Akebia Announces Initiation of Investigator-Sponsored Study Evaluating Vadadustat for Prevention and Treatment of ARDS in Patients Hospitalized with COVID-19

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The University of Texas Health Science Center at Houston to conduct study with up to 300 patients to evaluate use of Akebia's investigational drug, vadadustat, as potential therapy to lessen the severity of COVID-19

CAMBRIDGE, Mass., July 14, 2020 /PRNewswire/ -- Akebia Therapeutics, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose of bettering the lives of people impacted by kidney disease, today announced the initiation of an investigator-sponsored study evaluating the use of vadadustat, Akebia's investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), as a potential therapy to prevent and lessen the severity of acute respiratory distress syndrome (ARDS), a complication of COVID-19 infection. The study will be conducted by The University of Texas Health Science Center at Houston (UTHealth) in Houston, Texas. Bentley J. Bobrow, MD, Chair of Emergency Medicine, and Holger K. Eltzschig, MD, PhD, Chair of the Department of Anesthesiology with McGovern Medical School at UTHealth, will serve as co-principal investigators of the study.

The randomized, double-blind, placebo-controlled study is intended to evaluate the safety and efficacy of vadadustat in up to 300 adult patients who have been hospitalized at Memorial Hermann-Texas Medical Center for hypoxemia due to COVID-19, the disease caused by SARS-CoV-2. Patients will be dosed with vadadustat or a placebo starting within 24 hours of hospital admission and continuing for up to 14 days. This study is being conducted under a U.S. Food and Drug Administration Investigational New Drug (IND) application.

"The prevalence of COVID-19 in Houston has recently surged and we are excited to be working toward developing better treatment options at UTHealth," said Dr. Bentley J. Bobrow. "Right now, we can support patients with COVID-related ARDS with supplemental oxygen and different forms of ventilation, but don't yet have effective treatments to protect their lungs and help them get better. Our goal is to prevent patients with the virus from progressing to requiring a ventilator and, if they do require a ventilator, to decrease the time they are on that ventilator. We are thrilled to collaborate with Akebia on this study of vadadustat."

"While Akebia's highest priority remains the continued successful execution of our global Phase 3 program to advance vadadustat as a potential new standard of care for adult patients with anemia due to chronic kidney disease (CKD), we are also committed to doing what we can to help with the COVID-19 pandemic," said John P. Butler, President and Chief Executive Officer of Akebia Therapeutics. "We're pleased that our work presents the opportunity to collaborate with UTHealth and explore a potential therapy to help COVID patients."

Vadadustat is currently in global Phase 3 development for the treatment of anemia due to CKD. The Company recently reported positive primary and key secondary efficacy and safety endpoint results from INNO$_2$VATE, the first of its two global Phase 3 cardiovascular outcomes programs (please refer to Akebia's INNO$_2$VATE Data Announcement for the top-line data). Vadadustat is approved as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients in Japan. Vadadustat is not approved by the U.S. Food and Drug Administration (FDA) or any regulatory authority for use outside of Japan.

As outlined by the CDC, people infected with COVID-19 have reported a wide range of symptoms including mild respiratory problems to severe respiratory illness including ARDS, which could result in rapid decline of respiratory function and death.

The HIF Mechanism
Akebia's investigational oral HIF-PHI, vadadustat, leverages the HIF mechanism and is designed to mimic the body's physiologic response to hypoxia (low oxygen) such as seen at high-altitudes. At higher altitudes, the body responds to lower oxygen availability with stabilization of HIF, which can lead to increased red blood cell production and improved oxygen delivery to tissues. Several HIF target-genes have been implicated in decreasing lung injury in ARDS and protecting other organs including the heart, intestine, kidneys, and liver in the setting of hypoxia.

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.

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 development plans for vadadustat; evaluation of vadadustat as a potential therapy to lessen the severity of COVID-19; Akebia's highest priority as the continued successful execution of its global Phase 3 program to advance vadadustat as a potential new standard of care for adult patients with anemia due to CKD; and Akebia's commitment to helping with the COVID-19 pandemic. 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 that vadadustat may not be an effective treatment to lessen the severity of ARDS or approved for marketing by the FDA; 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; the risk that clinical trials may not be successful; manufacturing risks; risks associated with management and key personnel changes and transitional periods; the actual costs incurred in the clinical studies of vadadustat and the availability of financing to cover such costs; the risk that clinical studies are discontinued or delayed for any reason, including for safety, tolerability, enrollment, manufacturing or economic reasons; market acceptance and coverage and reimbursement of vadadustat, if approved; 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; the actual time it takes to initiate and complete preclinical and clinical studies; 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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