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Akebia Announces Positive Vadadustat Data Demonstrating No Clinically Significant Drug-Drug Interaction

- Results of CYP2C9 Analysis Presented at ERA-EDTA Annual Meeting -

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 presented positive results from a drug-drug interaction study of vadadustat, the Company's oral therapy for the treatment of anemia related to chronic kidney disease (CKD). The study demonstrated that vadadustat has no clinically significant interaction with CYP2C9-sensitive substrates and, therefore, may be administered with medications metabolized by CYP2C9 without the need to modify the dose of the co-administered drug. CYP2C9 is involved in the metabolism of many commonly prescribed drugs, such as cholesterol and blood pressure medications. These results were presented at the 53rd European Renal Association-European Dialysis and Transplant Association (ERA-EDTA) Congress in Vienna, Austria.

"These findings suggest that dose-modifications are not necessary when medications commonly prescribed to patients with kidney disease that are metabolized by CYP2C9 are taken concomitantly with vadadustat," stated Brad Maroni, Chief Medical Officer of Akebia. "The area under the concentration-time curve (AUC) for celecoxib, a sensitive CYP2C9 substrate, was similar in the presence or absence of vadadustat, which supports vadadustat as a potential best-in-class treatment for patients with CKD."

The data are from an open-label, single-sequence, drug-interaction study in 12 healthy male volunteers who received a single, oral 200 mg dose of celecoxib, a CYP2C9 substrate, on Day 1. Oral 600 mg doses of vadadustat were then administered on Days 3 through 9 with an additional single dose of celecoxib administered on Day 8. Serial blood samples were collected over a 48-hour period to determine the concentrations of celecoxib when administered alone on Day 1 and when co-administered with vadadustat on Day 8.

The mean half-life of celecoxib was comparable when administered with (10.3 hr) and without (10.8 hr) vadadustat. Co-administration of vadadustat and celecoxib resulted in a 12% and 11% increase in celecoxib AUC_{0-t} and AUC_{0-inf}, respectively. Based on the 90% confidence intervals for the geometric mean ratios for AUC_{0-t} and AUC_{0-inf}, no significant drug-drug interaction was observed between vadadustat and celecoxib. Vadadustat was well-tolerated when administered with celecoxib, and importantly, vadadustat may be administered with medications metabolized by CYP2C9, such as losartan and rosuvastatin, without the need to modify the dose of the co-administered drug.

The poster is available on the Akebia website at http://akebia.com/media/publications.

About Vadadustat

Vadadustat is an oral therapy currently in development for the treatment of anemia related to CKD. Vadadustat is designed to stabilize HIF, a transcription factor that regulates the expression of genes involved with red blood cell (RBC) production in response to changes in oxygen levels, by inhibiting the hypoxia-inducible factor prolyl hydroxylase (HIF-PH) enzyme. Vadadustat 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 (EPO) production to increase RBC production and, ultimately, improve oxygen delivery.

As a HIF stabilizer with best-in-class potential, vadadustat raises hemoglobin levels predictably and sustainably, with a dosing regimen that allows for a gradual and controlled titration. Vadadustat has been shown to improve iron mobilization, potentially eliminating the need for intravenous iron administration and reducing the overall need for iron supplementation.

About Anemia Related to CKD

Approximately 30 million people in the United States have CKD, with an estimated 1.8 million of these patients suffering from anemia. Anemia results from the body's inability to coordinate RBC 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 ESAs, 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 (HIF) biology. Akebia has completed Phase 2 development of its lead product candidate, vadadustat (formerly AKB-6548), an oral therapy for the treatment of anemia related to chronic kidney disease (CKD) in both non-dialysis and dialysis patients. Enrollment in the PRO_2TECT Phase 3 program in non-dialysis dependent patients commenced in late 2015 and the $INNO_2$VATE Phase 3 program in dialysis dependent patients is expected to commence in 2016. Akebia's second product candidate, AKB-6899, is expected to commence clinical development in 2016. 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 1 study of AKB-6899 and 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 and AKB-6899; 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 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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