New England Journal of Medicine Publishes Results of Global Phase 3 Clinical Program of Vadadustat for the Treatment of Anemia Due to Chronic Kidney Disease

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Program Evaluated the Safety and Efficacy of Vadadustat in Adult Patients with Anemia Due to CKD on Dialysis and Not on Dialysis

CAMBRIDGE, Mass., April 28, 2021 /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 the *New England Journal of Medicine* (*NEJM*) has published the results of the global Phase 3 clinical program of vadadustat for the treatment of anemia due to chronic kidney disease (CKD) in adult patients on dialysis (INNO$_2$VATE) and adult patients not on dialysis (PRO$_2$TECT) in two separate manuscripts.

Vadadustat, an investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), is Akebia's lead product candidate. In late March 2021, the Company submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for vadadustat for the treatment of anemia due to CKD in both adult patients on dialysis and adult patients not on dialysis.

"Having recently submitted our NDA for vadadustat, we are proud to have the results of our global Phase 3 clinical program published in the prestigious *New England Journal of Medicine* for review by the broader medical community," said Steven K. Burke, M.D., Chief Medical Officer of Akebia Therapeutics. "The publications, authored by members of the independent Executive Steering Committee in collaboration with trial investigators and Akebia, are a testament to the work of these team members who designed this program after extensive dialogue with the FDA and European regulators. We extend our deepest appreciation to everyone involved in this program, including the physicians, investigators, site coordinators, and, most importantly, the nearly 7,500 patients who participated."

"The kidney community has been eagerly awaiting peer-reviewed publication of comprehensive and straight-forward analyses of cardiovascular safety and hematological efficacy results of a Phase 3 program evaluating the treatment of anemia associated with CKD with a novel HIF-PHI," said Glenn Chertow, M.D., M.P.H., Professor of Medicine at Stanford University School of Medicine, lead author of one of the manuscripts and Co-Chair of the independent Executive Steering Committee for the vadadustat global Phase 3 program. "We are honored to have vadadustat's global Phase 3 clinical program published in the *New England Journal of Medicine*. These publications reflect the clinical relevance, scientific rigor and transparency of the vadadustat development program."

Kai-Uwe Eckardt, M.D., Professor of Medicine and Head of the Department of Nephrology and Medical Intensive Care at the Charité in Berlin, Germany, and Co-Chair of the independent Executive Steering Committee for the vadadustat global Phase 3 program, is the lead author of the INNO$_2$VATE manuscript titled, "Safety and Efficacy of Vadadustat for Anemia in Patients Undergoing Dialysis." The manuscript states, "Among patients with anemia and CKD who were undergoing dialysis, vadadustat was noninferior to darbepoetin alfa with respect to cardiovascular safety and maintenance of hemoglobin concentrations."

Dr. Chertow is the lead author of the PRO$_2$TECT manuscript titled, "Vadadustat in Patients with Anemia and Non-Dialysis-Dependent CKD," which states, "Vadadustat, as compared with darbepoetin alfa, met the prespecified noninferiority criterion for hematologic efficacy but not the prespecified noninferiority criterion for cardiovascular safety.

The New England Journal of Medicine is recognized as the world's leading medical journal and website. Published continuously for over 200 years, *NEJM* delivers high-quality, peer-reviewed research and interactive clinical content to physicians, educators, researchers, and the global medical community.

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 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.

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