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***FOR IMMEDIATE RELEASE***

**AKEBIA ANNOUNCES INITIATION OF PHASE 2A DOSE RANGE FINDING STUDY  
OF AKB-6548 FOR ANEMIA**

**Cincinnati, OH** June 23, 2011 – Akebia Therapeutics, Inc., a pharmaceutical discovery and development company focused on anemia and vascular disorders, today announced that it has initiated dosing in patients for a phase 2a dose ranging study of AKB-6548 in stage 3 and 4 chronic kidney disease (CKD) 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 controlled, gradual rise in hemoglobin in anemic patients. In a recently completed phase 2a dose escalation study, a controlled rise in hemoglobin and a corresponding decrease in ferritin were observed.

"This study represents an important step in the clinical pathway we have designed for AKB-6548, and we expect it will once again demonstrate the compound's ability to safely and effectively increase hemoglobin levels in a controlled manner, as well as help identify optimal dosing levels," said Joseph Gardner, Ph.D., president and chief executive officer of Akebia. "Patients with CKD are often undertreated for anemia, and there is a clear need for a new therapy that is safer and easier to use than the currently available injectable products."

The phase 2a randomized, double-blind, placebo-controlled dose range finding study is designed to evaluate the safety, tolerability and pharmacokinetics of AKB-6548 in stage 3 and 4 CKD patients, and will enable the selection of a dose regimen to be used in future studies. Subjects will be randomized into five different dosing groups, and AKB-6548 will be administered orally on an outpatient basis once daily for 42 days. The study will enroll 100 subjects at multiple 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 pre-dialysis patients with chronic renal disease, a large patient population that is 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 generated over \$9 billion in worldwide sales in 2010, is dominated by injectable forms of recombinant EPO. There are currently no approved 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 Tie-2 activator (HPTP $\beta$  inhibitor), AKB-9778, for the treatment of diabetic macular edema and vascular leak syndrome which is scheduled to commence phase 1 clinical trials in the second half of 2011.

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

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