



Aerpio and Quantum Leap Announce First Patients Dosed with Razuprotafib in the I-SPY COVID Trial to Treat ARDS in Critically-ill COVID-19 Patients

September 1, 2020

SAN FRANCISCO and CINCINNATI, Sept. 1, 2020 /PRNewswire/ -- Aerpio Pharmaceuticals, Inc. ("Aerpio") (Nasdaq: ARPO) and Quantum Leap Healthcare Collaborative™ (Quantum Leap) announced today dosing of the first patient with razuprotafib in the I-SPY COVID Trial (NCT04488081), a phase 2 platform trial aimed at improving treatment of acute respiratory distress syndrome (ARDS) in severely ill COVID-19 (adult) patients. Further details about the study can be found [here](#).

"Finding an effective therapeutic agent to treat patients who get critically ill in response to the COVID-19 infection is of utmost importance regardless of whether we have a vaccine," said Laura Esserman, the founder of the I-SPY programs. "Our group is focused on screening promising agents and quickly identifying therapies that work. Razuprotafib was selected because of its potential to reverse the lung damage by activating Tie2 and stabilizing the leaky blood vessels that cause some of the damage. This has the potential to prevent death and improve time to recovery, which is what we need for this pandemic and any other that comes along in the future."

"We are extremely pleased by the rapid progress in study site selection and patient screening in this trial," said Joseph Gardner, President and Founder. "We believe that razuprotafib has the potential to benefit critically ill COVID-19 patients, and hope to provide additional updates on progress before the end of the year."

The I-SPY COVID TRIAL, is an adaptive platform trial sponsored by Quantum Leap Healthcare Collaborative. The goal of the trial is to rapidly screen, in parallel, multiple promising agents in order to identify drugs that will have a high impact on reducing mortality, and avoid or reduce the duration of mechanical ventilation for critically-ill COVID-19 patients. 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.

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 the I-SPY TRIALS

The I-SPY 2 TRIAL for stage II and III breast cancer is the longest running and most successful adaptive platform trial in oncology. Quantum Leap was able to use the existing I-SPY 2 TRIAL infrastructure methodology to develop the I-SPY COVID Trial (Investigation of Serial studies to Predict Your COVID Therapeutic Response with biomarker Integration and Adaptive Learning). The I-SPY COVID Trial is designed to rapidly screen promising experimental treatments, and re-purpose existing agents to identify the most effective treatments for severely ill COVID-19 patients. 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.quantumleaphealth.org, www.ispytrials.org or contact Karyn DiGiorgio karyn.digiorgio@quantumleaphealth.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 all I-SPY Trials. For more information, visit www.quantumleaphealth.org.

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 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 and the therapeutic potential thereof, the Company's plans and expectations with respect to razuprotafib and the development thereof 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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SOURCE Quantum Leap Healthcare Collaborative

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