Akebia Therapeutics Announces First Commercial Launch of VAFSEO™ (vadadustat tablets), a New Oral Treatment for Anemia Due to Chronic Kidney Disease, in Japan

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VAFSEO Launch Marks Availability of Convenient Once-Daily Oral Treatment for Adult Patients on Dialysis and Not on Dialysis in Japan

CAMBRIDGE, Mass., Aug. 26, 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 that vadadustat, its oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), is now commercially available in Japan as a treatment for anemia due to chronic kidney disease (CKD) under the trade name VAFSEO ™. VAFSEO has been included in the Japan National Health Insurance drug price listing and was granted regulatory approval 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 in June 2020. The starting dose for VAFSEO is indicated at 300 mg with a maximum dose indicated at 600 mg.

VAFSEO provides adult patients in Japan with a once-daily treatment option and has the potential to set a new oral standard of care for the treatment of renal anemia in Japan. 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. Anemia due to CKD can result in serious complications including irregular or unusually fast heartbeat, enlargement of the heart, and heart failure and also has well-documented impacts on quality of life. Injectable erythropoiesis-stimulating agents (ESAs) are currently the standard of care.

In 2015, Akebia and Mitsubishi Tanabe Pharma Corporation (MTPC) entered into a collaboration agreement that provided MTPC with exclusive rights to develop and commercialize vadadustat in Japan and certain other Asian countries. Under the terms of the agreement, Akebia is eligible to receive up to approximately $190 million in future milestone payments from MTPC, based upon achievement of certain regulatory and sales milestones. MTPC is also obligated to 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.

Vadadustat is in global Phase 3 development for the treatment of anemia due to CKD and is not yet approved outside of Japan.

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 is in global Phase 3 development for the treatment of anemia due to CKD and 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 as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients.

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 the commercialization of VAFSEO in Japan, prevalence of CKD, and related milestone and royalty payments. 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 and material contracts; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements and material contracts; 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 June 30, 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.

Akebia Therapeutics

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