



## **Aerpio Therapeutics Initiates Phase 1a Study of AKB-4924, a First in Class Once-Daily, Orally Administered HIF-1 Stabilizer, in Development to Treat Inflammatory Bowel Disease (IBD)**

- **In preclinical studies, AKB-4924 has demonstrated efficacy in multiple models of IBD**
- **Aerpio's Phase 1a trial in healthy volunteers will assess safety and tolerability of AKB-4924 with preliminary results expected in Q4 2016**

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CINCINNATI--(BUSINESS WIRE)--Aerpio Therapeutics, Inc., today announced that it has dosed the first subject in a Phase 1a clinical trial evaluating its product candidate AKB-4924 for the treatment of IBD. This novel, orally administered agent that stabilizes hypoxia inducible factor 1 alpha (HIF-1 $\alpha$ ), a cellular protein which plays a crucial role in the resolution of inflammation and maintenance of epithelial barrier integrity. In multiple *in vivo* preclinical models of IBD, AKB-4924 has been shown to markedly reduce disease activity, with decreased levels of inflammation and preservation of mucosal integrity. AKB-4924 also led to marked reductions in multiple inflammatory cytokines in plasma and colon tissue.

"Initiating the clinical development program for AKB-4924 represents a major milestone," commented Kevin Peters, M.D., Aerpio's Chief Scientific Officer. "AKB-4924 has the potential to be the first orally administered agent to target both the resolution of inflammation and the restoration of epithelial barrier function, the two major drivers of IBD pathogenesis."

Joseph Gardner, Aerpio's CEO stated, "Currently, patients with moderate to severe IBD are treated with steroids or biologics, both of which have significant side effects. We believe that AKB-4924 provides a groundbreaking treatment for IBD that could reduce the dependence of IBD patients on both steroids and biologics."

### **About the AKB-4924 Study**

Aerpio's Phase 1a, randomized, double-blind, placebo-controlled study is designed to enroll up to 48 healthy volunteers. Twelve individuals will receive placebo and 36 will receive AKB-4924 in up to six dose cohorts in an ascending-dose design. The study's primary objective is to assess the safety and tolerability of a single oral dose of AKB-4924. The study will also assess pharmacokinetics and pharmacodynamics of AKB-4924.

### **About AKB-4924**

AKB-4924 is a small molecule, HIF-1 $\alpha$  stabilizing agent. HIF-1 $\alpha$  is critical for the regulation of innate immune responses and maintenance of epithelial barrier function, particularly in the gut. AKB-4924 is being developed as a once-daily, orally-administered therapy for IBD.

### **About Aerpio Therapeutics**

Aerpio Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development of novel therapeutics based on two mechanisms, Tie2 activation for vascular disorders with a concentration on diseases of the eye and the stabilization of HIF-1 $\alpha$  for the treatment of IBD. The Company's lead program, AKB-9778, is a first-in-class small molecule stabilizer of the Tie2 pathway and is in clinical development for diabetic eye disease. Aerpio has also commenced clinical testing of AKB- 4924, a HIF-1 stabilizer, for the treatment of IBD. More information is available at [www.aerpio.com](http://www.aerpio.com).

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