



Aerpio Announces Initiation of 28-Day Phase 2 Razuprotafib Glaucoma Trial

June 24, 2020

CINCINNATI, June 24, 2020 (GLOBE NEWSWIRE) -- Aerpio Pharmaceuticals, Inc. ("Aerpio") (Nasdaq: ARPO), a biopharmaceutical company focused on developing compounds that activate Tie2 to treat ocular diseases, ARDS associated with COVID-19, and diabetic complications, today announced that it has commenced patient enrollment in its double-blind, placebo-controlled Phase 2 trial in patients with elevated intraocular pressure (IOP) associated with open angle glaucoma (OAG) or ocular hypertension (OHT). There are now 20 clinical sites actively enrolling patients and 30 patients have been screened and enrolled.

The study is designed to evaluate the safety and efficacy of a topical formulation of razuprotafib in approximately 195 patients followed over a 28-day period. Patients enrolled in the trial will be administered a baseline of latanoprost ophthalmic solution 0.005%, and then randomized in a 1:1:1 fashion to receive adjunctive therapy consisting of placebo, 40 mg/ml razuprotafib once-daily, or 40 mg/ml razuprotafib twice-daily. The primary endpoint of the study will be mean diurnal IOP at 28 days in the razuprotafib treated groups compared to the latanoprost monotherapy group.

"We are extremely pleased by the enthusiasm and productivity of the ophthalmology clinics participating in this trial," said Kevin Peters, M.D., Chief Scientific Officer and Chief Medical Officer of Aerpio. "We are now likely to have topline data in Q4 2020, in spite of potential slowdowns in clinic visits associated with the COVID-19 pandemic. We also attribute the rapid pace of patient enrollment to heightened interest from patients and healthcare providers as a result of the differentiated and novel mechanism of action of razuprotafib." The Company will provide another update on enrollment during its second quarter earnings call in August.

About Razuprotafib

Razuprotafib 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 and more recently has been shown to contribute to the development of increased IOP and glaucoma. Razuprotafib 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. Aerpio is studying a topical ocular formulation of razuprotafib in open angle glaucoma and exploring the utility of subcutaneous razuprotafib for diabetic complications, including diabetic nephropathy.

About Aerpio Pharmaceuticals

Aerpio Pharmaceuticals, Inc. is a biopharmaceutical company focused on developing compounds that activate Tie2 to treat ocular diseases and diabetic complications. Recently published mouse and human genetic data implicate the Angpt/Tie2 pathway in maintenance of Schlemm's canal, a critical component of the conventional outflow tract. The Company's lead compound, razuprotafib (formerly AKB-9778), a first-in-class small molecule inhibitor of vascular endothelial protein tyrosine phosphatase ("VE-PTP"), is being developed as a potential treatment for open angle glaucoma, and the Company intends to investigate the therapeutic potential of razuprotafib in other indications. The Company is also evaluating development options for ARP-1536, a humanized monoclonal antibody, for its therapeutic potential in the treatment of diabetic vascular complications including nephropathy and diabetic macular edema ("DME"). The Company's third asset is a bispecific antibody that binds both VEGF and VE-PTP which is designed to inhibit VEGF activation and activate Tie2. This bispecific antibody has the potential to be an improved treatment for wet age-related macular degeneration and DME via intravitreal injection. Finally, the Company has exclusively out-licensed AKB-4924 (now called GB004), a first-in-class small molecule inhibitor of hypoxia-inducible factor-1 (HIF). GB004 is being developed by AKB-4924's exclusive licensor, Gossamer Bio, Inc. (Nasdaq: GOSS). For more information, please visit www.aerpio.com.

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 Company's product candidates, including razuprotafib, ARP-1536 and the bispecific antibody asset, the clinical development plan therefor and the therapeutic potential thereof, the Company's plans and expectations with respect to razuprotafib and the development therefor and therapeutic potential thereof in addressing COVID-19 and the intended benefits from the Company's collaboration with Gossamer Bio for GB004, including the continued development of GB004 and the milestone and royalty payments related to the collaboration. Actual results could differ from those projected in any forward-looking statements due to several risk factors. Such factors include, among others, the continued development of GB004 and maintaining and deriving the intended benefits of the Company's collaboration with Gossamer Bio; ability to continue to develop razuprotafib or other product candidates, including in indications related to COVID-19; the inherent uncertainties associated with the drug development process, including uncertainties in regulatory interactions, the design of planned or future clinical trials, commencing clinical trials and enrollment of patients in clinical trials; obtaining any necessary regulatory clearances in order to commence and conduct planned or future clinical trials; the impact of the ongoing COVID-19 pandemic on the Company's business operations, including research and development efforts and the ability of the Company to commence, conduct and complete its planned clinical activities; and competition in the industry in which the Company operates and overall market conditions; and the additional factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2019, as updated by our subsequent Quarterly Reports on Form 10-Q and our other subsequent filings with the SEC.

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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