Akebia Initiates INNO2VATE Phase 3 Program for Vadadustat in Dialysis Patients With Anemia Related to Chronic Kidney Disease

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-- Company's Phase 3 PRO$_2$TECT Program for Non-Dialysis Patients is Ongoing --

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Akebia Therapeutics, Inc. (NASDAQ:AKBA), a biopharmaceutical company focused on delivering innovative therapies to patients with kidney disease through the biology of hypoxia-inducible factor (HIF), today announced that the company has initiated a global Phase 3 program to evaluate vadadustat for a second indication in renal anemia. Known as INNO$_2$VATE, the program consists of two studies designed to evaluate vadadustat in patients with anemia related to chronic kidney disease who are undergoing dialysis. Akebia's ongoing Phase 3 PRO$_2$TECT program in non-dialysis dependent patients with anemia related to chronic kidney disease commenced at the end of last year.

"The launch of the INNO$_2$VATE program represents an important milestone for our global vadadustat Phase 3 program," stated John P. Butler, President and Chief Executive Officer of Akebia. "Similar to our parallel Phase 3 PRO$_2$TECT program in patients who are not currently on dialysis, INNO$_2$VATE is designed to demonstrate the best-in-class potential of vadadustat to treat patients who are suffering from anemia related to chronic kidney disease."

The INNO$_2$VATE program includes two separate studies and will collectively enroll approximately 2,600 dialysis-dependent patients with anemia related to chronic kidney disease. Both studies will include a 1:1 randomization and an open label, active-control, non-inferiority design. Primary endpoints include an efficacy assessment of the hemoglobin response and an assessment of cardiovascular safety as measured by standard major adverse cardiovascular events (MACE) criteria. The INNO$_2$VATE-*Correction* study will evaluate patients not currently being treated with recombinant erythropoiesis stimulating agents (rESAs). The INNO$_2$VATE-*Conversion* study will evaluate patients currently receiving rESA who will be converted to either vadadustat or the active control, with the goal of maintaining their baseline hemoglobin levels.

About Vadadustat
Vadadustat is an oral hypoxia-inducible factor (HIF) stabilizer with best-in-class potential for the treatment of anemia related to chronic kidney disease. Vadadustat, currently in development, exploits the same mechanism of action used by the body to naturally adapt to lower oxygen availability associated with a moderate increase in altitude. At higher altitudes, the body responds to lower oxygen availability with increased production of HIF, which coordinates the interdependent processes of iron mobilization and erythropoietin production to increase red blood cell production and, ultimately, improve oxygen delivery.

About Anemia Related to Chronic Kidney Disease
Approximately 30 million people in the U.S. have chronic kidney disease (CKD), with an estimated 1.8 million of these patients suffering from anemia. Anemia results from the body's inability to coordinate red blood cell production in response to lower oxygen levels due to the progressive loss of kidney function, which occurs in patients with CKD. Left untreated, anemia significantly accelerates patients' overall deterioration of health with increased morbidity and mortality. Renal anemia is currently treated with injectable recombinant erythropoiesis stimulating agents, which are associated with inconsistent hemoglobin responses and well-documented safety risks.

About Akebia Therapeutics
Akebia Therapeutics, Inc. is a biopharmaceutical company headquartered in Cambridge, Massachusetts, focused on delivering innovative therapies to patients with kidney disease through hypoxia-inducible factor biology. Akebia's lead product candidate, vadadustat, is an oral therapy in development for the treatment of anemia related to chronic kidney disease in both non-dialysis and dialysis patients. Akebia has commenced its vadadustat Phase 3 Program, which includes the PRO$_2$TECT studies for non-dialysis patients with anemia secondary to chronic kidney disease and INNO$_2$VATE studies for dialysis dependent patients. For more information, please visit our website at www.akebia.com.

Forward-Looking Statements
This press release includes forward-looking statements. Such forward-looking statements include those about Akebia's strategy, future plans and prospects, including statements regarding the potential indications and benefits of vadadustat and the plans for the INNO$_2$VATE and PRO$_2$TECT Phase 3 programs. The words "anticipate," "appear," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions 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 risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; the ability of Akebia to successfully complete the clinical development of vadadustat; the funding required to develop Akebia's product candidates and operate the company, and the actual expenses associated therewith; the cost of the Phase 3 studies of vadadustat and the availability of financing to cover such costs; the timing and content of decisions made by the FDA and other regulatory authorities; the rate of enrollment in clinical studies of vadadustat; the actual time it takes to initiate and complete clinical studies; the success of competitors in developing product candidates for diseases for which Akebia is currently developing its product candidates; and Akebia's ability to obtain, maintain and enforce patent and other intellectual property protection for vadadustat. Other risks and uncertainties include those identified

under the heading "Risk Factors" in Akebia's Annual Report on Form 10-Q for the quarter ended March 31, 2016, and other filings that Akebia may make with the Securities and Exchange Commission in the future. Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

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Akebia Contact:
AJ Gosselin, 617-844-6130
Manager, Corporate Communications
agosselin@akebia.com

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