Akebia Announces Swissmedic Approval of Vafseo® (vadadustat)

June 20, 2023

CAMBRIDGE, Mass., June 20, 2023 /PRNewswire/ -- Akebia Therapeutics®, Inc. (Nasdaq: AKBA) today announced that the Swiss Agency for Therapeutic Products (Swissmedic) has granted marketing authorization for Vafseo® (vadadustat), an oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor for the treatment of symptomatic anemia associated with chronic kidney disease (CKD) in adults on chronic maintenance dialysis.

"With Swissmedic marketing authorization of Vafseo, we're pleased to note that vadadustat is now approved in 34 countries," said John P. Butler, Chief Executive Officer of Akebia. "We anticipate our partner Medice will launch Vafseo in Europe this year, and we are eager to support the launch to bring an additional therapeutic option to patients on dialysis."

Anemia due to CKD, common among patients on dialysis, is often associated with adverse clinical outcomes. Throughout Europe, it is estimated that at least 325,000 dialysis patients are currently treated for anemia associated with CKD.

The Swissmedic approval of Vafseo 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.

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).

IMPORTANT SAFETY INFORMATION
The prescribing information for Vafseo® (vadadustat) will be available on the Swissmedic website here.

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.

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 plans and expectations with respect to commercializing Vafseo in Europe, including the timing thereof. The terms "expect," "anticipate", "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: the potential demand and market potential and acceptance of, as well as coverage and reimbursement related to, vadadustat; 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; 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; 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.

Akebia Therapeutics Contact
Mercedes Carrasco
mcarrasco@akebia.com

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