
FOR IMMEDIATE RELEASE**AKEBIA ANNOUNCES SUCCESSFUL COMPLETION OF SINGLE ASCENDING DOSE
PHASE 2A PILOT STUDY OF AKB-6548 FOR ANEMIA****- Findings from 28 day study support once daily dosing; controlled rise in hemoglobin -**

Cincinnati, OH May 3, 2011 – Akebia Therapeutics, Inc., a pharmaceutical discovery and development company focused on anemia and vascular disorders, today announced that it has successfully completed a 28 day open label phase 2a dose escalation for 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. A controlled rise in hemoglobin and a corresponding decrease in ferritin was observed during the 28 day study. The compound was found to be safe and well tolerated, with no serious adverse events.

"In this study, all of the CKD patients saw a significant increase in hemoglobin levels while taking AKB-6548. Additionally, we saw no significant increase in the compound's half life in this group of renally compromised patients which supports the once-daily, oral dosing regimen," said Dr. Robert Shalwitz, M.D., chief medical officer of Akebia. "Our goal is to develop a more convenient, safer alternative to the injectable EPO products that are currently available. With this encouraging data in hand, we will shortly begin a larger multi-dose phase 2b study."

The phase 2a open label pilot study was designed to evaluate the safety, tolerability and pharmacokinetics of 28 days of repeat oral doses of AKB-6548 in a cohort of stage 3 and stage 4 CKD patients. Stage 3 CKD patients and stage 4 CKD patients were started at low dose of AKB-6548. The dose was escalated and adjusted periodically according to a specific set of criteria. The efficacy of AKB-6548 was determined by measuring EPO, hemoglobin and other biomarkers including VEGF, hepcidin, transferrin and ferritin.

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 β 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.

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