Akebia Announces Otsuka's Submission of Initial Marketing Authorization Application to the European Medicines Agency for Vadadustat for the Treatment of Patients with Anemia due to Chronic Kidney Disease

October 29, 2021

CAMBRIDGE, Mass., Oct. 29, 2021 /PRNewswire/ -- Akebia Therapeutics, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose of bettering the lives of people impacted by kidney disease, and its collaborator, Otsuka Pharmaceutical Co., Ltd. (Otsuka), today announced that Otsuka Pharmaceutical Netherlands B.V. has submitted an initial marketing authorization application (MAA) to the European Medicines Agency for vadadustat, an investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor, for the treatment of anemia associated with chronic kidney disease (CKD) in adults.

"Otsuka's submission of the vadadustat MAA is an important step toward potentially bringing to market a new oral treatment option for patients living with anemia due to CKD. We are pleased to have collaborated on a comprehensive submission," said John P. Butler, Chief Executive Officer of Akebia. "We will continue to work closely with Otsuka through the review process, and to ensure we are well positioned to support a successful commercial launch of vadadustat in Europe, if approved."

"We are excited to reach this regulatory milestone in collaboration with Akebia, demonstrating our continued commitment to patients with chronic kidney disease," said Andy Hodge, CEO of Otsuka Pharmaceutical Europe Ltd. and Otsuka Pharmaceutical Development and Commercialisation Europe GmbH.

Akebia and Otsuka are collaborating on the development and commercialization of vadadustat in the U.S., Europe, China, Russia, Canada, Australia, the Middle East, and certain other territories.

About Vadadustat

Vadadustat is an oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) 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. The New Drug Application (NDA) for vadadustat for the treatment of anemia due to chronic kidney disease (CKD) is under review by the U.S. Food and Drug Administration (FDA). Vadadustat is an investigational new drug and is not approved by the FDA or any regulatory authority with the exception of Japan's Ministry of Health, Labour and Welfare (MHLW). 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.

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 Otsuka

Otsuka Pharmaceutical Co., Ltd. is a global healthcare company with the corporate philosophy: "Otsuka people creating new products for better health worldwide." Otsuka researches, develops, manufactures, and markets innovative products, focusing on pharmaceutical products to meet unmet medical needs and nutraceutical products for the maintenance of everyday health.

In pharmaceuticals, Otsuka is a leader in the challenging areas of mental, renal and cardiovascular health and has additional research programs in oncology and on several under-addressed diseases including tuberculosis, a significant global public health issue. These commitments illustrate how Otsuka is a "big venture" company at heart, applying a youthful spirit of creativity in everything it does.

Forward-Looking Statements

Statements in this press release regarding Akebia's or Otsuka'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, including, but not limited to, statements regarding: the commercial launch of vadadustat, if approved, and the timing associated with bringing a new oral treatment option to patients living with anemia due to CKD, and Akebia's ability to support a commercial launch of vadadustat in Europe. The terms "expect," "will,"

"confident," "expect," "plan," "continue," "potential," and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including, but not limited to: the timing of certain regulatory filings and approvals; interactions with FDA, including reviews and inspections, the timing related thereto and the outcome thereof; the potential therapeutic benefits, safety profile and effectiveness of vadadustat; the direct or indirect impact of the COVID-19 pandemic on Akebia's and Otsuka's businesses, operations, and the markets and communities in which Akebia and Otsuka and their partners, collaborators, vendors and customers operate; the timing and content of advice given and decisions made by health authorities, including approval and labeling decisions; and the potential indications, demand and market potential and acceptance of, as well as coverage and reimbursement related to vadadustat, if approved, including estimates regarding the potential market opportunity for vadadustat and the size of eligible patient populations. 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 June 30, 2021 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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