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Citius Pharmaceuticals Forms Scientific Advisory Board for the Planned Development of its Proprietary Treatment for Acute Respiratory Disease Associated with COVID-19

- Pulmonology opinion leaders in ARDS therapies will bring invaluable insight in Company's clinical trial design

CRANFORD, N.J., July 22, 2020 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("CITIUS") ("Company") (NASDAQ: CTXR), a specialty pharmaceutical company focused on developing and commercializing critical care drug products, announced today the formation of the Citius ARDS (Acute Respiratory Distress Syndrome) Scientific Advisory Board to provide the company expert guidance on its planned development of induced mesenchymal stem cells (*i*MSCs) under option from Novellus, Inc. to treat and reduce the severity of acute respiratory distress syndrome (ARDS) associated with COVID -19.

The ARDS Advisory Board consultants are:
Michael A. Matthay, MD, Professor of Medicine and Anesthesia at the University of California at San Francisco (UCSF), a Senior Associate at the Cardiovascular Research Institute, and Associate Director of the Critical Care Medicine at UCSF. Dr. Matthay's basic research has focused on the pathogenesis and resolution of the acute respiratory distress syndrome (ARDS), with an emphasis on translational work and patient-based research, including clinical trials. Dr. Matthay's recent research has focused on the biology and potential clinical use of allogeneic bone marrow derived mesenchymal stromal cells (MSCs) for ARDS. He is currently leading the "Mesenchymal Stromal Cells For Acute Respiratory Distress Syndrome (STAT)," a United States Department of Defense supported study of MSCs for ARDS.

Mitchell M. Levy, MD, Chief, Division of Pulmonary, Critical Care, and Sleep Medicine, Department of Medicine, The Warren Alpert Medical School of Brown University, where he is Professor of Medicine. Dr. Levy also serves as Medical Director of the Medical ICU at Rhode Island Hospital. He has been an investigator on numerous pharmacologic and biologic trials intended to treat sepsis, cardiovascular and pulmonary pathology. He has expertise in trial design, clinical trial execution and trial management and is one of the three founding members of the Surviving Sepsis Campaign (SSC). Dr. Levy is Past-President of the Society of Critical Care Medicine (2009).

Lorraine B. Ware, MD, Professor of Medicine and Ralph and Lulu Owen Endowed Chair, Professor of Pathology, Microbiology and Immunology, Vanderbilt University; Director, Vanderbilt Medical Scholars Program. Dr. Lorraine Ware's comprehensive bench-to-

bedside research program centers on the pathogenesis and treatment of sepsis and acute lung injury with a current focus on mechanisms of lung epithelial and endothelial oxidative injury by cell-free hemoglobin. Dr. Ware is also a lead investigator for the "Mesenchymal Stromal Cells For Acute Respiratory Distress Syndrome (STAT)" study.

"We are extremely pleased to have been able to attract such a prestigious group of experts to advise and guide us in the Company's planned development of iMSC's for the treatment of ARDS" said Mr. Myron Holubiak, CEO of Citius. "These individuals are recognized opinion leaders and expert in the planning and execution of clinical trials in this therapeutic area. We will be seeking their advice in all phases of our clinical trial design."

About Citius Pharmaceuticals, Inc.
Citius is a late-stage specialty pharmaceutical company dedicated to the development and commercialization of critical care products, with a focus on anti-infectives and cancer care. For more information, please visit www.citiuspharma.com.

About Citius *i*MSC
Citius's planned induced mesenchymal stem cell (*i*MSC) product is derived from a human induced pluripotent stem cell (*i*PSC) line generated using a proprietary non-immunogenic and non-viral mRNA-based (non-viral) reprogramming process. Unlike the MSCs derived from bone marrow, placenta, umbilical cord, or adipose tissue these proprietary *i*MSCs are based on a clonal process and therefore are genetically homogeneous and exhibit superior potency and higher cell viability. The Citius *i*MSC is an allogeneic (unrelated donor) mesenchymal stem-cell product manufactured by expanding material from an *i*MSC master cell bank. The master cell bank produces "off-the-shelf" *i*MSCs that are uniform as compared to MSCs using donor-sourced cells, which is subject to batch-to-batch and cell-to-cell variability that can affect clinical safety and efficacy. *In vitro* studies demonstrate that *i*MSCs are shown to secrete higher levels of immunomodulatory proteins than donor-derived cells, and may reduce or prevent pulmonary injury associated with acute respiratory distress syndrome (ARDS) in patients with COVID-19.

About Acute Respiratory Distress Syndrome (ARDS)
ARDS is a type of respiratory failure characterized by rapid onset of widespread inflammation in the lungs. ARDS is a rapidly progressive disease that occurs in critically ill patients – most notably now in those diagnosed with COVID-19. ARDS affects approximately 200,000 patients per year in the U.S., exclusive of the current COVID-19 pandemic, and has a 30% to 50% mortality rate. ARDS is sometimes initially diagnosed as pneumonia or pulmonary edema (fluid in the lungs from heart disease). Symptoms of ARDS include shortness of breath, rapid breathing and heart rate, chest pain (particularly while inhaling), and bluish skin coloration. Among those who survive ARDS, a decreased quality of life is relatively common.

Safe Harbor
This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements are made based on our expectations and beliefs concerning future events impacting Citius. You can identify these statements by the fact that they use words such as "will," "anticipate," "estimate," "expect," "should," and "may" and other words and terms of similar meaning or use of future dates. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could

negatively affect our business, operating results, financial condition and stock price.

Factors that could cause actual results to differ materially from those currently anticipated are: the risk of successfully negotiating within the option period a license agreement with Novellus, Inc. for our planned *i*MSCs therapy for ARDS; our need for substantial additional funds; risks associated with conducting clinical trials and drug development; the estimated markets for our product candidates and the acceptance thereof by any market; risks related to our growth strategy; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; the early stage of products under development; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; our ability to identify, acquire, close and integrate product candidates and companies successfully and on a timely basis; our dependence on third-party suppliers; our ability to attract, integrate, and retain key personnel; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

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