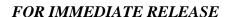
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# AKEBIA ANNOUNCES POSITIVE RESULTS FOR AKB-6548 PHASE 1 CLINICAL STUDY

## AKB-6548 increased production of erythropoietin with no serious adverse events

**Cincinnati, OH** January 5, 2010– Akebia Therapeutics, Inc., a small molecule discovery and development company focused on anemia and vascular disorders, today announced that it has successfully completed the first-in-man phase 1a study for AKB-6548 in healthy volunteers. AKB-6548 is an orally bioavailable hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor designed to increase the natural production of erythropoietin (EPO) in anemic patients. In the clinical study, a single dose of AKB-6548 increased EPO levels and was found to be safe and well tolerated.

"The completion of this phase 1a study is clearly an important milestone for Akebia, and we are very pleased to have human safety data and markers of efficacy in humans," said Dr. Robert Shalwitz, M.D., chief medical officer of Akebia. "After carefully selecting AKB-6548 from a series of analogs and moving it into human trials it is very gratifying to see the drug perform so well. There were no serious adverse events at any of the doses tested, and the compound produced a robust, dose responsive increase in EPO concentration. Based on the results from this phase 1a trial we look forward to moving AKB-6548 into phase 1b and 2a clinical trials in 2010."

The phase 1a study involving 48 healthy volunteers was designed to evaluate the safety, tolerability, pharmacokinetic and pharmacodynamic responses to single ascending doses of AKB-6548. The efficacy of AKB-6548 was determined by measuring EPO and other biomarker responses. In particular, doses of AKB-6548 producing significant increases in EPO did not change levels of vascular endothelial growth factor (VEGF). VEGF is a biomarker that potentially is upregulated by HIF stabilization. Separation of the EPO response from a VEGF response is critical for a chronic therapeutic that may be used in patients with anemia associated with either chemotherapy or chronic kidney disease. The Phase 1a trial was conducted at Medpace, Inc. in Cincinnati, Ohio.

### **About HIF-PH**

Hypoxia-inducible factors (HIFs) are transcription factors that respond 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.

#### **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. 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 1 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 HPTPβ 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 mid-2010.

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