Aerpio Pharmaceuticals Completes Patient Enrollment in TIME-2b Study, a Phase 2b Clinical Trial of Lead Candidate AKB-9778 in Patients with Diabetic Retinopathy

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CINCINNATI--(BUSINESS WIRE)--Feb. 9, 2018-- Aerpio Pharmaceuticals, Inc. (OTCQB:ARPO) ("**Aerpio**"), a biopharmaceutical company focused on advancing first-in-class treatments for ocular diseases, announced today the completion of patient enrollment in the company's TIME-2b study, a Phase 2b clinical trial designed to assess the efficacy and safety of Aerpio's lead candidate AKB-9778 for patients with moderate to severe non-proliferative diabetic retinopathy.

The TIME-2b study is a double-masked, placebo-controlled, multi-center trial that has enrolled 167 patients randomized to receive 48-weeks of treatment with either AKB-9778 15 mg subcutaneously once daily, AKB-9778 15 mg subcutaneously twice daily, or placebo subcutaneously twice daily. The primary endpoint of the TIME-2b study is the percentage of patients who improve by 2 or more steps in diabetic retinopathy severity score (DRSS) in the study eye. Secondary objectives include assessment of DRSS improvement in the fellow eye in patients with bilateral disease, proportion of patients that develop diabetic macular edema and/or proliferative diabetic retinopathy, and improvement in renal function. More information about the clinical trial is available at: https://clinicaltrials.gov/ct2/show/NCT03197870.

"AKB-9778 is a drug candidate with tremendous potential," stated Victor H. Gonzalez, M.D. of Valley Retina Institute (McAllen, TX), who enrolled the first patient in TIME-2b. "Enrolling 167 patients into this trial in just over seven months speaks to the need for earlier treatment of diabetic eye disease, as well as the need for an alternative to repeated intravitreal injections."

"We are pleased that the enrollment rate achieved in this trial beat expectations by over two months, and we believe this is strong evidence that physicians and their patients recognize the potential advantages of AKB-9778 to potentially treat not only their diabetic retinopathy, but possibly other systemic effects of diabetic microvascular disease," commented Aerpio's Chief Medical Officer, Steve Pakola, M.D. "We look forward to the data which will be available in the second quarter of 2019."

About Aerpio Pharmaceuticals

Aerpio Pharmaceuticals, Inc. is a biopharmaceutical company focused on advancing first-in-class treatments for ocular diseases. The Company's lead compound, AKB-9778, is a small molecule activator of the Tie2 pathway and is in clinical development for the treatment of non-proliferative diabetic retinopathy. For more information please visit www.aerpio.com.

About AKB-9778

AKB-9778 is being developed as a subcutaneous injection for the treatment of non-proliferative diabetic retinopathy. AKB-9778 binds to and inhibits vascular endothelial phosphotyrosine phosphatase (VE-PTP), the most critical negative regulator of Tie2. AKB-9778 has demonstrated the ability to activate the Tie2 receptor irrespective of extracellular levels of its binding ligands, angiopoietin-1 (agonist) or angiopoietin-2 (antagonist), and may be the most efficient pharmacologic approach to activating Tie2.

About Diabetic Retinopathy

Diabetic retinopathy (DR) is a complication of diabetes caused by damage to blood vessels in the retina, and occurs in roughly one of three patients with diabetes, and in those, in both eyes approximately 75% of the time. Severity of DR ranges from mild non-proliferative diabetic retinopathy to more advanced proliferative diabetic retinopathy, the hallmark of which is the development of new abnormal blood vessels. DR is the leading cause of blindness among working aged adults around the world, affecting roughly 140 million diabetics globally.

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