Aerpio Announces Strategic Review after Topline Results from Razuprotafib Glaucoma Phase 2 Trial

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CINCINNATI, Jan. 05, 2021 (GLOBE NEWSWIRE) -- Aerpio Pharmaceuticals, Inc. (“Aerpio” or the “Company”) (Nasdaq: ARPO), a biopharmaceutical company focused on developing compounds that activate Tie2, today announced that its Board of Directors has initiated a process to explore and review a range of strategic alternatives focused on maximizing stockholder value from the Company’s clinical assets and cash resources, which amounted to $47.3 million as of September 30, 2020.

As part of this process, the Company will explore strategic options for partnering its programs, as well as, the potential for an acquisition, company sale, merger, business combination, asset sale, in-license, out-license or other strategic transaction. Ladenburg Thalmann & Co. Inc. will continue to act as Aerpio’s financial advisor with respect to the strategic review process. There can be no assurance that this exploration of strategic alternatives will result in the Company entering or completing any transaction.

Aerpio programs to be incorporated into this review include:

- **Phase 2 program of razuprotafib in glaucoma:** a recently completed a Phase 2 trial in glaucoma patients showed that the change from baseline in diurnal mean IOP at Day 28 of study eyes treated with razuprotafib BID plus latanoprost was statistically significant (two-sided p-value 0.0130 and LS mean difference of -0.92 mmHg) compared to those treated with latanoprost monotherapy. Further analysis of the results demonstrated that razuprotafib had a larger IOP reduction after longer duration dosing (28 days versus 14 days) consistent with its potential mechanism of repairing Schlemm’s canal. Razuprotafib also produced larger IOP reductions in patients with higher starting IOP, or a 1.6 mmHg IOP reduction in patients with post wash-out IOP’s of >26 mmHg. The razuprotafib topical drops were well tolerated in this trial.

- **Phase 2 program of razuprotafib in COVID-19:** the Company has two ongoing clinical trials of razuprotafib to prevent or mitigate acute respiratory distress syndrome (ARDS) in COVID-19 patients where patient enrollment and dosing continues. If successful, these trials may open the door to treating ARDS across a broader array of infections.

- **Preclinical Tie2 activating antibodies:** the Company also has Tie2 activating antibodies in early development, including both a monospecific antibody that may be used to treat diabetic complications, and a bispecific antibody that may be used to treat retinal diseases such as diabetic macular edema (DME) and wet age related macular edema (wAMD).

Aerpio does not intend to make any further disclosures regarding the strategic review process unless and until specific actions are approved.

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. 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 strategic alternatives review process and the potential transactions that may be identified and explored as a result of that process, 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 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 ability to identify and consummate strategic alternatives that yield additional value for shareholders; the timing, benefits and outcome of the Company's strategic alternatives review process, including the determination of whether or not to pursue or consummate any strategic alternative; the structure, terms and specific risks and uncertainties associated with any potential strategic transaction; potential disruptions in our business and the stock price as a result of our exploration, review and pursuit of strategic alternatives or the public announcement thereof and any decision or transaction resulting from such review; 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 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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