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Akebia Initiates Phase 2 FO2RWARD Study of Vadadustat in Dialysis Patients with Anemia Related to Chronic Kidney Disease Hyporesponsive to Treatment with Erythropoiesis-Stimulating Agents

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 dosed the first patient in its Phase 2 FO_2RWARD study of vadadustat in dialysis-dependent chronic kidney disease (DD-CKD) patients who are hyporesponsive to erythropoiesis-stimulating agents (ESAs). Vadadustat is an oral HIF stabilizer currently in Phase 3 development for the treatment of anemia related to chronic kidney disease.

FO_2RWARD is a randomized, open-label study that will assess the safety and efficacy of vadadustat versus an active comparator, epoetin alfa, in approximately 80 DD-CKD patients with ESA hyporesponse in the United States. The primary outcome measure will be the percent reduction in previously prescribed epoetin alfa dose and change in hemoglobin level over the course of the study. Akebia expects to report data from FO_2RWARD by the end of 2018.

"Patients who do not adequately respond to ESA treatment represent approximately 10-15% of DD-CKD patients, yet hyporesponders account for 30-40% of total ESA use," said John P. Butler, President and Chief Executive Officer of Akebia. "These patients have demonstrated a persistently higher risk of mortality than non-hyporesponders, and represent a high unmet need. We believe that vadadustat may provide a solution for these patients, and we anticipate results from FO_2RWARD next year."

In a previously published retrospective analysis conducted by Akebia in collaboration with DaVita Clinical Research, a wholly-owned subsidiary of DaVita HealthCare Partners Inc., persistently greater mortality, greater iron and ESA use, and lower hemoglobin levels were observed in DD-CKD patients with ESA hyporesponse compared to non-ESA hyporesponsive patients. 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*, and is available here.

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 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, investigational 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_2TECT 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, and the expected timing of the hyporesponder study data. 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 program for vadadustat; the funding required to develop Akebia's product candidates and operate the company, and the actual expenses associated therewith; the actual costs incurred in the global Phase 3 studies of vadadustat, including the hyporesponder study, and the availability of financing to cover such costs; the timing of any additional studies initiated by Akebia or its collaborators for vadadustat; the timing and content of decisions made by 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 around the world. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Report on Form 10-Q for the quarter ended March 31, 2017, 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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