
FOR IMMEDIATE RELEASE**AKEBIA ANNOUNCES POSITIVE RESULTS FOR
AKB-6548 PHASE 2A CLINICAL STUDY****- Findings support once daily dosing; no serious adverse events -**

Cincinnati, OH October 5, 2010 – Akebia Therapeutics, Inc., a pharmaceutical discovery and development company focused on anemia and vascular disorders, today announced that it has successfully completed a phase 2a study for AKB-6548 in stage 3 and 4 chronic kidney disease patients. AKB-6548 is an orally bioavailable hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor designed to increase the natural production of erythropoietin (EPO) and cause a gentle rise in hemoglobin in anemic patients. In the clinical study patients receiving a single, oral dose of AKB-6548 experienced significantly increased EPO levels eight and 12 hours post administration, with levels returning to baseline within 24 hours, supporting the potential of once daily dosing. The compound was found to be safe, with no serious adverse events.

"There is a clear need for new alternatives to currently used EPO products, which suffer from safety issues and are only available in injectable formulations. These phase 2a study results add to our existing clinical and preclinical data supporting the potential of AKB-6548 as a safer, more convenient alternative," said Dr. Robert Shalwitz, M.D., chief medical officer of Akebia. "We plan to continue building on this body of data with 28 day phase 2a studies in stage 3 and 4 chronic kidney disease patients."

The phase 2a open label study included 22 stage 3 and stage 4 chronic kidney disease patients, and was designed to evaluate the safety, tolerability and pharmacokinetics of AKB-6548. The patients each received a single, oral dose of AKB-6548, and EPO levels were measured at eight, 12 and 24 hours post-administration. Additional blood tests and clinical assessments were also conducted on day eight. The efficacy of AKB-6548 was determined by measuring EPO and other biomarkers including VEGF, hepcidin, transferrin and ferritin. The Phase 2a trial was conducted at two sites in the United States.

About HIF-PH

Hypoxia-inducible factors (HIFs) are transcription factors that regulate the body's response to decreases in oxygen, or hypoxia, in the cellular environment. HIF-PH's are the hypoxia-inducible factor prolyl hydroxylase enzymes that normally regulate the levels of HIF in bodily tissues. By inhibiting HIF-PH enzymes, HIFs can be stabilized or up-regulated, allowing the body to better respond to reduced oxygen, injury and infection. The ability to stabilize HIFs may lead to treatments for many conditions including anemia, fractures, wounds, and other conditions where the HIF mechanism is not functioning optimally.

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About AKB-6548

AKB-6548 is an orally bioavailable HIF-PH inhibitor designed to increase natural production of EPO, a glycoprotein hormone that controls red blood cell production, and cause a gentle rise in hemoglobin levels. Inadequate EPO production by the kidney is a common cause of anemia. Akebia will initially target patients with chronic renal disease and pre-dialysis patients, two patient populations that are currently undertreated for anemia. AKB-6548 potentially promises to be a safe, cost effective, orally dosed drug that delivers the efficacy of injectable EPO stimulating agents.

The market for chronic anemia drugs, which generates over \$10 billion in worldwide sales, is dominated by injectable forms of recombinant EPO. There are currently no orally dosed small molecule drugs for the treatment of chronic anemia.

About Akebia Therapeutics

Akebia Therapeutics is a discovery and development company focused on anemia and vascular disorders. Akebia's lead program, AKB-6548, an orally bioavailable HIF-prolyl hydroxylase (HIF-PH) inhibitor for patients with anemia, is in phase 2 clinical trials. AKB-6548 potentially promises to be a safer, less expensive, orally dosed pharmaceutical to stimulate endogenous EPO production. Additionally, Akebia has a novel HPTP β inhibitor / Angiopoietin 2 modulator, AKB-9778, for the treatment of vascular leak syndrome and critical limb ischemia which is scheduled to commence phase 1 clinical trials in early 2011.

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