June 26, 2020

Citius Receives FDA Response on Pre-Investigational New Drug (PIND) Application for its Induced Mesenchymal Stem Cells (iMSCs) to Treat Acute Respiratory Distress Syndrome (ARDS) in Patients with COVID-19

- FDA provides very specific guidelines to study iPSC-derived MSCs

- Company intends to submit an IND application for its iMSC therapy for patients with ARDS associated with COVID-19

CRANFORD, N.J., June 26, 2020 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius" or the "Company") (Nasdaq: CTXR), a specialty pharmaceutical company focused on developing and commercializing critical care drug products, announced today that the Company has received a written response from the U.S. Food and Drug Administration (FDA) in regards to its pre-investigational new drug (PIND) application for its induced mesenchymal stem cells (*i*MSCs) to treat and reduce the severity of acute respiratory distress syndrome (ARDS) in patients with COVID-19.

The FDA acknowledged that the Company could apply for fast track designation and also provided Citius with the chemistry, manufacturing, and control (CMC) requirements for the proposed trials. The Company plans to initiate actions on the FDA's recommendations and follow up with the FDA with an Investigational New Drug (IND) application under the Coronavirus Treatment Acceleration Program (CTAP).

Myron Holubiak, Chief Executive Officer of Citius, commented, "We appreciate the FDA's thoughtful guidance on our unique, allogenic mesenchymal stem cells derived from induced pluripotent stem cells (iPSCs). We understand that iPSC-derived stem cells are not the same as adult-donor derived cells and, therefore, would require different proof of concept studies. Since we believe in the advantages of iPSC MSCs over donor-derived cells, we intend to develop assays recommended by the FDA and demonstrate the safety of these MSCs in our preclinical studies. We are committed to the successful completion of the required clinical trials to provide an effective and safe therapy for ARDS due to COVID-19."

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 mesenchymal stem cell therapy product is derived from a human induced pluripotent stem cell (iPSC) line generated using a proprietary mRNA-based (non-viral) reprogramming process. The *i*MSCs produced from this clonal technique are differentiated from adult donor-derived MSCs (bone marrow, placenta, umbilical cord, adipose tissue, or dental pulp) by providing genetic homogeneity. In in-vitro studies, *i*MSCs exhibit superior potency and high cell viability. The *i*MSCs secrete immunomodulatory proteins that may reduce or prevent pulmonary symptoms associated with acute respiratory distress syndrome (ARDS) in patients with COVID-19. The Citius *i*MSC is an allogeneic (unrelated donor) mesenchymal stem-cell product manufactured by expanding material from a master cell bank.

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.

About Coronavirus Treatment Acceleration Program (CTAP)
In response to the pandemic, the FDA has created an emergency program called the Coronavirus Treatment Acceleration Program (CTAP) to accelerate the development of treatments for COVID-19. By redeploying staff, the FDA is responding to COVID-19-related requests and reviewing protocols within 24 hours of receipt. The FDA said CTAP "uses every available method to move new treatments to patients as quickly as possible, while at the same time finding out whether they are helpful or harmful." In practice, that means developers of potential treatments for COVID-19 would benefit from an unusually faster track at the FDA to shorten wait times at multiple steps of the process.

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 a license agreement for a potential ARDS therapy with Novellus, Inc. within the option period; the ability to access the FDA's CTAP program for our planned ARDS therapy; risks associated with developing our product candidates, including any licensed from Novellus, Inc., including that preclinical results may not be predictive of clinical results and our ability to file an IND for such candidates; our need for substantial additional funds; risks associated with conducting our Phase 3 trial for Mino-Lok, including

completing patient enrollment, opening study sites and achieving the required number of catheter failure events; the estimated markets for our product candidates, including those for ARDS, and the acceptance thereof by any market; risks related to our growth strategy; our ability to identify, acquire, close and integrate product candidates and companies successfully and on a timely basis; 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 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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