Akebia and Otsuka Announce FDA Acceptance for Filing of New Drug Application for Vadadustat for the Treatment of Anemia Due to Chronic Kidney Disease in Adult Patients on Dialysis and Not on Dialysis

June 1, 2021

- Vadadustat assigned PDUFA target action date of March 29, 2022

CAMBRIDGE, Mass. and TOKYO, June 1, 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 the U.S. Food and Drug Administration (FDA) accepted for filing the New Drug Application (NDA) for vadadustat for the treatment of anemia due to chronic kidney disease (CKD) in both adult patients on dialysis and adult patients not on dialysis.

The FDA has assigned the application standard review and a Prescription Drug User Fee Act (PDUFA) target action date of March 29, 2022. The FDA also indicated that they are not currently planning to hold an Advisory Committee meeting to discuss the application.

"The acceptance of our vadadustat NDA filing marks another important milestone for Akebia and Otsuka, as we work to bring a new oral treatment option to patients living with anemia due to CKD," said John P. Butler, Chief Executive Officer of Akebia. "We remain confident in the clarity and quality of our data, and we look forward to working with the FDA during their review of our application. In addition, we continue to collaborate with our partners to ensure we are well positioned to support a successful commercial launch of vadadustat, upon FDA approval."

Kabir Nath, board member of Otsuka Pharmaceutical Co., Ltd. and president and CEO of its North American pharmaceutical business noted, "With Akebia, we are proud to have achieved this milestone in the development of vadadustat. This achievement highlights the teams' ongoing execution as well as our shared commitment to advancing vadadustat with the goal of bringing this novel therapeutic to patients as soon as possible, subject to regulatory approval."

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.

In addition, Otsuka is working with Akebia to prepare a Marketing Authorization Application for vadadustat for submission to the European Medicines Agency expected this year.

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. Vadadustat recently completed its global Phase 3 clinical development program for the treatment of anemia due to CKD. Vadadustat is not approved by the U.S. Food and Drug Administration (FDA) or any regulatory authority with the exception of Japan's Ministry of Health, Labour and Welfare (MHLW). In Japan, vadadustat is approved and marketed under the tradename Vafseo™, 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., headquartered in Tokyo, Japan, is a global healthcare company with a focus on pharmaceutical products to meet unmet medical needs and nutraceutical products for the maintenance of everyday health. All Otsuka stories start by taking the road less traveled. Learn more about Otsuka in the U.S. at www.otsuka-us.com and about Otsuka Pharmaceutical globally at www.otsuka.co.jp/en/.

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: FDA's current plans not to hold an Advisory Committee meeting to discuss Akebia's NDA application for vadadustat; 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 the timing of submission of an MAA for vadadustat to EMA. 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 Akebia 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 March 31, 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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