Akebia Therapeutics Resubmits New Drug Application to the FDA for Vadadustat

September 28, 2023

CAMBRIDGE, Mass., Sept. 28, 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 it has resubmitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for vadadustat, Akebia's investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor, for the treatment of anemia due to chronic kidney disease (CKD) in adult patients on dialysis. Vadadustat is currently approved for use in 35 countries.

"We are pleased to have resubmitted the NDA for vadadustat following multiple discussions with the FDA and clear direction from the agency, a significant milestone that reflects our team's commitment to patients and conviction in the benefit we believe vadadustat can deliver to patients on dialysis," said John P. Butler, Chief Executive Officer of Akebia. "Our team assembled a comprehensive resubmission, which now includes post-marketing safety data from tens of thousands of patients in Japan where vadadustat is approved and has been in market for more than three years. We look forward to working with the FDA during the review process and are eager to offer a new oral therapeutic to patients if approved."

Based on standard NDA resubmission review timelines, a letter from the FDA acknowledging that the resubmission is complete, classifying the resubmission, and setting the PDUFA date is expected in 30 days. Akebia expects the FDA to set a PDUFA date of six months from the date of submission.

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 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 Japan 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 beliefs about the comprehensive nature of its NDA resubmission for vadadustat and expectations regarding the acceptance by the FDA and a decision by the FDA on its NDA for vadadustat, including the timing thereof; Akebia's beliefs about the benefits vadadustat can deliver to patients on dialysis; and Akebia's plans with respect to commercializing vadadustat in the U.S. if approved. 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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