Aerpio Pharmaceuticals, Inc. and Quantum Leap Healthcare Collaborative Announce the Selection of Razuprotafib for Evaluation in the I-SPY COVID Trial for the Treatment of Acute Respiratory Distress Syndrome in COVID-19 Patients

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SAN FRANCISCO and CINCINNATI, May 27, 2020 /PRNewswire/ -- Aerpio Pharmaceuticals, Inc. ("Aerpio") (Nasdaq: ARPO) and Quantum Leap Healthcare Collaborative™ (Quantum Leap) announced today an agreement has been reached to evaluate razuprotafib in a new randomized, investigational treatment arm in the I-SPY COVID Trial for the treatment of acute respiratory distress syndrome (ARDS) in adult patients with moderate to severe COVID-19.

Approximately 10-15% of those infected with the highly contagious SARS-CoV2 virus, the cause of COVID-19, develop ARDS with a death rate in the 2-10% range. Nearly 70% of COVID-19 patients admitted to the ICU require ventilation for a mean of 14 days, and over 50% will not survive. The unprecedented rate of SARS-CoV-2 (COVID-19) infection, over 5.6 million world-wide, has already led to more than 350,000 deaths.

The goal of this the I-SPY COVID Trial is to rapidly screen multiple promising agents, in the setting of an adaptive platform trial, for the treatment of critically ill COVID-19 patients to identify agents that will have a high impact on reducing mortality, and the need for as well as duration of, mechanical ventilation.

Preclinical models, large human observational studies, and human genetic studies from leading groups worldwide have independently arrived at the concept that a vascular endothelial receptor, Tie2, may play a pivotal role in the defense against microvascular breach in acute respiratory distress syndrome (ARDS) [1-4]. We hypothesize that razuprotafib, a being developed as a first-in-class Tie2 activating compound, will exhibit an acceptable safety profile and show efficacy for the treatment of COVID-19 associated ARDS as a potentially life-saving therapeutic for patients suffering from the devasting respiratory effects of COVID-19.

This study arm will evaluate razuprotafib's potential to sufficiently stabilize the pulmonary vasculature, in order to slow or prevent the progression of COVID-19 associated pulmonary pathology, decrease the need for ventilator support, and reduce mortality.

"The I-SPY COVID Trial is designed to rapidly identify and test agents with the potential to provide substantial benefit to patients suffering with acute respiratory distress syndrome (ARDS) from COVID-19, a condition where effective agents are lacking. We are delighted that Aerpio has agreed to participate in this trial with their agent razuprotafib, as we look forward to evaluating its potential to improve care for this group of patients," said James Palazzolo, CEO of Quantum Leap Healthcare Collaborative.

Joseph Gardner, PhD, Aerpio's President and Founder, commented "We are very pleased to have razuprotafib selected for inclusion in the I-SPY clinical trial. It will allow us to evaluate the drug in severely ill COVID-19 patients and quickly assess both preliminary safety and efficacy and guide future development plans. If successfully developed, approved and commercialized, razuprotafib has the potential to help save lives and render the disease less life threatening in the patients most at risk."

As part of the collaboration, Aerpio will supply the investigational drug and provide financial and regulatory support. The Quantum Leap/ I-SPY team, as sponsor, will provide the clinical sites and clinical expertise. Aerpio has already produced subcutaneous razuprotafib to support the rapid start-up of this arm of the trial.

Quantum Leap, sponsor of the I-SPY 2 TRIALs which is well-known for its adaptive platform trial in breast cancer, announced plans on April 28 to employ a similar methodology and launch a new trial to study acute respiratory distress syndrome (ARDS) in COVID-19 patients. The I-SPY COVID Trial, sponsored by Quantum Leap, will include ARDS experts from the University of California at San Francisco and from more than 20 I-SPY 2 U.S. sites along with the COVID R&D Consortium, a consortium organized by the R&D heads of major US and European pharmaceutical and biotechnology companies. It is a Phase 2 randomized, controlled, multicenter study with an innovative adaptive design aimed to identify and rapidly test promising new treatments for their potential use against COVID-19 related ARDS.

About the I-SPY COVID Trial

The I-SPY COVID Trial (Investigation of Serial studies to Predict Your Therapeutic Response with Imaging And molecular analysis) was designed to rapidly screen promising experimental treatments and identify those most effective in specific patient subgroups based on molecular characteristics (biomarker signatures). The trial is a unique collaborative effort by a consortium that includes the U.S. Food and Drug Administration (FDA), industry, patient advocates, philanthropic donors, and clinicians from multiple major U.S. research centers. Under the terms of the collaboration agreement, Quantum Leap Healthcare Collaborative is the trial sponsor and manages all study operations. For more information, visit **www.ispytrials.org**.

About Quantum Leap Healthcare Collaborative
Quantum Leap Healthcare Collaborative (Quantum Leap) is a 501c(3) charitable organization established in 2005 as a collaboration between medical researchers at University of California, San Francisco and Silicon Valley entrepreneurs. Our mission is to integrate high-impact research with clinical processes and systems technology, resulting in improved data management and information systems, greater access to clinical trial matching and sponsorship, and greater benefit to providers, patients, and researchers. Quantum Leap provides operational, financial, and regulatory oversight to I-SPY. For more information, visit **www.quantumleaphealth.org**.

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 ARDS associated with COVID-19 infections.

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.

References:

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SOURCE Quantum Leap Healthcare Collaborative

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