March 10, 2015

Akebia Announces Completion of Enrollment in Phase 2 Trial of AKB-6548 in Dialysis Patients with Anemia Related to Chronic Kidney Disease

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 completion of enrollment in the third and final cohort of its Phase 2 clinical study evaluating AKB-6548, a once-daily oral therapy, in patients with anemia related to chronic kidney disease (CKD) who are undergoing dialysis. The company expects to report top-line results from the study in the third quarter of 2015.

"The completion of enrollment in this dialysis study marks an important milestone for both the company and our AKB-6548 renal anemia program," said John P. Butler, President and Chief Executive Officer of Akebia. "We have already reported positive Phase 2b data for AKB-6548 in non-dialysis CKD patients, demonstrating the potential of AKB-6548 to effectively raise and maintain hemoglobin levels in a safe, predictable and controlled manner in that patient population. This study will build on that data set to provide us with a greater understanding of AKB-6548's potential in patients with chronic kidney disease receiving dialysis."

Brad Maroni, M.D., Senior Vice President and Chief Medical Officer of Akebia, added, "The faster than expected enrollment in all three cohorts speaks to investigator enthusiasm for AKB-6548 as a potential treatment for CKD patients undergoing dialysis who are suffering from anemia. Now that we are fully enrolled, we look forward to reporting top-line results from the study in the third quarter."

The Phase 2 multi-center, open-label study enrolled three cohorts, each consisting of approximately 30 CKD patients with anemia undergoing dialysis who were switched from injectable recombinant erythropoiesis-stimulating agent therapy to AKB-6548. Patients in the first two cohorts receive once-daily doses of AKB-6548, while patients in the third cohort receive AKB-6548 three times per week in conjunction with their hemodialysis schedule. The study will evaluate approximately 90 patients for 16 weeks of treatment, including an assessment of hemoglobin (HGB) response to AKB-6548 during an initial eight-week dosing period, followed by an assessment of HGB response to algorithm-guided dose adjustments of AKB-6548 during an additional eight weeks of treatment.

About AKB-6548

AKB-6548 is a once-daily, oral therapy currently in development for the treatment of anemia related to CKD. AKB-6548 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. AKB-6548 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, AKB-6548 raises hemoglobin levels predictably and sustainably, with a dosing regimen that allows for a gradual and controlled titration. AKB-6548 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 erythropoiesis-stimulating agents, or rESAs, 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 HIF biology. Akebia's lead product candidate, AKB-6548, is a

once-daily, oral therapy which has completed a Phase 2b study for the treatment of anemia related to CKD in non-dialysis patients and is also being tested in a Phase 2 study for the treatment of anemia in patients undergoing dialysis. For more information on Akebia, please visit 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 AKB-6548, the development plan for the Phase 2 study in dialysis patients with renal-anemia, the potential data to be obtained from the study, and the expected timing of the announcement of study results. 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 AKB-6548; the funding required to develop Akebia's product candidates and operate the company, and the actual expenses associated therewith; the timing and content of decisions made by the FDA and other regulatory authorities; the actual time it takes to complete the Phase 2 study and analyze the data; 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 AKB-6548. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Annual Report on Form 10-K for the fiscal year ended December 31, 2014, 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.

Investors:
Argot Partners
Susan Kim, +1-212-600-1902
susan@argotpartners.com
or
Media:
Argot Partners
Eliza Schleifstein, +1-917-763-8106
Eliza@argotpartners.com

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