



Aerpio Therapeutics Completes Enrollment of Phase 2 Study of Tie2 Activator AKB-9778 for the Treatment of Patients with Diabetic Macular Edema

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CINCINNATI--([BUSINESS WIRE](#))--Aerpio Therapeutics, Inc., a clinical-stage biopharmaceutical company focused on advancing innovative therapies for diabetic eye disease and diabetes complications, today announced completion of patient enrollment for the Company's Phase 2 trial, named "TIME-2", evaluating AKB-9778, a Tie2 activator, alone and in combination with ranibizumab (Lucentis®), for the treatment of diabetic macular edema (DME). AKB-9778 is a first-in-class inhibitor of human protein tyrosine phosphatase beta (HPTPβ) that activates the Tie2 pathway to promote vascular stability, preventing abnormal blood vessel growth and vascular leak.

"The need for new therapies in DME is significant."

"The Angiopoietin/Tie2 pathway is a central pathway controlling the maintenance and stabilization of retinal blood vessels," said Kevin Peters, MD, Chief Scientific Officer and Vice President of Research and Development at Aerpio. "Results from our earlier Phase 1b study demonstrated promising monotherapy activity with AKB-9778 in both treatment-naïve and treatment-resistant DME patients. We expect the current phase 2 trial will allow us to expand our understanding of the efficacy of AKB-9778, both as monotherapy and in combination with ranibizumab." Dr. Peters added, "Given that Tie2 activation is complementary to the action of anti-VEGF agents, we look forward to determining how our drug performs as a monotherapy and as an adjunct to anti-VEGF therapy."

"While intravitreal anti-VEGF treatments have become the standard of care in patients with DME, at least one-quarter of patients receiving monthly treatments do not have total resolution of their edema, and 40% do not achieve 20/40 vision," said David S. Boyer, MD, Retina-Vitreous Associates Medical Group. "The need for new therapies in DME is significant."

The randomized, double-masked, placebo-controlled, Phase 2 study is designed to assess the safety and efficacy of AKB-9778 administered over three months as monotherapy and as an adjunct with ranibizumab in subjects with DME. The study enrolled 144 subjects (48 patients/group) at nearly 40 sites in the United States, randomizing patients 1:1:1 in three groups – 1) AKB-9778 monotherapy AKB-9778 15 mg BID subcutaneous administration with monthly sham intravitreal injections, 2) combination therapy AKB-9778 15 mg BID with monthly intravitreal injections of ranibizumab 0.3 mg, and 3) a control group of placebo BID subcutaneous injection plus ranibizumab 0.3 mg monthly intravitreal injection. The primary endpoint of the study is change from baseline in central retinal thickness in the groups treated with AKB-9778 monotherapy and AKB-9778 as an adjunct with ranibizumab compared to ranibizumab monotherapy.

“AKB-9778 offers a needed new approach in DME. Pending the results of the ongoing clinical program, I believe this therapy has the potential to be transformative for the treatment of DME,” said Pravin U. Dugel, MD, Retina Consultants of Arizona.

Aerpio presented earlier this year the results of its Phase 1b/2a study in patients with DME, in which AKB-9778 administered subcutaneously as monotherapy over 28 days was well-tolerated, and produced clinically meaningful reductions in retinal thickness, correlating with improved visual acuity. The results were presented at the Association for Research in Vision and Ophthalmology Annual Meeting (ARVO) and the American Academy of Ophthalmology.

About AKB-9778

AKB-9778 is a first-in-class small molecule that inhibits the human protein tyrosine phosphatase β (HPTP β) enzyme, which acts as a negative regulator of the Tie2 receptor. By inhibiting this negative regulator, Tie2 signaling is restored, overcoming the effects of the Ang2-induced vascular destabilization. Aerpio is currently focusing development of its lead candidate, AKB-9778, in diabetic macular edema (DME); however, Tie2 activators have potential utility in a range of important clinical indications. In a Phase 1b/2a study in DME patients, AKB-9778 was well-tolerated throughout 28 days of dosing, with evidence of disease improvement in some patients. A Phase 2 study (TIME-2) to confirm efficacy of AKB-9778 alone and in combination with ranibizumab in patients with DME is currently ongoing.

About Aerpio Therapeutics

Aerpio Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on advancing innovative therapies for vascular diseases. Aerpio is a leader in the development of small molecule drugs based on Tie2 activation and the stabilization of hypoxia-inducible factor 1 α (HIF-1 α). The Company's lead program, AKB-9778, is a first-in-class stabilizer of the Tie2 pathway and is in clinical development for diabetic macular edema. More information is available at www.aerpio.com.

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