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Citius Pharmaceuticals Signs an Exclusive Worldwide Licensing Agreement with Novellus Therapeutics for Unique iMSC-Therapy for Acute Inflammatory Respiratory Conditions including COVID-19 Related Acute Respiratory Distress Syndrome (ARDS)

-- NoveCite, a newly formed subsidiary of Citius Pharmaceuticals, Inc., plans to develop, manufacture and commercialize a unique induced mesenchymal stem cells (NC-iMSCs)

-- Novellus, a Cambridge, Mass-based cell engineering company, has developed patented, non-immunogenic mRNA-based induced mesenchymal stem cell (iMSC) platform

-- NC-iMSCs demonstrate higher potency, uniformity and consistency - significant advantages over donor derived MSCs

CRANFORD, N.J., Oct. 7, 2020 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius" or the "Company") (Nasdaq: CTXR), a specialty pharmaceutical company developing and commercializing critical care drug products, announced that it has signed an exclusive agreement with Novellus Therapeutics Limited ("Novellus") to license iPSC-derived mesenchymal stem cells (iMSCs), and has created a new subsidiary, NoveCite, that will be focused on developing cellular therapies.

NoveCite has a worldwide exclusive license from Novellus, an engineered cellular medicines company, to develop and commercialize NoveCite mesenchymal stem cells ("NC-*i*MSCs") to treat acute respiratory conditions with a near term focus on Acute Respiratory Distress Syndrome ("ARDS") associated with COVID-19. Several cell therapy companies using donor-derived MSC therapies in treating ARDS have demonstrated that MSCs reduce inflammation, enhance clearance of pathogens and stimulate tissue repair in the lungs. Almost all these positive results are from early clinical trials or under the emergency authorization program.

NC-*i*MSCs are the next generation mesenchymal stem cell therapy. They are believed to be differentiated and superior to donor-derived MSCs. Human donor-derived MSCs are sourced from human bone marrow, adipose tissue, placenta, umbilical tissue, etc. and have

significant challenges (e.g., variable donor and tissue sources, limited supply, low potency, inefficient and expensive manufacturing). iMSCs overcome these challenges because they:

- Are more potent and secrete exponentially higher levels of immunomodulatory proteins;
- Have practically unlimited supply for high doses and repeat doses;
- Are from a single donor and clonal so they are economically produced at scale with consistent quality and potency, as well as being footprint free (compared to viral reprogramming methods); and,
- Have significantly higher expansion capability.

Globally, there are 3 million cases of ARDS every year out of which approximately 200,000 cases are in the United States. The COVID-19 pandemic has added significantly to the number of ARDS cases. Once the COVID patients advance to ARDS, they are put on mechanical ventilators. Death rate among patients on ventilators can be as high as 50% depending on associated co-morbidities. There are no approved treatments for ARDS, and the current standard of care only attempts to provide symptomatic relief.

"NoveCite iMSCs have the potential to be a breakthrough in the field of cellular therapy for acute respiratory conditions because of the high potency seen in Novellus' pre-clinical studies, and because iMSCs are iPSC-derived, and therefore overcome the manufacturing challenges associated with donor derived cells," said Myron Holubiak, Chief Executive Officer of Citius.

"We are excited to be part of this effort because of the promise to save lives and reduce long term sequelae in patients with devastating respiratory diseases such as ARDS caused by COVID-19," said Dr. Matthew Angel, Chief Science Officer of Novellus. "Our iMSC technology has multimodal immunomodulatory mechanisms of action that make it potentially promising therapy to treat acute respiratory diseases."

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 Novellus, Therapeutics, Limited

Novellus is a pre-clinical stage biotechnology company developing engineered cellular medicines using its patented non-immunogenic mRNA high specificity gene editing, mutation-free & footprint-free cell reprogramming and serum insensitive mRNA lipid delivery technologies. Novellus is privately held and is headquartered in Cambridge, MA. For more information, please visit www.novellus-inc.com.

About NoveCite iMSC (NC-iMSC)

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-iMSCs 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, NC-iMSCs exhibit superior potency and high cell viability. NC-iMSCs secrete immunomodulatory proteins that may reduce or prevent pulmonary symptoms associated with acute respiratory distress syndrome (ARDS) in patients with COVID-19. NC-iMSC 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 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; the estimated markets for our product candidates, including those for ARDS, and the acceptance thereof by any market; 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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