



Akebia Announces UK MHRA Approval of Vafseo® (vadadustat) for the Treatment of Symptomatic Anemia Associated with Chronic Kidney Disease in Adults on Chronic Maintenance Dialysis

May 22, 2023

CAMBRIDGE, Mass., May 22, 2023 /PRNewswire/ -- [Akebia Therapeutics® Inc.](#) (Nasdaq: AKBA) today announced that the United Kingdom (UK) Medicines and Healthcare products Regulatory Agency (MHRA) 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 the UK MHRA marketing authorization for Vafseo, we're pleased to add another approval in Europe," said John P. Butler, Chief Executive Officer of Akebia. "Again, I want to recognize our team, and the patients, physicians, investigators, and site coordinators who participated in our global trial and made this approval possible. We look forward to completing a partnership in Europe and bringing an additional therapeutic option to patients on dialysis in the United Kingdom."

Anemia due to CKD, common among patients on dialysis, is often associated with adverse clinical outcomes. The MHRA 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 (INNO₂VATE).

In the study of adult patients on dialysis, vadadustat achieved the primary and key secondary efficacy endpoint in each of the two INNO₂VATE 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 INNO₂VATE 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 INNO₂VATE studies.

IMPORTANT SAFETY INFORMATION

The full Summary of Product Characteristics (SPC/SmPC) for Vafseo® (vadadustat) will be available on the UK MHRA website at <https://products.mhra.gov.uk/>.

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). 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.

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 with respect to commercializing and completing a partnership 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 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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