

---

**FOR IMMEDIATE RELEASE****AKEBIA ANNOUNCES POSITIVE RESULTS FOR  
AKB-6548 PHASE 1B CLINICAL STUDY AND COMPLETES \$5M SECOND  
TRANCHE TO SERIES A FINANCING****AKB-6548 produces dose-dependent increase in erythropoietin and reticulocytes with no  
serious adverse events**

**Cincinnati, OH** June 16, 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 1b 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, healthy volunteers were orally dosed once daily with AKB-6548 for 10 days. AKB-6548 increased EPO and reticulocytes (immature red blood cells) and was found to be safe and well tolerated.

"We are very pleased with the results of this phase 1b study" said Dr. Robert Shalwitz, M.D., chief medical officer of Akebia. "After 10 days of dosing we saw a controlled, dose-dependent increase in erythropoietin and reticulocytes and no serious adverse events at any of the doses tested. We look forward to moving AKB-6548 into phase 2a clinical trials in July."

The phase 1b study involving 33 healthy volunteers was designed to evaluate the safety, tolerability, pharmacokinetic and pharmacodynamic responses to three ascending doses of AKB-6548. The volunteers were dosed with AKB-6548 once daily for 10 days. The efficacy of AKB-6548 was determined by measuring EPO, reticulocytes, hemoglobin and other biomarker responses. The Phase 1b trial was conducted at Medpace, Inc. in Cincinnati, Ohio.

Following the completion of the phase 1b study, Akebia also announced it has completed the second tranche of the Series A \$16 million financing round announced in July 2009. The tranche was increased from \$4 million to \$5 million, increasing the total round size from \$16 million to \$17 million. Together with earlier rounds of financing, the total raised in the Series A is \$28 million. Novartis Bioventures Ltd, Venture Investors, LLC, Triathlon Medical Ventures, Kearny Venture Partners, Athenian Venture Partners and Sigvion Capital all contributed to the second tranche.

"Achieving the additional financing and increasing its scheduled size is particularly gratifying," said Joseph Gardner, Ph.D., President and Chief Executive Officer of Akebia. "Expanding the tranche is indicative of the strong support we have from our investors and their desire to move the company forward. We are excited about the prospects of starting our phase 2a study for AKB-6548 very shortly and filing our second IND, for AKB-9778, later this year."

### **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.

### **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 HPTP $\beta$  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.

Website: [www.akebia.com](http://www.akebia.com).

CONTACT: Ian Howes, CFO & V.P. Corporate Development, Akebia Therapeutics, Inc.  
513/985-1923, [ihowes@akebia.com](mailto:ihowes@akebia.com)

Michelle Linn, Linnden Communications, 508/362-3087, [linnmich@comcast.net](mailto:linnmich@comcast.net)