June 8, 2021

Citius Pharmaceuticals Achieves Next Interim Analysis Milestone in its Mino-Lok® Phase 3 Trial

- Independent Data Monitoring Committee (DMC) to review Mino-Lok® safety, superiority, and futility data at upcoming meeting scheduled for June 29, 2021-

CRANFORD, N.J., June 8, 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 the next planned interim analysis in its Phase 3 trial of Mino-Lok®, an antibiotic lock solution for the treatment of patients with catheter-related blood stream infections (CRBSIs/CLABSIs) has been scheduled for the end of June 2021. In accordance with the independent Data Monitoring Committee (DMC) charter, the DMC will hold a meeting to review the trial data for safety, superiority and futility.

"We look forward to feedback from the DMC following their review of the trial data," stated Myron Holubiak, President and Chief Executive Officer of Citius.

According to the Mino-Lok® Phase 3 study protocol, the DMC is responsible for conducting interim analyses when 40%, 50% and 65% of the total number of anticipated events have been observed. The first two interim analyses were conducted by the DMC in 2019 and 2020, respectively. The next interim analysis meeting of the DMC will be held on June 29, 2021. At that time, the DMC will review unblinded study data and subsequently provide written recommendations to Citius within five business days.

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 randomized in a 1:1 ratio to receive either Mino-Lok® therapy or standard of care antibiotic lock therapy. To date, the Company has achieved more than 80% of the expected enrollment.

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.

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. A multicenter Phase 3 pivotal superiority trial is currently underway. 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.

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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