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Akebia Announces Publication of Phase 2a Results for Vadadustat in Patients with Anemia Related to Chronic Kidney Disease

-- Data Showed Vadadustat Increased Hemoglobin Levels and Improved Iron Mobilization When Compared to Placebo --

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 the publication of positive results from a Phase 2a study of vadadustat, a once-daily oral HIF stabilizer in development for the treatment of anemia related to chronic kidney disease (CKD). The study demonstrated that vadadustat increased hemoglobin levels in a dose-dependent manner and improved iron mobilization in non-dialysis CKD patients when compared to placebo. The peer-reviewed paper, titled "Clinical Trial of Vadadustat in Patients with Anemia Secondary to Stage 3 or 4 Chronic Kidney Disease," was published online by the *American Journal of Nephrology*. Vadadustat is currently being evaluated in a global Phase 3 clinical program in non-dialysis and dialysis patients with anemia related to CKD.

This multicenter, six-week, randomized, double-blind, placebo-controlled, dose-ranging Phase 2a trial evaluated the pharmacodynamic response, safety and tolerability of once-daily oral dose of vadadustat in non-dialysis patients with anemia related to CKD Stage 3 or 4. Ninety-three patients were randomized to one of five dose groups: 240, 370, 500, or 630 mg of once daily oral vadadustat or matching placebo for six weeks of treatment.

Findings from the study included:

- Vadadustat increased hemoglobin levels in patients across all treatment groups compared to placebo;
- Vadadustat improved iron mobilization compared to the placebo group, as measured by decreases in ferritin and hepcidin and increases in total iron binding capacity; and
- Safety findings were consistent with results of other studies of vadadustat and the proportion of patients with at least one treatment-emergent adverse event was similar between the vadadustat and placebo-treated groups, with no apparent dose-related effect.

"This Phase 2a publication further demonstrates the potential of vadadustat to set a new standard of care in renal anemia and provides a strong basis for our global Phase 3 program, which continues to enroll CKD patients in both the non-dialysis and dialysis dependent setting," said Brad Maroni, M.D., Chief Medical Officer at Akebia.

About Vadadustat

Vadadustat is an oral hypoxia-inducible factor (HIF) stabilizer currently in Phase 3 development for the treatment of anemia related to chronic kidney disease. Vadadustat exploits the same mechanism of action used by the body to adapt naturally 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 Associated with CKD

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 with inadequate erythropoietin production. Left untreated, anemia significantly accelerates patients' overall deterioration of health with increased morbidity and mortality. 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 investigational oral therapy in development for the treatment of anemia related to chronic kidney disease in both non-dialysis and dialysis patients. Akebia's global Phase 3 program for vadadustat, which includes the PRO$_2$TECT studies for non-dialysis patients with anemia secondary to chronic kidney disease and the INNO$_2$VATE studies for dialysis-dependent patients, is currently ongoing. 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. 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 funding required to develop vadadustat and operate the company, and the actual expenses associated therewith; the actual costs incurred in 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 actual time it takes to initiate and complete research and development; 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 and its other product candidates. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Annual Report on Form 10-K for the year ended December 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 Therapeutics, Inc.
Theresa McNeely, 617-844-6113
SVP, Corporate Communications
and Investor Relations
tmcneely@akebia.com

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