Akebia Therapeutics Announces Approval of Vadadustat in Japan for the Treatment of Anemia Due to Chronic Kidney Disease in Dialysis-Dependent and Non-Dialysis Dependent Adult Patients

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First Regulatory Approval for Akebia's HIF-PHI Marks Beginning of Next Phase of Akebia's Growth Story

CAMBRIDGE, Mass., June 29, 2020 /PRNewswire/ -- Akebia Therapeutics®, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today announced the first regulatory approval of vadadustat, its oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), for the treatment of anemia due to chronic kidney disease (CKD). Mitsubishi Tanabe Pharma Corporation (MTPC), Akebia's collaboration partner in Japan for vadadustat, has obtained manufacturing and marketing approval of vadadustat as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients by the Ministry of Health, Labour and Welfare in Japan on June 29, 2020. Vadadustat will be marketed by MTPC in Japan under the trade name VAFSEO ™.

An estimated 13 million people in Japan have advanced stages of CKD. Anemia is common in patients with CKD and its prevalence increases as CKD progresses. Injectable erythropoiesis-stimulating agents (ESAs) are currently the standard of care. Vadadustat provides adult patients with a convenient, once-daily oral therapeutic for the treatment of anemia due to CKD in Japan.

"Today's announcement represents the first regulatory approval of vadadustat and is a significant step forward for patients with anemia due to CKD in Japan," said John P. Butler, President and Chief Executive Officer of Akebia. "We believe this milestone marks the beginning of the next phase of Akebia's growth story and we are excited to support our collaboration partner, MTPC, with the expected commercialization of vadadustat in Japan later this year."

MTPC filed a Japanese New Drug Application for vadadustat in July 2019. The approval was based on data from the vadadustat development program, including MTPC's two Phase 3 active-controlled pivotal studies, which support the efficacy and safety of vadadustat in treating both adult patients on dialysis and those not on dialysis with anemia due to CKD in Japan.

Akebia and MTPC entered into a collaboration agreement in 2015 providing MTPC with exclusive rights to develop and commercialize vadadustat in Japan and certain other Asian countries. The regulatory approval announced today triggers a $15 million milestone payment from MTPC to Akebia. In addition, Akebia is eligible to receive up to approximately $190 million in additional milestone payments from MTPC, based upon achievement of certain regulatory and sales milestones. MTPC is also obligated make tiered double-digit royalty payments to Akebia of up to 20% on sales of vadadustat in Japan and certain other Asian countries, subject to regulatory approval of vadadustat.

About Vadadustat

Vadadustat is an oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor currently in global Phase 3 development for the treatment of anemia due to CKD. Vadadustat is 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 therapy and is not approved by the U.S. Food and Drug Administration (FDA).

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.

Forward-Looking Statements

Statements in this press release regarding 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, including but not limited to statements regarding Akebia's growth story and the commercialization of VAFSEO in Japan, including the timing thereof. The terms "believe," "expect" 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 the potential direct or indirect impact of the COVID-19 pandemic on our and our partners', collaborators', vendors' and customers' businesses, operations, and the markets and communities in which we and our partners, collaborators, vendors and customers operate; manufacturing risks; risks associated with management and key personnel changes and transitional periods; market acceptance and coverage and reimbursement of VAFSEO in Japan; the risks associated with potential generic entrants; early termination of any of Akebia's collaborations; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements; the timing and content of decisions made by regulatory authorities; the competitive landscape; the scope, timing, and outcome of any legal, regulatory and administrative proceedings; changes in the economic and financial conditions of the businesses of Akebia and its partners; and Akebia's and its partners' ability to obtain, maintain and enforce patent and other intellectual property protection. 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, 2020 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 Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

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