May 18, 2021

# Citius Pharmaceuticals to Feature Updated Positive Interim Results of i-MSC Study During Poster Presentation at International Society for Cell and Gene Therapy

## Poster to highlight positive safety and efficacy signals demonstrated in ongoing proof-of-concept large animal study evaluating i-MSC stem cell therapy in acute lung injury

CRANFORD, N.J., May 18, 2021 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius" or the "Company") (Nasdaq: CTXR), a biopharmaceutical company dedicated to the development and commercialization of first-in-class critical care products with a focus on anti-infective products in adjunct cancer care, unique prescription products and stem cell therapy, today announced that it will present a poster at the International Society for Cell and Gene Therapy (ISCT) Annual Meeting, to be held virtually May 26-28, 2021.

Dr. Perenlei Enkhbaatar, Professor and Director of the Translational Intensive Care Unit at The University of Texas Medical Branch, will present a poster describing interim results of a proof-of-concept study evaluating the efficacy and safety of novel induced pluripotent stem cell-derived mesenchymal stem cells (i-MSCs) in a clinically relevant conscious ovine model of acute lung injury.

Posters will be available starting on May 25, 2021, a pre-conference day dedicated to poster presentations.

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| **Abstract Title:** | "Novel Induced-Mesenchymal Stem Cells (i-MSCs) Attenuate Severity of ARDS in Septic Sheep" |
| **Authors:** | K. Hashimoto, N. Bazhanov, P. Enkhbaatar, M. Angel, A. Lader, M. Czuczman, and M. Matthay |
| **Abstract Number:** | 100 |
| **Date and Time:** | May 25, 2021 |
| **Session I** | 12:30 – 2:00 PM EDT |
| **Session II** | 8:00 – 9:30 PM EDT |

"We are encouraged by the positive safety and efficacy signals of i-MSCs, as outlined in the reported interim results of our sheep study. Acute respiratory distress syndrome (ARDS) is a serious and life-threatening condition for which there are no FDA-approved therapies. In future studies, our goal is to increase the sample size and investigate mechanistic pathways. These findings should provide important information in the development of a planned future human clinical trial in ARDS patients. We believe in the potential of our i-MSCs to offer a meaningful option for those suffering from ARDS," stated Dr. Czuczman, Chief Medical Officer and Executive Vice President of Citius Pharmaceuticals, Inc.

The poster will be available to conference attendees via theconference website. The poster will be available on Citius' website once the event commences.

**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.

**About Citius Pharmaceuticals, Inc.**

Citius is a late-stage biopharmaceutical company dedicated to the development and commercialization of first-in-class critical care products, with a focus on anti-infectives in adjunct cancer care, unique prescription products, and stem cell therapy. The Company's lead product candidate, Mino-Lok®, an antibiotic lock solution for the treatment of patients with catheter-related bloodstream infections (CRBSIs), is currently enrolling patients in a Phase 3 pivotal superiority trial. Mino-Lok® was granted Fast Track designation by the U.S. Food and Drug Administration (FDA). Through its subsidiary, NoveCite, Inc., Citius is developing a novel proprietary mesenchymal stem cell treatment derived from induced pluripotent stem cells (iPSCs) for acute respiratory conditions, with a near-term focus on Acute Respiratory Distress Syndrome (ARDS) associated with COVID-19. For more information, please visit www.citiuspharma.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," "plan," "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: risks relating to the results of research and development activities, including those for our NoveCite stem cell therapy; uncertainties relating to preclinical and clinical testing; the early stage of products under development; our dependence on third-party suppliers; our ability to successfully undertake and complete clinical trials and the results from those trials for our product candidates; the estimated markets for our product candidates and the acceptance thereof by any market; the ability of our product candidates to impact the quality of life of our target patient populations; our need for substantial additional funds; market and other conditions; risks related to our growth strategy; patent and intellectual property matters; our ability to attract, integrate, and retain key personnel; 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 procure cGMP commercial-scale supply; government regulation; competition;

as well as other risks described in our SEC filings. These risks have been and may be further impacted by Covid-19. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements. Risks regarding our business are described in detail in our Securities and Exchange Commission ("SEC") filings which are available on the SEC's website at www.sec.gov, including in our Annual Report on Form 10-K for the year ended September 30, 2020, filed with the SEC on December 16, 2020 and updated by our subsequent filings with the SEC. These forward-looking statements speak only as of the date hereof, and 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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