

May 13, 2020



## **Citius Announces Data on NoveCite Mesenchymal Stem Cells (NC-MSCs) to be Presented at the American Society of Gene and Cell Therapy (ASGCT) Annual Meeting**

- Induced pluripotent stem cell (iPSC)-derived MSCs demonstrate higher-level secretion of anti-inflammatory proteins and greater expansion potential than conventional, donor-derived MSCs**
- Data include comparative therapeutic benefit in an experimental autoimmune encephalomyelitis (EAE) mouse model**

CRANFORD, N.J., May 13, 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 announced that data on NoveCite MSCs will be presented this week at the American Society of Gene and Cell therapy (ASGCT) annual meeting. NC-MSCs are made by Novellus, Inc. ("Novellus"), a Cambridge-based biotechnology company, using its patented mRNA-based cell-reprogramming process. Earlier this year, Citius signed an exclusive option agreement to in-license NC-MSCs for acute respiratory distress syndrome (ARDS), including in COVID-19 patients, from Novellus.

The data to be presented show that NC-MSCs secrete higher levels of anti-inflammatory proteins compared to MSCs derived from bone marrow. From the abstract: "Comparative secretome analysis showed overexpression of multiple neuroprotective and anti-inflammatory factors, including CXCL1, VEGF-A, and CXCL5." In addition, NC-MSCs showed therapeutic benefit in an experimental autoimmune encephalomyelitis (EAE) mouse model, delaying disease progression and improving the clinical score compared to the control group, while bone marrow-derived MSCs showed no difference from the control.

"We are pleased to present these data at the annual meeting of the ASGCT," said Matt Angel, PhD, co-founder and Chief Science Officer at Novellus. "While conventional MSCs have shown promise in the treatment of inflammatory lung disease, protein secretion and manufacturability remain challenges for these approaches. The data that will be presented this week show that iPSC-derived MSCs secrete higher levels of anti-inflammatory proteins, and exhibit greater expansion potential than bone marrow-derived MSCs. We believe that these properties make iPSC-derived MSCs especially well-suited for an allogeneic cell therapy for ARDS."

"Last month Citius signed an exclusive option agreement with Novellus for worldwide development and commercial rights related to the use of these uniquely derived MSCs for

the treatment of ARDS. The pre-clinical data that is being presented at the ASGCT annual meeting adds to our confidence in the higher potency of these MSCs, which we expect will result in better outcomes for patients with COVID-19 and ARDS," stated Myron Holubiak, CEO of Citius Pharmaceuticals. "We intend to study these cells in the clinic later this year to determine safety, efficacy, and the optimal dose of these cells in moderate to severe ARDS patients with COVID-19."

Citius has submitted a pre-IND meeting request and supporting briefing documents to the Center for Biologics Evaluation and Research ("CBER") of the FDA under the Coronavirus Treatment Acceleration Program (CTAP) for use of these MSCs for patients with Acute Respiratory Distress Syndrome (ARDS) due to SARS-CoV-2 disease.

**Presentation Information:**

**Title:** Mesenchymal Stem Cells (MSCs) Generated Using mRNA Reprogramming Show Enhanced Growth Potential, Secretome, and Therapeutic Efficacy in a Demyelinating Disease Model

**Presenter:** Harris, Jasmine, Novellus, Inc.

**Date and Time:** Wednesday, May 13 | 5:30 PM - 6:30 PM

**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 will benefit from an unusually faster track at the FDA to shorten wait times at multiple steps of the process.

**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](http://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](http://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 ability to access the FDA's CTAP program for the MARCO trial; 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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