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Akebia Announces Publication Highlighting Need for New Solutions in Treating Dialysis Patients

-- Analysis Shows Greater Mortality in Patients with Erythropoiesis-Stimulating Agent Hyporesponse --

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 a retrospective analysis indicating persistently greater mortality in dialysis-dependent chronic kidney disease (DD-CKD) patients with erythropoiesis-stimulating agent hyporesponse (ESAhr). The article, titled "Spectrum and Burden of Erythropoiesis-Stimulating Agent Hyporesponsiveness Among Contemporary Hemodialysis Patients," was published online in the *American Journal of Kidney Diseases*.

"This large scale analysis shows a persistently greater risk of mortality among patients who are ESA hyporesponders when compared to non-hyporesponders," said Brad Maroni, MD, Chief Medical Officer of Akebia. "In addition, the hyporesponse persisted for more than two years, during which time patients required higher doses of ESA and iron. This is the first study of its kind since changes to ESA product labeling and reimbursement were implemented, and these findings highlight the need for new treatment options that can effectively manage patients with ESAhr. We believe that vadadustat may provide a solution for ESA hyporesponders and look forward to evaluating its potential benefits in this patient population."

The analysis of over 98,000 patients showed that ESAhr, defined as 2 consecutive hemoglobin measurements < 10 g/dL while receiving an ESA dose > 7,700 U/treatment, was associated with 1.5-2.5-fold increased risk of mortality and this association persisted for at least two years after ESAhr was identified. ESAhr was also associated with lower hemoglobin levels, greater ESA and iron use, and higher rates of missed hemodialysis treatment throughout the follow-up period. This study represents the first analysis of ESAhr since changes to both U.S. ESA product labeling and reimbursement policy for injectable drugs for dialysis patients were implemented in 2011, which resulted in marked ESA dose reductions for the treatment of anemia related to DD-CKD.

The retrospective analysis of data collected during 2012 and 2013 was conducted in collaboration with DaVita Clinical Research, a wholly-owned subsidiary of DaVita HealthCare Partners Inc. The dataset contained information on patient demographics, disease history, comorbidities, dialysis-specific information for each treatment session, laboratory results such as hemoglobin, and IV anemia medications administered at dialysis sessions (ESAs and iron). Patients included in the analysis had received in-center hemodialysis treatment at a DaVita facility, and had been receiving dialysis for six months or more to allow for stabilization of ESA dose following dialysis initiation. The full manuscript is available on the *American Journal of Kidney Diseases* website at: http://www.ajkd.org/article/S0272-6386(16)30282-7/fulltext.

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, MA, 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_2TECT studies for non-dialysis patients with anemia secondary to chronic kidney disease and $INNO_2VATE$ 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. 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 prepare for and initiate 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 June 30, 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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