



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

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CAMBRIDGE, Mass., Dec. 22, 2022 /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 an interim response from the U.S. Food and Drug Administration (FDA) to its Formal Dispute Resolution Request regarding the Complete Response Letter received in March 2022 for vadadustat, which had been submitted to the FDA as a treatment for anemia due to chronic kidney disease in adult patients.

Akebia met with the FDA in November to discuss its appeal and subsequently received a request for additional clarifying information from the Office of New Drugs, Center for Drug Evaluation and Research, which is deciding the appeal. Akebia remains engaged with the FDA and expects to submit the requested information to the FDA in January 2023. Based on FDA guidance, Akebia expects to receive a response to its appeal 30 days from the date Akebia submits the requested information.

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 with respect to when it will submit the information requested by the U.S. Food and Drug Administration (FDA) to the FDA in January 2023 and 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, with respect to Akebia's regulatory filings, including the New Drug Application and the Formal Dispute Resolution Request for vadadustat; the perceived therapeutic benefits, safety profile, and effectiveness of vadadustat; and 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. 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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