
FOR IMMEDIATE RELEASE**Akebia Initiates Phase 1 Study of First-In-Class HPTP β Inhibitor for Diabetic Macular Edema**

Cincinnati, OH, November 21, 2011 – Akebia Therapeutics, Inc., a small molecule discovery and development company focused on anemia and vascular disorders, today announced that it has dosed the first subjects in a first-in-man Phase 1 study of AKB-9778, a first-in-class human protein tyrosine phosphatase beta (HPTP β) inhibitor in development for diabetic macular edema (DME) and diabetic retinopathy (DR). AKB-9778 is designed to stabilize vessels in the back of the eye, preventing vascular leak and abnormal blood vessel growth associated with diabetic eye disease.

"Advancing this first-in-class drug candidate into human studies is an important milestone for Akebia," said Kevin Peters, MD, Vice President and Chief Scientific Officer of Akebia. "Based on years of research and data from preclinical studies, we believe that AKB-9778 has the potential to be a major advance for patients with DME and DR. By inhibiting HPTP β , AKB-9778 in turn activates Tie2, a receptor on vascular endothelial cells that is responsible for stabilizing the vasculature against abnormal blood vessel growth and vascular leak. This combination of activities is ideal to address the two principal causes of vision loss in patients with DME and DR and is backed by data in multiple preclinical models of retinopathy."

The Phase 1 study is designed to evaluate the safety, tolerability and pharmacokinetics of single ascending doses of AKB-9778 in healthy volunteers. In addition, the pharmacology of AKB-9778 will be ascertained by measuring biomarker responses. The trial will involve up to 48 healthy volunteers and is being conducted at Medpace, Inc. in Cincinnati, OH. The study is expected to be completed this year.

About AKB-9778 and HPTP β

Akebia has a platform of first-in-class HPTP β inhibitors that enhance Tie2 receptor activation. Tie2 is a receptor tyrosine kinase expressed on endothelial cells that plays a critical role in maintenance of vascular integrity. HPTP β is an endothelial tyrosine phosphatase that dephosphorylates Tie2, limiting Tie2 signaling.

AKB-9778 is a novel, highly selective, small molecule HPTP β inhibitor. Inhibition of HPTP β restores Tie2 signaling and overcomes the effect of the natural Tie2 inhibitor, Ang2, restoring vascular stability and, in turn, reducing vascular leak and pathologic angiogenesis. There are currently no treatments for DME or DR that target the Tie2 pathway.

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. 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 erythropoietin (EPO). AKB-6548 has the potential to be a safer, less expensive, orally dosed pharmaceutical to stimulate endogenous EPO production. Additionally, Akebia has a novel HPTP β inhibitor/Tie2 activator, AKB-9778, for the treatment of DR which is now in Phase 1 clinical trials.

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