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Citius Pharmaceuticals Subsidiary NoveCite Announces Data from a Study of Induced Mesenchymal Stem Cell ("i-MSC") Therapy in an in vivo Model of Acute Respiratory Distress Syndrome ("ARDS")

--Interim results indicate i-MSC therapy improves oxygenation and reduces lung injury

--Efficiently manufactured higher potency mesenchymal stem cells offer promising therapeutic approach

CRANFORD, N.J., Dec. 8, 2020 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius" or the "Company") (Nasdaq: CTXR), a specialty pharmaceutical company developing and commercializing critical care drug products, today announced interim data from a proof-of-concept ("POC") large animal study of its proprietary *induced* mesenchymal stem cell ("*i*-MSC") therapy for acute inflammatory respiratory conditions including COVID-19 related Acute Respiratory Distress Syndrome ("ARDS"). The available results of *i*-MSC therapy in the study show improvement in critical parameters, such as improved oxygenation, less systemic shock, and reduced lung injury, compared to the control group. The study was conducted in a widely accepted large animal model.

As previously announced, Citius signed an exclusive worldwide licensing agreement with Novellus Therapeutics Limited to develop and commercialize iPSC-derived *i*-MSCs. In conjunction with the licensing agreement, the Company established a new subsidiary, NoveCite, Inc., to develop, manufacture and commercialize these induced mesenchymal stem cells. NoveCite has already filed a Pre-Investigational New Drug Application (Pre-IND) with the FDA and has received guidance on the requirements for the proposed trials.

Citius believes that the NoveCite *i*-MSCs overcome some of the challenges of human donor-derived MSCs which are often associated with limited supply, batch inconsistencies, lower potency, and expensive manufacturing. *i*-MSCs are derived from engineered iPSCs (induced pluripotent stem cells), a process that facilitates the robust expansion of uniform MSCs that have higher potency, secrete higher levels of immunomodulatory proteins, and offer practically unlimited supply.

"We believe Novellus's patented, non-immunogenic mRNA cell reprogramming is clearly a superior methodology to generating MSCs compared to the donor-derived model," said Myron Holubiak, Chief Executive Officer of Citius. "The Novellus process provides a consistent cell bank source, near unlimited supply, greater expansion potential with comparatively less senescent cells. These early results from our proof of concept study are

encouraging and indicate potent action which could lead to a treatment candidate for COVID-19 related ARDS." Mr. Holubiak continued, "The development opportunities are significant, and we believe our breakthrough *i*-MSC therapy has the potential to be a strong catalyst for the advancement of our business strategy."

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 NoveCite iMSC (*i*-MSC)

NoveCite'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 NC-*i*-MSCs produced from this clonal technique are differentiated from human 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. *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 NoveCite *i*-MSC is an allogeneic (unrelated donor) mesenchymal stem-cell product manufactured by expanding material from a master cell bank.

First generation (human donor-derived) MSCs are isolated from donated tissue followed by culture expansion. Since only a relatively small number of cells are isolated from each donation, first generation MSCs are increased by growing the cells in culture. Unfortunately, these type of MSCs start to lose potency, and ultimately become senescent. Each donation produces a limited number of MSCs, so a continuous supply of new donors is needed to produce commercial scale. The number and quality of MSCs that can be isolated from different donors can vary substantially.

About Acute Respiratory Distress Syndrome (ARDS)

ARDS is an inflammatory process leading to build-up of fluid in the lungs and respiratory failure. It can occur due to infection, trauma and inhalation of noxious substances. ARDS accounts for approximately 10% of all ICU admissions and almost 25% of patients requiring mechanical ventilation. Survivors of ARDS are often left with severe long-term illness and disability. ARDS is a frequent complication of patients with COVID-19. 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 risks associated with developing the NoveCite technology as a treatment for ARDS; risks associated with developing any of our product candidates, including that preclinical results may not be predictive of clinical results and our ability to file an IND for such candidates; the estimated markets for our product candidates, including those for ARDS, and the acceptance thereof by any market; our need for substantial additional funds; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; the early stage of products under development, including the NoveCite technology; our ability to obtain, perform under and maintain licensing, financing and strategic agreements and relationships; our ability to attract, integrate, and retain key personnel; risks related to our growth strategy; our ability to identify, acquire, close and integrate product candidates and companies successfully and on a timely basis; 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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