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Citius Announces Positive Outcome of Interim Futility Analysis for its Phase 3 Mino-Lok® Pivotal Trial

- Data Monitoring Committee recommends continuation of the trial with no changes

CRANFORD, N.J., Dec. 19, 2019 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius" or the "Company") (NASDAQ: CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical care drug products, today announced a positive outcome of the pre-specified interim futility analysis for the Phase 3 clinical trial of Mino-Lok® vs. standard-of-care antibiotic locks. The analysis was conducted by the Mino-Lok trial Data Monitoring Committee ("DMC"), an independent panel of experts charged with periodically monitoring the safety and efficacy of the progress of the pivotal trial. The Company reached and completed the prespecified 40% enrollment required for the interim futility analysis in late September and, based on the analysis of the data and recommendations of the DMC, will proceed with the current trial as planned. Topline data from the superior efficacy interim analysis, the next major milestone in the Mino-Lok trial, is expected in the first half of 2020. The market potential for an effective antibiotic lock therapy is estimated at $750 million per year in the U.S. and approximately $1.5 billion per year worldwide.

"We are extremely happy and proud that the first independent expert review of the patient data in our Mino-Lok trial concludes that our study is on track. Enrollment has continued since finalizing the 40% level futility report, and we have now reached the midpoint of our study. The DMC will evaluate clinical data at the 75% level of enrollment to see if Mino-Lok demonstrates superior efficacy versus standard-of-care antibiotic locks," said Myron Holubiak, the Chief Executive Officer of Citius. "We would also like to thank all of the patients, study investigators, and support personnel at the 32 clinical sites that are participating in our trial. Lastly, we also want to acknowledge the research and guidance of Dr. Issam Raad and his team at MD Anderson Cancer Center in advancing this novel therapy."

About Citius Pharmaceuticals, Inc.
Citius is a specialty pharmaceutical company dedicated to the development and commercialization of critical care products, with a focus on anti-infectives, cancer care and unique prescription products that use innovative, patented or proprietary formulations of previously-approved active pharmaceutical ingredients. We seek to achieve leading market positions by providing therapeutic products that address unmet medical needs; by using previously approved drugs with substantial safety and efficacy data, we seek to reduce the risks associated with pharmaceutical product development and regulatory requirements. Citius develops products that have intellectual property protection and competitive advantages to existing therapeutic approaches. For more information, please visit www.citiuspharma.com.

About MD Anderson Cancer Center
The University of Texas MD Anderson Cancer Center in Houston ranks as one of the world's most respected facilities for cancer patient care, research, education and prevention. The institution's sole mission is to end cancer for patients and their families around the world. MD Anderson is one of only 45 comprehensive cancer centers designated by the National Cancer Institute (NCI) and is ranked No.1 for cancer care in U.S. News & World Report's most recent "Best Hospital's" survey. The center has ranked as one of the nation's top two hospitals since the survey began in 1990, and has ranked first for 11 of the past 14 years. MD Anderson receives a cancer center support grant from the NCI of the National Institutes of Health (P30 CA016672).

About Mino-Lok®
Mino-Lok® is an antibiotic lock solution being developed as an adjunctive therapy in patients with central line-associated bloodstream infections (CLABSIs) or catheter-related bloodstream infections (CRBSIs). CLABSIs/CRBSIs are very serious, especially in cancer patients receiving therapy through central venous catheters (CVCs) and in hemodialysis patients where venous access presents a challenge. There are currently no approved therapies to salvage infected CVCs.

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: risks associated with conducting our Phase 3 trial for Mino-Lok, including completing patient enrollment; our need for substantial additional funds; the estimated markets for our product candidates and the acceptance thereof by any market; risks relating to the results of research and development activities; risks associated with developing Mino-Wrap, including that preclinical results may not be predictive of clinical results and our ability to file an IND; 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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