Akebia Therapeutics Completed Type A Meeting with the FDA and Expects to Resubmit Vadadustat NDA in Third Quarter 2023

July 18, 2023

CAMBRIDGE, Mass., July 18, 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 Akebia completed an End of Dispute Type A meeting with the U.S. Food and Drug Administration (FDA) to discuss Akebia's forthcoming resubmission of its New Drug Application (NDA) for vadadustat as a treatment for anemia due to chronic kidney disease (CKD) in adult patients on dialysis.

"We're pleased to report we recently met with the FDA to align on the content of our NDA resubmission for vadadustat," said John P. Butler, Chief Executive Officer of Akebia. "The meeting was informative and productive, and we're eager to advance the U.S. regulatory process and potentially bring a new oral treatment to dialysis patients with anemia due to CKD."

Akebia expects to receive the FDA's meeting minutes by mid-August and plans to resubmit its NDA for vadadustat by the end of the third quarter of 2023. Upon acceptance of the NDA, Akebia expects the FDA to set a PDUFA date of six months from the date of submission.

Vadadustat is currently approved for use in 34 countries, it was most recently approved by the Swiss Agency for Therapeutic Products (Swissmedic) in June 2023. 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.

Important Safety Information
For safety information, view the European Summary of Product Characteristics (SPC/SmPC) for Vafseo® (vadadustat) at https://ec.europa.eu/health/documents/community-register/2023/20230424158854/anx_158854_en.pdf, https://products.mhra.gov.uk/, and will be available via SwissMedic here.

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 data to be included therein; Akebia's expectations regarding the timing for a decision by the FDA on its NDA for vadadustat once resubmitted and statements regarding the potential to bring vadadustat to dialysis patients with anemia due to CKD. 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 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, vadadustat; the results of preclinical and clinical research; 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; 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 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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