Aerpio Announces Statistically Significant Topline Results from Razuprotafib Glaucoma Phase 2 Trial

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Primary endpoint achieved with twice-daily dose group at 28 day time point versus latanoprost control group.

Patient enrollment and dosing continues in both COVID-19 clinical trials

CINCINNATI, Dec. 11, 2020 (GLOBE NEWSWIRE) -- Aerpio Pharmaceuticals, Inc.(Aerpio) (Nasdaq: ARPO), a biopharmaceutical company focused on developing compounds that activate Tie2 to treat ocular diseases and diabetic complications, as well as other indications in which the Company believes that activation of Tie2 may have therapeutic potential, including acute respiratory distress syndrome (“ARDS”) associated with COVID-19 infections, today announced that razuprotafib met the primary efficacy endpoint at Day 28 with the twice-daily (“BID”) dose group in Aerpio’s double-blind, placebo-controlled Phase 2 trial in patients with elevated intraocular pressure (“IOP”) associated with open angle glaucoma (“OAG”) or ocular hypertension (“OHT”). The change from baseline in diurnal mean IOP at Day 28 of study eyes treated with razuprotafib BID plus latanoprost showed a statistically significant improvement, or drop in IOP, (two-sided p-value 0.0130 and LS mean difference of -0.92 mm Hg) compared to those treated with latanoprost monotherapy. The razuprotafib once-daily (“QD”) dose group did not show a statistically significant improvement at Day 28.

The study was designed to evaluate the safety and efficacy of a topical ocular formulation of razuprotafib as an adjunct to standard of care latanoprost. A total of 194 patients completed a 28-day washout period and were randomized in a 1:1:1 fashion to receive latanoprost ophthalmic solution 0.005% once daily with adjunctive therapy consisting of placebo, 40 mg/ml razuprotafib once-daily, or 40 mg/ml razuprotafib twice-daily. The primary endpoint of the study was mean diurnal IOP at 28 days in the razuprotafib treated groups compared to the latanoprost monotherapy group.

“Tie2 activation with razuprotafib once again was associated with a measurable effect consistent with its mechanism for vessel stabilization, in this case Schlemm’s canal, in the front of the eye,” stated Joseph Gardner, President and Founder. “We expect to receive the full dataset later in the month and will review the data in more detail as well as our strategic plans with respect to our glaucoma program.”

Our two ongoing clinical trials of razuprotafib in COVID-19 patients continue to progress with patient enrollment and dosing. If successful, these trials may open the door to treating ARDS across a broader array of infections. We remain on track to provide additional updates on these Phase 2 clinical trials in the first half of 2021.

About Aerpio Pharmaceuticals

Aerpio Pharmaceuticals, Inc. is a biopharmaceutical company focused on developing compounds that activate Tie2 to treat ocular diseases and diabetic complications, as well as other indications in which the Company believes that activation of Tie2 may have therapeutic potential, including acute respiratory distress syndrome (“ARDS”) associated with COVID-19 infections. 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.

About Razuprotafib (formerly known as AKB-9778)

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 we believe that it 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. In addition, a subcutaneous formulation of razuprotafib is being explored for its therapeutic potential in treating or preventing ARDS associated with COVID-19.

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, including planned timelines for upcoming data releases 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 ARDS related thereto 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; our review and evaluation of additional data from and strategic plans for our razuprotafib glaucoma program; 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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