



Akebia Therapeutics Expects to Resubmit Vadadustat NDA in Third Quarter 2023

August 24, 2023

Akebia Received Type A Meeting Minutes from the FDA

CAMBRIDGE, Mass., Aug. 24, 2023 /PRNewswire/ -- [Akebia Therapeutics® Inc.](https://www.akebia.com) (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today announced that the company expects to resubmit its New Drug Application (NDA) for vadadustat as a treatment for anemia due to chronic kidney disease in adult patients on dialysis by the end of the third quarter of 2023. Upon acceptance of the NDA, Akebia expects the U.S. Food and Drug Administration (FDA) to set a PDUFA date of six months from the date of submission.

Akebia received Meeting Minutes summarizing the productive and informative discussion held during an End of Dispute Type A meeting with the FDA in July 2023. The minutes reflect Akebia's plan for the NDA resubmission discussed at the meeting.

Vadadustat is currently approved for use in 34 countries. Vafseo® (vadadustat) is marketed in Japan by Mitsubishi Tanabe Pharma Corporation.

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 (FDA). Vadadustat is approved in Europe for the treatment of symptomatic anemia due to CKD in adult patients on chronic maintenance dialysis. 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 and plans with respect to the resubmission of its NDA for vadadustat, including the timing thereof and information to be included therein; and Akebia's expectations regarding the timing for a decision by the FDA on its NDA for vadadustat once resubmitted. The terms "intend," "believe," "plan," "goal," "expect," "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 the FDA with respect to Akebia's resubmission of its NDA for 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; decisions made by health authorities, such as the FDA, with respect to regulatory filings, including the anticipated resubmission of the New Drug Application for vadadustat; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat; 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 March 31, 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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