Aerpio Pharmaceuticals Announces Completion of Patient Dosing in TIME-2b Study of AKB-9778 in Diabetic Retinopathy

January 17, 2019

CINCINNATI--(BUSINESS WIRE)--Jan. 17, 2019-- Aerpio Pharmaceuticals, Inc. (Nasdaq: ARPO), a biopharmaceutical company focused on developing compounds that activate Tie2 to treat ocular diseases and diabetic complications, today announced the completion of patient dosing 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 (NPDR).

"We are pleased to announce completion of patient dosing in our 48-week Phase 2b trial, TIME-2b," said Stephen Hoffman, M.D., Ph.D., Chief Executive Officer of Aerpio. "We now expect to announce top-line results in March 2019, earlier than our previous guidance of the second quarter of 2019. AKB-9778 is our first-in-class, systemically-administered Tie2 activator in development for the treatment of diabetic retinopathy, as well as complications of diabetes and other ocular diseases. The data obtained in our TIME-2 Phase 2a study were very encouraging, not only in demonstrating improvement in diabetic retinopathy, but also showing, in a *post-hoc* analysis, improvement of kidney function. We believe AKB-9778 has the potential to provide patients with diabetes a significant treatment option, spanning multiple diabetic complications."

TIME-2b Study Overview

The TIME-2b study is a double-masked, placebo-controlled, multi-center trial evaluating the effect of AKB-9778 in 167 patients with moderate to severe NPDR. Patients were randomized to receive 48 weeks of treatment with either AKB-9778 15 mg subcutaneously once daily (and placebo 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. One of the secondary objectives, the urine albumin to creatinine ratio or UACR, was prospectively included based on a *post-hoc* analysis of this biomarker in the TIME-2 Phase 2a clinical trial of AKB-9778. Initial results from this trial are expected in March 2019.

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 protein tyrosine phosphatase (VE-PTP), an important negative regulator of Tie2. Decreased Tie2 activity contributes to vascular instability in many diseases including diabetes. AKB-9778 activates 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 maintain normal Tie2 activation.

About Diabetic Retinopathy

Diabetic retinopathy (DR) is a complication of diabetes caused by damage to blood vessels in the retina. DR occurs in roughly one of three patients with diabetes and involves both eyes 75% of these patients. 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.

About Aerpio Pharmaceuticals

Aerpio Pharmaceuticals, Inc. is a biopharmaceutical company focused on advancing first-in-class compounds that activate Tie2 to treat ocular diseases and complications of diabetes. The Company's lead compound, AKB-9778, is a systemically-administered small molecule activator of the Tie2 pathway (via highly selective and potent deactivation of VE-PTP) and is in clinical development for the treatment of non-proliferative diabetic retinopathy. AKB-9778 is also being investigated for its potential utility in treating diabetic nephropathy and an eyedrop formulation is in development as a potential treatment for open-angle glaucoma. For more information, please visit www.aerpio.com.

View source version on businesswire.com: https://www.businesswire.com/news/home/20190117005089/en/

Source: Aerpio Pharmaceuticals, Inc.

Investor & Media:
Aerpio Pharmaceuticals, Inc.
Michael Rogers
Chief Financial Officer
mrogers@aerpio.com
or
Burns McClellan, on behalf of Aerpio Pharmaceuticals, Inc.
Media:
Nancie Steinberg / Robert Flamm, Ph.D.
nsteinberg@burnsmc.com / rflamm@burnsmc.com
or

Investors:
John Grimaldi
jgrimaldi@burnsmc.com