

October 25, 2023

March 27, 2024 Set as User Fee Goal Date

CAMBRIDGE, Mass., Oct. 25, 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 the U.S. Food and Drug Administration (FDA) has acknowledged that the resubmission to its New Drug Application (NDA) for vadadustat as a treatment for anemia due to chronic kidney disease (CKD) in adult patients on dialysis, was complete. The FDA has classified this as a class 2 response, which results in a six-month review period from the date of resubmission, and the FDA set a user fee goal date ("PDUFA" date) of March 27, 2024.

"We're extremely pleased the FDA acknowledged our resubmission to our NDA for vadadustat was complete following our productive interactions over the past year. We look forward to working closely with the agency to finalize the review," said John P. Butler, Chief Executive Officer of Akebia. "With this significant milestone, we expect to have vadadustat available shortly following an approval and are preparing for a commercial launch in the second half of 2024 as we are eager to offer an alternative oral medication to U.S. dialysis patients if approved."

Akebia's resubmission to its NDA addressed the issues raised in the complete response letter. The filing included post-marketing safety data from tens of thousands of patients in Japan where vadadustat is approved and has been on the market for more than three years. Vadadustat is currently approved for use in 35 countries.

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.

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 not approved by the U.S. Food and Drug Administration. Vadadustat is approved in 35 countries, including Europe and Australia, for the treatment of symptomatic anemia due to CKD in adult patients on chronic maintenance dialysis and in Japan as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis-dependent adult patients.

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 expectations regarding the a decision by the FDA on its NDA for vadadustat, including the timing thereof; and Akebia's plans with respect to commercializing vadadustat in the U.S. if approved, including the timing thereof. The terms "intend," "believe," "plan," "goal," "expect," "potential," "anticipate," "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, with respect to regulatory filings, including the anticipated FDA decision on the NDA for vadadustat; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat; the potential demand and market potential and acceptance of, as well as coverage and reimbursement related to, Auryxia, including estimates regarding the potential market opportunity; the competitive landscape for Auryxia, including potential generic entrants; the ability of Akebia to attract and retain qualified personnel; Akebia's ability to implement cost avoidance measures and reduce operating expenses; the results of preclinical and clinical research; 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; and early termination of any of Akebia's collaborations. 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 June 30, 2023, 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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