Akebia Receives European Commission Approval for Vafseo™ (vadadustat) for the Treatment of Symptomatic Anaemia Associated with Chronic Kidney Disease in Adults on Chronic Maintenance Dialysis

April 25, 2023

CAMBRIDGE, Mass., April 25, 2023 /PRNewswire/ -- Akebia Therapeutics®, Inc. (Nasdaq: AKBA) today announced that the European Commission (EC) has granted marketing authorisation for 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 approval is applicable to all 27 European Union member states plus Iceland, Norway and Liechtenstein. Vadadustat is now approved in 32 countries.

"We're extremely pleased the EC has approved Vafseo, an important milestone for Akebia but even more impactful for the hundreds of thousands of Europeans diagnosed with anaemia associated with CKD on dialysis," said John P. Butler, Chief Executive Officer of Akebia. "We believe patients receiving chronic maintenance dialysis would benefit from additional therapeutic options. With approval, we're eager to select a European partner who can quickly bring Vafseo to those patients."

Anemia associated with CKD, common in patients on dialysis, is a debilitating condition which may be associated with many adverse clinical outcomes. Vafseo, approved in 150 mg, 300 mg and 450 mg film-coated tablets, provides a once-daily oral treatment option for dialysis dependent patients with symptomatic anaemia associated with CKD. Throughout Europe, more than 200,000 dialysis patients are currently treated for anemia associated with CKD.

The approval follows the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) positive opinion issued in February 2023 recommending the EC approve Vafseo. The approval is based 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.

John Butler added, "We are grateful for the patients, physicians, investigators, and site coordinators who participated in our clinical trials that led to this important approval. I want to also express my deep appreciation for our team at Akebia as the approval is a culmination of years of work and a demonstration of their commitment to bettering the lives of people impacted by kidney disease."

Important Safety Information
The full European Summary of Product Characteristics (SPC/SmPC) for Vafseo™ (vadadustat) will be available from the European Medicines Agency at https://www.ema.europa.eu.

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. In April 2023, the European Commission granted marketing authorization for vadadustat for the treatment of symptomatic anaemia associated with chronic kidney disease in adults 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 beliefs in the benefits of Vafseo (vadadustat) for the treatment of symptomatic anaemia associated with chronic kidney disease in adults on chronic maintenance dialysis; and 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, 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 Annual Report on Form 10-K for the year ended December 31, 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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