Akebia Announces Manuscript Highlighting Global Phase 3 INNO2VATE Program Rationale, Study Design and Baseline Characteristics Published in Peer-Reviewed Medical Journal

November 16, 2020

CAMBRIDGE, Mass., Nov. 16, 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 publication of a manuscript detailing the study design and methodology for its global Phase 3 $INNO_2VATE$ program in *Nephrology Dialysis Transplantation (NDT)*, the official journal for the European Renal Association-European Dialysis and Transplant Association (ERA-EDTA). The publication of Akebia's manuscript in *NDT* marks the first publication in a peer-reviewed journal related to a global Phase 3 program of an oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) being evaluated as a potential treatment for anemia due to chronic kidney disease (CKD).

The manuscript, titled "Global Phase 3 programme of vadadustat for treatment of anaemia of chronic kidney disease: rationale, study design and baseline characteristics of dialysis-dependent patients in the $INNO_2VATE$ trials," includes a detailed description of design and methodology of the two Phase 3 $INNO_2VATE$ trials and summarize demographic and baseline characteristics of randomized patients. Importantly, the manuscript notes that "demographics and baseline characteristics of patients enrolled in the two studies are comparable to those typically observed in patients with DD (dialysis dependent)-CKD, suggesting the results of the $INNO_2VATE$ studies will be generalizable to a large proportion of the DD-CKD population."

$INNO_2VATE$ evaluated the efficacy and safety of vadadustat, Akebia's investigational oral HIF-PHI, versus darbepoetin alfa for the treatment of anemia due to CKD in adult patients on dialysis. As previously reported, vadadustat achieved the primary and key secondary efficacy endpoints and the primary safety endpoint of the $INNO_2VATE$ program, defined as non-inferiority of vadadustat versus darbepoetin alfa in time to first occurrence of a major adverse cardiovascular event (MACE), which is the composite of all-cause mortality, non-fatal myocardial infarction, or non-fatal stroke across both $INNO_2VATE$ studies. In addition, vadadustat achieved non-inferiority to darbepoetin alfa on key secondary safety endpoints that included expanded MACE, cardiovascular MACE, cardiovascular mortality, and all-cause mortality.

"Achieving the first publication of a manuscript on the design of our global Phase 3 program focused on a HIF-PHI for anemia in a well-regarded, peer-reviewed nephrology journal is an important achievement for our company," said Steven K. Burke, M.D., Senior Vice President, Research & Development and Chief Medical Officer of Akebia Therapeutics. "We believe publication of the manuscript reinforces the clinical rigor that guided the development of our $INNO_2VATE$ program, which has since successfully produced clear and consistent results. Our medical team continues to support vadadustat's potential with a comprehensive publication plan that is expected to yield additional peer-reviewed publications this year and next year."

Nephrology Dialysis Transplantation: an international basic science and clinical renal journal (*NDT*) is the leading nephrology journal in Europe and renowned worldwide, devoted to original clinical and laboratory research in nephrology, dialysis and transplantation. *NDT* is an official journal of the ERA-EDTA. Published monthly, the journal provides an essential resource for researchers and clinicians throughout the world. All research articles in the journal have undergone peer review.

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 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 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 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.

Forward Looking Statements
This press release includes forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, including but not limited to the statement regarding Akebia's expectations with respect to additional peer-reviewed publications and the timing thereof. These statements are not historical facts, but instead represent only Akebia's beliefs regarding future events, many of which, by their nature, are

inherently uncertain and outside of Akebia's control. For a discussion of risks related to the forward-looking statements in this statement see the "Risk Factors" section of Akebia's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, and other filings that Akebia may make with the SEC 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.

Investor Contact
Kristen K. Sheppard, Esq.
ir@akebia.com

View original content to download multimedia:http://www.prnewswire.com/news-releases/akebia-announces-manuscript-highlighting-global-phase-3-inno2vate-program-rationale-study-design-and-baseline-characteristics-published-in-peer-reviewed-medical-journal-301173615.html

SOURCE Akebia Therapeutics