July 7, 2021

Citius Pharmaceuticals, Inc. Provides First Half 2021 Business Update, Highlights Upcoming Milestones

- Phase 3 Mino-Lok® trial proceeding as planned following recommendation by independent Data Monitoring Committee (DMC), highlighting important safety and efficacy signals -

- Mino-Lok® New Drug Application (NDA) submission planned for 2022 following anticipated completion of Phase 3 trial by the end of 2021 or early 2022 -

- Citius financial flexibility expanded with $127.6 million in financing activities during the first half of 2021, including $16.9 million in cash proceeds from warrants exercised during the quarter ended June 30, 2021 -

CRANFORD, N.J., July 7, 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 provided a business update for the six-month period ended June 30, 2021 and reported on recent corporate developments.

Recent Highlights and Upcoming Milestones

- On July 1, 2021, Citius reported that the independent DMC recommended continuation of the Phase 3 Mino-Lok® pivotal superiority trial as planned with no modifications or safety concerns,
- Citius expects to complete the Mino-Lok® trial by the end of 2021 or early 2022, subject to continued easing of COVID-19 restrictions in the U.S.,
- Citius plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in 2022 following completion of its Phase 3 Mino-Lok® trial, and
- Subsequent to March 31, 2021, Citius issued 11.2 million shares of Citius common stock upon the exercise of warrants, for aggregate proceeds of $16.9 million during the quarter and a total of $127.6 million in financing activities during the first half of 2021.

"On July 1, 2021, we reported that the independent Data Monitoring Committee (DMC), following its third interim review, recommended continuing the Phase 3 trial for Mino-Lok® without modification. This recommendation affirms that there is an important efficacy signal that merits moving forward with the trial, there are no safety concerns to warrant halting the

trial, and that the full data set upon trial completion may support statistically significant superiority. Whether Mino-Lok® demonstrates statistical superiority will only be known to us once the trial is finished and the data is unblinded. We view the recommendation of the DMC as a strong positive signal, and remain fully committed to completing the trial in a timely manner," stated Myron Holubiak, President and Chief Executive Officer of Citius.

"Mino-Lok® trial patients represent an extremely ill population, which is challenging to enroll under the best of circumstances. Like many clinical trials conducted during the pandemic, the timeline for our study has been impacted by COVID-19. It has taken longer than anticipated to enroll patients due to restrictions established at our trial sites during the height of the pandemic. These restrictions, in place for close to half of the duration of our trial, reflect a series of challenges including: site closures, limited site and patient access, reallocation of resources away from clinical trials to COVID-patient treatment, modifications to catheter infection treatment protocols, and lengthy approval time to qualify new study sites, resulting in fewer monthly patient screenings compared to pre-pandemic levels. The ability of sites to ramp back up for the Mino-Lok® trial depends largely on how these varied and complex factors are addressed. Several institutions have resumed our trial, and provided that COVID restrictions continue to ease and are not reinstated, we believe it would be possible for our trial sites to complete enrollment in the Mino-Lok® study as early as the end of the year. That would put us on target to submit an NDA in 2022," added Mr. Holubiak.

"We intend to aggressively pursue all options to expedite completion of the Mino-Lok® trial. During the first half of 2021, we raised more than $127 million, of which approximately $17 million was from warrants exercised since March 31, 2021. We intend to leverage these resources to accelerate our outreach efforts to advance the trial. Moreover, we believe we are well capitalized to advance Mino-Lok® beyond trial completion, and will engage closely with the FDA in the coming months to do so. Concurrently, we are actively advancing three additional first-and-only or novel pipeline products as outlined in our updated corporate presentation published on our website this morning. With a late-stage product candidate moving toward completion of its Phase 3 trial, depth in our pipeline, and the financial resources to execute our near-term strategy, we believe Citius is better positioned than ever before to deliver long-term value to shareholders," concluded Mr. Holubiak.

About Mino-Lok®

Citius is developing Mino-Lok®, an antibiotic lock solution to treat patients with catheter-related blood stream infections that was licensed from The University of Texas MD Anderson Cancer Center. Citius believes Mino-Lok® provides a superior alternative to removing and replacing a central venous catheter (CVC), leading to a reduction in serious adverse events and cost savings to the healthcare system. If approved, Mino-Lok® would be the first-and-only FDA-approved treatment that salvages central venous catheters that cause central line-related blood stream infections.

The Mino-Lok® Phase 3 pivotal superiority trial is a multi-center, randomized, open-label, blinded study to determine the efficacy and safety of Mino-Lok® (MLT), a novel antibiotic lock therapy that combines minocycline with edetate disodium. The primary endpoint for this study is the time (in days following randomization) to a catheter failure event between randomization and TOC (Week 6) in the Intent-to-Treat (ITT) Population.

Approximately 144 subjects diagnosed with CRBSI/CLABSI and who meet all necessary criteria for the study are to be randomized in a 1:1 ratio to receive either Mino-Lok® therapy or standard of care antibiotic lock therapy.

Subjects in the Mino-Lok® arm receive one MLT dose daily with a dwell time of two to four hours for a total of seven doses. For subjects in the Control arm, the investigator determines the antibiotic used in the lock, dose, dwell time, and number of days of administration based on institutional standards or Infectious Diseases Society of America (IDSA) guidelines.

Three planned interim analyses were performed as defined by the study protocol. The primary role of the independent DMC, defined in the DMC charter, is to safeguard the interests of study participants, assess the safety of the treatment, and monitor the overall conduct of the study. In order to ensure the protection of patients enrolled in the trial and to assure the timely and efficient completion of the study, each DMC recommendation is bound by strict parameters outlined in the DMC charter. A recommendation to continue the trial as planned indicates that the data reviewed by the DMC, at this juncture, is within the statistical boundaries determined by Citius in order to complete the trial with the protocol-defined sample size and power to achieve the primary endpoint.

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: our ability to successfully undertake and complete clinical trials and the results from those trials for our product candidates, including Mino-Lok®; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; the early stage of products under development; 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 obtain, perform under and maintain financing and strategic agreements and relationships; our dependence on third-party suppliers; 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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