Akebia Therapeutics Regaining Rights to Vadadustat in the United States, Europe, China and Access Consortium Countries upon Termination of Collaboration and License Agreements with Otsuka

June 30, 2022

- Companies finalize termination with an agreed-upon settlement fee of $55M to be paid to Akebia
- Akebia to assume responsibility for regulatory review processes previously led by Otsuka

CAMBRIDGE, Mass., June 30, 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 it has executed an agreement to terminate the U.S. and ex-U.S. vadadustat Collaboration and License Agreements with Otsuka Pharmaceutical Co., Ltd. (Otsuka). As part of the termination, Otsuka has agreed to pay Akebia a settlement fee of $55 million.

As a result of the termination of the agreements, Akebia is regaining the rights from Otsuka for vadadustat, an investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor, in the United States, Europe, China, Russia, Canada, Australia, the Middle East, and certain other territories.

"We continue to believe in the potential of vadadustat as an oral treatment for patients with anemia due to chronic kidney disease, and we are pleased to be regaining the full rights to the product in these important markets," said John Butler, Chief Executive Officer of Akebia. "Otsuka has been a strong partner for many years, and we appreciate their desire to have an efficient transfer of the responsibilities back to Akebia. We plan to continue to pursue approval for vadadustat to make it available to patients in these territories, and we are excited about the potential additional value this brings to Akebia, as we continue to work to build the company into the future."

In October 2021, Otsuka submitted an initial marketing authorization application (MAA) to the European Medicines Agency (EMA) for vadadustat for the treatment of anemia associated with chronic kidney disease (CKD) in adults. The review is in progress. Otsuka and Akebia will coordinate to transfer the MAA to Akebia through processes outlined by the EMA. Vadadustat is also under review in the United Kingdom, Switzerland, and Australia through the Access Consortium. Responsibilities for that review will transfer to Akebia as well at a date to be agreed upon.

In the U.S., Akebia received a Complete Response Letter from the U.S. Food & Drug Administration (FDA) for vadadustat. Akebia plans to evaluate and determine potential next steps for vadadustat in the U.S. following the end of review conference with the FDA.

In the U.S., Akebia separately has a distribution agreement in place with Vifor Pharma, providing potential access to up to 60% of U.S. dialysis patients through existing Vifor Pharma relationships. Mitsubishi Tanabe Pharma Corporation owns development and commercialization rights to vadadustat in Japan and certain other Asian counties.

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.

About Anemia due to Chronic Kidney Disease (CKD)

Anemia is a condition in which a person lacks enough healthy red blood cells to carry adequate oxygen to the body's tissues. It commonly occurs in people with CKD because their kidneys do not produce enough erythropoietin (EPO), a hormone that helps regulate production of red blood cells. Anemia due to CKD can have a profound impact on a person's quality of life as it can cause fatigue, dizziness, shortness of breath and cognitive dysfunction. Left untreated, anemia leads to deterioration in health and is associated with increased morbidity and mortality in people with CKD.

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 belief in vadadustat as an oral treatment for patients with anemia due to chronic kidney disease; Akebia's plans to pursue approval for vadadustat to make it available to patients in the U.S., Europe, China, Russia, Canada, Australia, the Middle East and certain other territories and the associated value that would bring to Akebia; Akebia's future plans with respect to its strategic growth and operating plans, including as they relate to next steps for regulatory submissions outside of the U.S. and plans to evaluate and determine potential next steps for vadadustat in the U.S. following the end of review conference with the U.S. Food and Drug Administration ("FDA"); and the number of U.S. dialysis patients that could be accessed as a result of the distribution agreement in place with Vifor Pharma. The terms "believe," "plan," "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 implementation of the provisions of the termination agreement with Otsuka, including the ability of Akebia to pursue regulatory approval outside the U.S.; decisions made by health authorities, such as the FDA and the European Medicines Agency, with respect to regulatory filings, including the New Drug Application for vadadustat; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat; the impact of the workforce reduction on Akebia's business; the ability of Akebia to attract and retain qualified personnel; Akebia's ability to implement cost avoidance measures and reduce overhead costs; 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 March 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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