Akebia and Mitsubishi Tanabe Pharma Announce Collaboration to Develop and Commercialize Vadadustat in Asia

– Agreement Includes Total Upfront and Milestone Payments of up to $350 Million, Including $100 Million in Upfront and Development Payments, as well as Tiered Double Digit Royalties –

CAMBRIDGE, Mass., and OSAKA, Japan, December 15, 2015 -- Akebia Therapeutics, Inc. (NASDAQ:AKBA), and Mitsubishi Tanabe Pharma Corporation (TSE:4508) (MTPC) announced today that they have entered into a development and commercialization agreement for vadadustat, an oral therapy for the treatment of anemia related to chronic kidney disease (CKD), in Japan and certain other countries in Asia.

Under the terms of the agreement, MTPC will make payments up to $100 million for development costs of vadadustat, including $40 million after signing. In addition, Akebia is eligible to receive up to approximately $250 million in additional milestone payments, based upon achievement of certain development and sales milestones. MTPC will also make tiered royalty payments, from low teens up to twenty percent, on sales of vadadustat in the territory, which includes Japan, Taiwan, South Korea, Singapore, Malaysia, Indonesia and other Asian countries.

“Vadadustat offers a new paradigm for the treatment of anemia for CKD patients. This partnership with MTPC validates vadadustat’s therapeutic potential and helps ensure that its potential is realized in Asia,” said John P. Butler, President and CEO of Akebia. “MTPC is one of the largest, most successful pharmaceutical companies in Japan with a substantial presence in these Asian markets. They are committed to the development and commercialization of innovative products, with a strategic focus on products for renal disease and diabetes, making them an ideal partner for Akebia.”

“A safer treatment for managing anemia related to chronic kidney disease remains a significant unmet need globally,” stated Masayuki Mitsuka; President and Representative Director, CEO of Mitsubishi Tanabe Pharma Corporation. “We see great potential in vadadustat to advance the care of chronic kidney disease patients. We look forward to our collaboration with Akebia.”

About Vadadustat
Vadadustat is an oral therapy currently in development for the treatment of anemia related to chronic kidney disease (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. 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 reducing the need for iron supplementation.
About Anemia Related to CKD
In Japan, approximately 11 million people include in dialysis patients (about 320,000 people) have CKD stage 3 or higher, with many 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.

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. The company has completed Phase 2 development of its lead product candidate, vadadustat, an oral therapy for the treatment of anemia related to CKD in both non-dialysis and dialysis patients, and plans to initiate its Phase 3 program in 2015. http://akebia.com/

About Mitsubishi Tanabe Pharma Corporation
Mitsubishi Tanabe Pharma Corporation is a research-driven pharmaceutical company based in Osaka, Japan. MTPC is taking on the challenge of drug discovery in the fields of autoimmune disorders, central nervous system diseases, diabetes and kidney diseases, and vaccines. To those ends, MTPC is strengthening its R&D pipeline. MTPC contributes to the healthier lives of people around the world through the creation of pharmaceuticals. http://www.mt-pharma.co.jp/e.

Akebia Contacts
Investors:  
Ed Joyce  
Phone: (617) 844-6130  
Email: ejoyce@akebia.com

Media:
Eliza Schleifstein  
Phone: (917) 763-8106  
Email: Eliza@argotpartners.com

Mitsubishi Tanabe Pharma Contacts
Investors:  
Phone: +81-6-6205-5211

Media:  
Phone: +81-6-6205-5211

###