Aerpio Pharmaceuticals Announces Presentation of Renal Function Data from TIME-2 Study of AKB-9778 in Diabetic Retinopathy Patients at American Society of Nephrology Kidney Week 2018

October 25, 2018

CINCINNATI--(BUSINESS WIRE)--Oct. 25, 2018-- Aerpio Pharmaceuticals, Inc. (Nasdaq:ARPO), a biopharmaceutical company focused on advancing first-in-class treatments for ocular diseases, today announced that the Company will present renal function data obtained from the TIME-2 Phase 2 clinical trial of AKB-9778 in diabetic retinopathy patients at the American Society of Nephrology (ASN) Kidney Week 2018, Oct. 23-28, in San Diego.

“VE-PTP, an inhibitor of Tie2, is expressed in the kidney and may be upregulated in patients with diabetes,” said Kevin Peters, M.D., chief scientific officer of Aerpio Pharmaceuticals. “This is important because Tie2 is a key regulator of vascular stability and decreased Tie2 activity is associated with diabetic complications including diabetic nephropathy. This post-hoc analysis of kidney function in the TIME-2 trial shows the potential utility of AKB-9778 to improve kidney function. If prospectively confirmed in TIME-2b and future clinical trials, AKB-9778 could be a significant treatment option that could cover a number of diabetic complications due to its systemic administration. We look forward to disclosing the results from the TIME-2b study, which remains on track to report in the second quarter of 2019.”

The TIME-2 study was designed to evaluate AKB-9778 in patients with diabetic macular edema and diabetic retinopathy (see trial description below for details). Approximately one-half of the subjects had signs of renal disease based on a urine albumin-to-creatinine ratio (UACR) of ≥30mg/g at baseline and these patients were approximately evenly distributed across the three treatment groups. UACR was also measured at the end of the study treatment period of three months. In a post-hoc analysis, there was a 21% reduction (geometric mean) in UACR from baseline in AKB-9778 treatment arms but an overall increase in UACR in the placebo arm. The study provides clinical evidence of the potential beneficial effects of Tie2 activation in diabetic kidney disease.

Presentation Information
Title: Tie2 Activation via VE-PTP Inhibition for Treatment of Diabetic Kidney Disease
Authors: K.G. Peters, et al.
Day and Time: Saturday, October 27, 2018, 10 a.m. to noon PDT
Location: San Diego Convention Center

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 the TIME-2 Study

The TIME-2 study evaluated 144 diabetic macular edema (DME) patients randomized equally (1:1:1) to AKB-9778 as monotherapy or in combination with Lucentis® compared with Lucentis® alone for a treatment period of 3 months, followed by a 2-month observation period. The study’s primary endpoint measure was mean change from baseline in CST at 3 months. Pre-specified analyses of change in diabetic retinopathy severity score were done by treatment group in the study eye. Evaluation of the fellow eye was done by combining groups that received subcutaneous AKB-9778, AKB-9778 monotherapy and AKB-9778 + Lucentis® combination therapy groups and comparing changes in diabetic retinopathy severity score in patients that received subcutaneous placebo (ranibizumab monotherapy group).

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.

Forward Looking Statements

This press release contains forward-looking statements. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, the development of the Company’s product candidates and the related clinical studies, including AKB-9778 for non-proliferative diabetic retinopathy or otherwise, the therapeutic potential of the Company’s product candidates, including AKB-9778, the potential timing for disclosure of the results from the Company’s TIME-2b study. Actual results could differ from those projected in any forward-looking statements due to several risk factors. Such factors include, among others, the ability to raise the additional funding needed to continue to develop AKB-9778 or other product development plans, the inherent uncertainties associated with the FDA and drug development process, competition in the industry in which the Company operates and overall market conditions. These forward-looking statements are made as of the date of this press release, and the Company assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents the Company files with the SEC available at www.sec.gov.

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