Aerpio Pharmaceuticals, Inc. Announces a Second Clinical Trial with Funding from MTEC to Evaluate Razuprotafib for the Prevention and Treatment of ARDS in Patients with Moderate to Severe COVID-19

August 4, 2020

CINCINNATI, Aug. 04, 2020 (GLOBE NEWSWIRE) -- Aerpio Pharmaceuticals, Inc. (“Aerpio”) (Nasdaq: ARPO) and The U.S. Government operating through the Medical Technology Enterprise Consortium (MTEC) announced today that an agreement has been reached to evaluate razuprotafib in a new randomized, investigational trial for the prevention and treatment of Acute Respiratory Distress Syndrome (ARDS) in adult patients with moderate to severe COVID-19 as part of MTEC-20-09-COVID-19 Treatment Military Infectious Disease Research Program (MIDRP) “Development of Treatments for COVID-19.” MTEC will provide up to $5.1 million in funding toward the clinical trial. Aerpio will support the trial with “in kind” spending in the amount of $2.8 million. MTEC is a 501(c)3 non-profit organization constructed by the U.S. Army Medical Research and Development Command (USAMRDC). The Medical Technology Enterprise Consortium (MTEC) was established as an enterprise partnership including industry and academia to facilitate research and development activities. Protecting U.S. forces from COVID-19 is a key priority for the U.S. military. The partnership between Aerpio and MTEC will provide resources to support a second COVID-19 Phase 2 clinical trial with razuprotafib, a drug candidate being investigated for its potential to prevent and treat the severe respiratory distress observed in COVID-19 patients.

Aerpio Pharmaceuticals is developing a potent and selective small molecule inhibitor of vascular endothelial protein tyrosine phosphatase (VE-PTP), razuprotafib (AKB-9778), that restores Tie2 pathway activation in endothelial cells to stabilize blood vessels during vascular injury and inflammation. Emerging data indicate that SARS-Cov2, the virus that causes COVID-19, may attack vascular endothelium and destabilize blood vessels in multiple organs including the lung, kidneys and heart leading to substantial morbidity and mortality. Based on these findings, Aerpio and a distinguished team of clinical investigators have developed a plan to investigate the therapeutic potential of subcutaneous razuprotafib for the prevention and treatment of ARDS in patients with moderate to severe COVID-19.

Wesley H. Self, MD, MPH Associate Professor and Vice Chair for Research in the Department of Emergency Medicine at Vanderbilt University Medical Center and Aerpio COVID-19 Steering Committee stated, “A Tie2 activator that can be administered without an IV to stabilize the pulmonary vasculature would be a breakthrough for reducing the devastating effects of COVID-19 associated pulmonary pathology. This therapeutic could result in fewer COVID-19 patients requiring mechanical ventilation, earlier recovery with decreased time in the hospital and ICU and an overall reduction in morbidity and mortality”.

Jeff Sabados MPP MBA, member of Aerpio’s COVID-19 Steering Committee, who served for 20 years in both Active and Reserve Duty in the U.S. Navy, commented, “The subcutaneous administration of razuprotafib to activate Tie2 makes this particularly attractive to active duty military personnel around the globe because razuprotafib has the potential to save lives in the next pandemic and return soldiers back to the front lines. I am very proud to be a part of this effort.”

About the MTEC Trial
We hypothesize that razuprotafib, a first-in-class Tie2 activating compound, will exhibit an acceptable safety profile and show efficacy for treatment of ARDS in patients with moderate to severe COVID-19 and be a life-saving therapeutic for service members in the field suffering from the devasting respiratory and vascular effects of COVID-19. Aerpio, through the support of MTEC will conduct a Phase 2 clinical trial of subcutaneous razuprotafib for the treatment of patients with moderate to severe COVID-19**.** The Phase 2 trial will be conducted at approximately 10 clinical sites and is expected to be completed in the first quarter of 2021.

About MTEC
The Medical Technology Enterprise Consortium (MTEC) is a 501(c)(3) biomedical technology consortium collaborating under an Other Transaction Agreement (OTA) with the U.S. Army Medical Research and Development Command (USAMRDC) that serves those who serve our nation.

About Razuprotafib (previously 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. 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. As seen preclinically, activation of Tie2 by razuprotafib stabilizes vasculature which may have beneficial effects in a variety of disease states, including COVID-19.

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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