
FOR IMMEDIATE RELEASE**AKEBIA ANNOUNCES INITIATION OF PHASE 1 CLINICAL STUDY OF AKB-6548****First-in-man study started for compound designed to increase natural production of erythropoietin**

Cincinnati, OH September 15, 2009 – Akebia Therapeutics, Inc., a small molecule discovery and development company focused on anemia and vascular disorders, today announced that it has initiated dosing of healthy volunteers in the first-in-man Phase 1 study for AKB-6548, an orally bioavailable hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor in development for anemia. AKB-6548 has been designed to increase the natural production of erythropoietin (EPO) in anemic patients.

"The initiation of this phase 1 study is clearly an important milestone for Akebia, and we are very pleased to have moved AKB-6548 into the clinic," said Joseph Gardner, Ph.D., president and chief executive officer of Akebia. "Based on years of research and data from preclinical studies, we have carefully designed a product candidate that we feel has many unique advantages over current approaches to addressing anemia. These advantages include simple oral dosing and potentially an improved safety profile. We look forward to the successful completion of this trial and to moving AKB-6548 forward into the next stage of development."

The phase 1 study is designed to evaluate the safety, tolerability and pharmacokinetics of single ascending doses of AKB-6548 in healthy volunteers. In addition, the efficacy of AKB-6548 will be ascertained by measuring erythropoietin and other biomarker responses. The trial will involve up to 48 healthy volunteers and will be conducted at Medpace, Inc. in Cincinnati, OH. The study is expected to be completed this year.

About HIF-PH

Hypoxia-inducible factors (HIFs) are transcription factors that respond to decreases in oxygen, or hypoxia, in the cellular environment. 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. Akebia will initially target patients with chronic renal disease and pre-dialysis patients, two patient populations that are currently undertreated for anemia. Anemia is the most common disorder of the blood and results from reduced production of red blood cells. AKB-6548 has been designed to match the efficacy of injectable EPO stimulating agents, but in a more cost effective, patient friendly and safe manner.

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. The market for chronic anemia drugs, which generates over \$10 billion in worldwide sales, is dominated by injectable forms of the recombinant protein growth factor EPO. There are currently no orally dosed small molecule drugs for chronic anemia. 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 mid-2010.

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