

**FOR IMMEDIATE RELEASE****Akebia Therapeutics Announces Initiation of Phase 2b Trial of Oral Anemia Candidate**

**Cincinnati, OH, July 24, 2013** – Akebia Therapeutics, a biotech company focused on developing and commercializing small molecules to treat anemia and cancer, today announced that it has dosed the first patient in the Phase 2b trial of AKB-6548 for the treatment of anemia associated with chronic kidney disease (CKD). AKB-6548 is an orally available, hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor, which is designed to stabilize HIF2 $\alpha$ , a critical regulator of red blood cell production and iron absorption. By working in this manner, AKB-6548 achieves a very controlled and natural stimulation of red blood cell production that is similar to the effect of modest increases in altitude.

“By inducing this natural response in patients with CKD, AKB-6548 has been demonstrated to produce a predictable increase in hemoglobin, which may provide these patients with a safer, more convenient and effective alternative to injectable erythropoiesis stimulating agents, the current standard of care,” said Robert Shalwitz, M.D., Senior Vice President and Chief Medical Officer of Akebia. “The initiation of this Phase 2b represents a significant step forward in bringing a new treatment option to patients, and we look forward to the outcome of the trial.”

The Phase 2b randomized, double-blind, placebo-controlled study is designed to evaluate the safety and efficacy of AKB-6548 for the treatment of anemia associated with CKD. The trial will enroll 200 patients at over 50 sites in the United States and evaluate the patients over a treatment period of 140 days. The primary endpoint will evaluate the hemoglobin response.

**About AKB-6548**

AKB-6548 is an orally available, hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor that stabilizes HIF2 $\alpha$  and is currently in development by Akebia for the treatment of anemias secondary to CKD and end stage renal disease (ESRD or dialysis). These diseases are currently treated with injectable erythropoiesis stimulating agents (ESAs), which generated approximately \$8 billion in global revenues in 2011, despite having “black box” warnings for increased cardiovascular risk in patients with CKD and increased rate of tumor growth and chance of death in patients with cancer. By contrast, due to its different mechanism of action, AKB-6548 has demonstrated the potential to be a safer, more efficacious, less expensive, orally dosed alternative to the injectable ESAs that are currently used to treat a variety of anemias. Instead of binding directly to and saturating the EPO receptor for prolonged periods of time, AKB-6548 acts by stimulating the body’s natural response to anemia that is carried out by stabilization of HIF2 $\alpha$ . The drug response is similar to the physiological adjustment made by the body to an increase in altitude. In this way, once-daily dosing of this oral HIF-PH inhibitor can restore the normal diurnal variation of EPO for a patient with anemia in a way that an injectable ESA cannot. This approach leads to a consistent, predictable and controllable rise in hemoglobin levels.

**About Akebia Therapeutics**



**Phone: 513-985-1920**

**Fax: 513-985-0999**

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

**Akebia Therapeutics, Inc.**

**9987 Carver Road**

**Suite 420**

**Cincinnati, OH 45242**

---

Akebia Therapeutics is a biotech company that is based in Cincinnati, OH and was spun out of Procter & Gamble Pharmaceuticals in 2007. The Company's lead program, AKB-6548, is an orally bioavailable HIF-PH inhibitor that is in Phase 2 clinical trials for anemia associated with CKD. AKB-6548 potentially promises to be a safer, less expensive, orally dosed pharmaceutical to stimulate endogenous EPO production ([www.akebia.com](http://www.akebia.com)).

**Contact**

William Daly, Chief Business Officer, Akebia Therapeutics, Inc., 513.985.1928,  
[wdaly@akebia.com](mailto:wdaly@akebia.com)

MacDougall Biomedical Communications

Michelle Avery, 781.235.3060, [mavery@macbiocom.com](mailto:mavery@macbiocom.com) or

Christine Labaree, 650.339.7533, [clabaree@macbiocom.com](mailto:clabaree@macbiocom.com)