

May 25, 2021



# Citius Pharmaceuticals Selected to Receive Best Poster Award at the International Society for Cell and Gene Therapy 2021 Annual Meeting

**Poster highlighting proof-of-concept study of Citius' iPSC-derived stem cell therapy in acute lung injury chosen for Best Poster Award at ISCT 2021 from among 336 posters selected from 400 abstracts submitted**

CRANFORD, N.J., May 25, 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 has received the Best Poster Award at the prestigious International Society for Cell and Gene Therapy (ISCT) 2021 Annual Meeting.

The poster, titled "Novel Induced-Mesenchymal Stem Cells (*i*-MSCs) Attenuate Severity of ARDS in Septic Sheep," will be presented today, May 25, 2021 by Dr. Perenlei Enkhbaatar, Professor and Director of the Translational Intensive Care Unit at The University of Texas Medical Branch.

"The ISCT annual meeting brings together the brightest minds in cell and gene therapy and highlights cutting edge research in the field," stated Dr. Myron Czuczman, Chief Medical Officer and Executive Vice President of Citius. "We are honored to be selected for the Best Poster Award from among this distinguished peer group. The interim results demonstrate a marked improvement in *i*-MSC treated animals over control animals in key clinical parameters including: improved oxygenation, less systemic shock, and reduced bacterial burden and vascular injury to the lungs. We are encouraged by the data and welcome the support and engagement of the scientific research community," concluded Dr. Czuczman.

Myron Holubiak, President and Chief Executive Officer of Citius added, "We are grateful to be recognized by our peers for this award as we advance our novel stem cell program for the treatment of ARDS. In parallel to the expansion of our proof-of-concept ARDS sheep study, we are following guidance from the U.S. Food and Drug Administration (FDA) in the development of a cGMP Master Cell Bank of *i*-MSCs. I am pleased to report that we have completed the development of an *i*-MSC Accession Cell Bank (ACB) which is to serve as the basis for a scalable cGMP compliant manufacturing capability to support all of our planned pre-clinical and clinical trials. Compared with donor-derived cells that require a continuous supply of new donors, we believe our *i*-MSCs, derived from a single clonal induced pluripotent stem cell (iPSC), offer multiple advantages including consistent and scalable manufacturing and a potentially limitless supply of *i*-MSCs to meet our future needs. Moreover, we believe that our *i*-MSC stem cell program has the potential to meaningfully

impact the treatment of ARDS and we appreciate the recognition received from the cell and gene therapy community as we advance our program."

Citius' *i*-MSCs are derived from iPSCs originating from a qualified single-donor dermal fibroblast, resulting in one homogeneous, validated source for all future cells. A patented synthetic, non-immunogenic mRNA high efficiency cell reprogramming technique is applied to create a clonal iPSC Master Cell Bank from which our *i*-MSCs are differentiated and expanded to create an *i*-MSC Accession Cell Bank. Citius has completed the development of its *i*-MSC ACB and is currently testing (as per FDA guidance) and expanding the cells to create an allogeneic cGMP *i*-MSC Master Cell Bank to support all future *i*-MSC needs.

The poster will be available to conference attendees via the [conference website](#). The poster will be available on [Citius' website](#) once the event commences.

### Conference Details:

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

### 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<sup>®</sup>, 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<sup>®</sup> 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](http://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](http://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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[selected-to-receive-best-poster-award-at-the-international-society-for-cell-and-gene-therapy-2021-annual-meeting-301299189.html](https://www.fda.gov/oc/ohrt/selected-to-receive-best-poster-award-at-the-international-society-for-cell-and-gene-therapy-2021-annual-meeting-301299189.html)

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