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Citius Receives Positive FDA Feedback on Its Submitted Plan to Study Catheter Compatibility for Mino-Lok® Therapy

- Compatibility plan includes testing representative samples of all commercially available CVCs and PICCs

- Plan is designed to be conducted in parallel with the completion of the Phase 3 pivotal trial

- Targeted worldwide market for Mino-Lok® is expected to reach $1.84 billion by 2028

CRANFORD, N.J., June 2, 2020 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius" or the "Company") (Nasdaq: CTXR), a specialty pharmaceutical company focused on developing and commercializing critical care drug products, today announced that it has received positive feedback from the Food and Drug Administration (FDA) on its proposed catheter compatibility studies for the Company's Mino-Lok® therapy. The studies, if and when successfully completed, should allow Mino-Lok to be labeled for use with all commercially available central venous catheters (CVCs) and peripherally inserted central catheters (PICCs) on the U.S. market. It is further assumed that these studies will meet European and world standards.

The ability to be labeled without restrictions with respect to catheter type would allow Mino-Lok unrestricted access to the full U.S. and world markets for an effective antibiotic lock therapy for central line-associated bloodstream infections (CLABSIs), which are estimated to be over $1.5 billion per year worldwide. The catheter compatibility studies will be conducted in parallel with the completion of the ongoing Phase 3 clinical study. The Company announced in early February 2020 that this pivotal trial had reached the halfway point for enrollment. The next milestone in the trial is the result of an interim efficacy analysis, which is expected to occur in the second half of 2020.

"We believe we continue to check all the boxes required for an NDA submission," commented Myron Holubiak, Chief Executive Officer of Citius. "According to our planned dosing recommendations, the Mino-Lok solution dwells in the catheter for two hours per day for 5 to 7 days. This would be between 10 to 14 hours of aggregate, but intermittent, exposure time of the catheter to Mino-Lok. We believe that this exposure is far lower than what is recommended for home-brewed antibiotic lock solutions, which should lead to less intrusive therapy and fewer days on therapy for patients."

"The shorter dwell time for Mino-Lok also means that the catheter is available for its intended purpose, allowing treatment for the underlying disease to continue. Additionally, and more

importantly, our pivotal trial is designed to show the superiority of Mino-Lok to standard antibiotic locks in time-to-catheter-failure. If all these studies prove to be successful, we believe ready-to-use Mino-Lok will be superior to home-brewed antibiotic locks in both efficacy and dosing schedules," Mr. Holubiak concluded.

Mino-Lok is an antibiotic lock solution used to treat patients with CLABSIs and catheter-related bloodstream infections (CRBSIs) in combination with an appropriate systemic antibiotic(s) to preserve central venous access and to avoid the complications and morbidities associated with catheter removal and reinsertion procedures. It has the potential to change the standard of care, which currently calls for a procedure to remove and replace the infected catheter. Each year, up to 500,000 CVCs of the 7 million used become infected and lead to CLABSIs, increasing both patient morbidity risk and costs to the medical system. It has been shown that antibiotics alone are unable to penetrate the biofilm caused by bacteria, and there are currently no approved therapies for salvaging infected central venous catheters. According to DelveInsight, the market size of CLABSIs and closely associated CRBSIs in the global market is expected to reach $1.84 billion in 2028, up from $1.24 billion in 2017.

About Citius Pharmaceuticals, Inc.
Citius is a late-stage specialty pharmaceutical company dedicated to the development and commercialization of critical care products, with a focus on anti-infectives and cancer care. For more information, please visit www.citiuspharma.com.

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, for whom venous access presents a challenge. There are currently no approved therapies for salvaging 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 of FDA acceptance of our compatibility studies and, if so, the successful completion of and results from the studies; our need for substantial additional funds; the estimated markets for our product candidates, and the acceptance thereof by any market; risks associated with conducting trials for our product candidates, including our Phase III trial for Mino-Lok; risks relating to the results of research and development activities; risks associated with developing our product candidates, including that preclinical results may not be predictive of clinical results and our ability to file an IND for such candidates; 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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