April 1, 2020

Citius Signs Exclusive Option with Novellus to License Novel Stem-Cell Therapy for Acute Respiratory Distress Syndrome (ARDS) Associated with COVID-19

- Novellus's patented mRNA-based cell-reprogramming technology creates unique mesenchymal stem cells (MSCs) with superior immunomodulatory properties and manufacturing advantages over primary adult donor-derived MSCs - much greater supply and faster scale-up

- MSCs prevent and suppress cytokine storm believed to be the cause of the severe inflammation of ARDS and now seen in COVID-19 patients

CRANFORD, N.J., April 1, 2020 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius" or the "Company") (Nasdaq: CTXR), a specialty pharmaceutical company focused on developing and commercializing critical care drug products, today signed an exclusive six-month option agreement to in-license a stem-cell therapy for acute respiratory distress syndrome (ARDS) from a subsidiary of Novellus, Inc., a preclinical-stage biotechnology company based in Cambridge, MA.

Novellus's patented process uses its exclusive non-immunogenic synthetic messenger ribonucleic acid (mRNA) molecules to create induced pluripotent stem cells (iPSCs) that, in turn, generate mesenchymal stem cells (MSCs) with superior immunomodulatory properties. MSCs have been shown to be safe in over 900 clinical trials and to be safe and effective in treating a number of inflammatory diseases, including ARDS.

"ARDS is the most common cause of respiratory failure and mortality in COVID-19 patients. Currently, there is no proven treatment for ARDS. Literature supports the use of counter-inflammatory MSCs for ARDS, and papers published in China have shown that at least seven COVID-19 patients with ARDS responded to MSC therapy. Clearly this is an avenue that shows promise and should be pursued as a potential treatment for ARDS. We believe Novellus is at the forefront of creating allogeneic, iPSC-derived MSCs. These cells have the potential to overcome the limitations of MSCs derived from adult donors, which are telomere shortened and introduce variability into the manufacturing process," said Citius Chief Executive Officer Myron Holubiak.

Novellus Chief Science Officer Matt Angel, PhD, stated, "Using our mRNA-based cell-reprogramming technology, Novellus can provide a near-unlimited supply of MSCs for

treating patients with ARDS, including those critically ill from COVID-19. These will be allogeneic ('off-the-shelf') cells that *in vitro* have demonstrated much greater expansion potential and much higher immunomodulatory protein expression than donor-derived MSCs. We are excited to employ our technology to such an urgent medical crisis and believe that our MSCs represent an ideal source of cells to be used in this extremely important development effort."

Holubiak added, "No effective pharmacotherapy for ARDS exists, and ARDS-related morbidity and mortality are high. MSCs have been studied in the treatment of lung injury, and we aim to build upon this work with Novellus's iPSC-derived MSCs to improve the immunomodulatory response in humans. We have assembled a team of experts who are dedicated to advancing this project to an Investigational New Drug (IND) application as quickly as possible."

About ARDS
Acute respiratory distress syndrome (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 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, Inc.
Novellus is a pre-clinical stage biotechnology company developing engineered cellular medicines using its non-immunogenic mRNA, nucleic-acid delivery, gene editing, and cell reprogramming technologies. Novellus is privately held and is headquartered in Cambridge, MA. For more information, please visit www.novellus-inc.com.

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 with Novellus within the option period; 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 associated with conducting trials for our product candidates, including those expected to be required for any

treatment for ARDS and our Phase III trial for Mino-Lok; risks relating to the results of research and development activities; risks associated with developing our product candidates, including any licensed from Novellus, including that preclinical results may not be predictive of clinical results and our ability to file an IND for such candidates; uncertainties relating to preclinical and clinical testing; the early stage of products under development; risks related to our growth strategy; 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 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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