Akebia Receives Positive CHMP Opinion in Europe for Vafseo™ (vadadustat) for the Treatment of Symptomatic Anaemia Associated with Chronic Kidney Disease in Adults on Chronic Maintenance Dialysis

February 23, 2023

CAMBRIDGE, Mass., Feb. 23, 2023 /PRNewswire/ -- Akebia Therapeutics®, Inc. (NASDAQ: AKBA) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending the European Commission (EC) to approve Vafseo™ (vadadustat), an oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor for the treatment of symptomatic anaemia associated with chronic kidney disease (CKD) in adults on chronic maintenance dialysis. The EC will review the CHMP recommendation and deliver a final decision in approximately two months. The decision will be applicable to all 27 European Union member states plus Iceland, Norway and Liechtenstein.

"We are extremely pleased by the CHMP's positive opinion for our marketing authorisation application for Vafseo for patients on dialysis," said John P. Butler, Chief Executive Officer of Akebia. "We are driven to better the lives of people impacted by chronic kidney disease and a positive opinion is a critical step toward delivering on this purpose. We believe more treatment options are needed for patients with anaemia on dialysis, and if we receive a positive EC decision Vafseo could offer an oral treatment to help address this need. This is also an important milestone in our process to identify and secure a potential partner in Europe to bring Vafseo to those patients."

The CHMP based its positive opinion on data from a comprehensive development program that included over 7,500 patients, including the global Phase 3 clinical program of vadadustat for the treatment of anemia due to CKD in adult patients on dialysis ($INNO_2VATE$).

In the study of adult patients on dialysis, vadadustat achieved the primary and key secondary efficacy endpoint in each of the two $INNO_2VATE$ studies, demonstrating non-inferiority to darbepoetin alfa as measured by a mean change in hemoglobin (Hb) between baseline and the primary evaluation period (weeks 24 to 36) and secondary evaluation period (weeks 40 to 52). Vadadustat also achieved the primary safety endpoint of the $INNO_2VATE$ program, defined as non-inferiority of vadadustat versus darbepoetin alfa in time to first occurrence of major adverse cardiovascular events, which is the composite of all-cause mortality, non-fatal myocardial infarction, or non-fatal stroke across both $INNO_2VATE$ studies.

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). 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 on the timing of a decision from the European Commission and, if approved, Akebia's plans with respect to commercializing and identifying a partner for Vafseo in Europe. 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 and the European Medicines Agency, with respect to regulatory filings; 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; early termination of any of Akebia's collaborations; 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 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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