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Citius Provides Clinical Update And Progress Of The Mino-Lok® Phase 3 Trial

PIVOTAL TRIAL ASSESSES THE EFFECTIVENESS AND SAFETY OF MINO-LOK IN THE TREATMENT OF INDIVIDUALS WITH CATHETER RELATED BLOOD STREAM INFECTIONS (CRBSIs)

CRANFORD, N.J., July 9, 2018 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius") ("Company") (NASDAQ: CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical care drug products, provided a status report on the progress of the Mino-Lok Phase 3 clinical program. The Mino-Lok Phase 3 Trial is planned to enroll 700 patients in 50 participating institutions, all located in the U.S. There will be interim analyses at the 50% and 75% point of the trial as measured by the number of patients treated.

Citius reports that as of this past week there are 12 active sites currently enrolling patients including such academic centers as MD Anderson Cancer Center, Henry Ford Health Center, Georgetown University Medical Center, University of Chicago, and others. There are 13 additional well renowned medical centers in startup mode. When these study centers are activated, site recruitment will have reached 50% of the target institutions planned; and, there are another 13 centers in feasibility stage.

"We have pre-screened over 328 patients with CRBSIs in a short period of time demonstrating that these infections continue to be highly prevalent and present a significant unmet need. Although our patient recruitment is slower than initially planned, we have adjusted the inclusion/exclusion criteria to be able to enroll patients at a greater rate. In addition we have deployed experienced clinical research associates to ensure that medical staff in the participating institutions are aware of this study that could benefit their patients and shed light on alternatives to removing and replacing infected central lines in very sick patients. We expect to have all 50 sites activated in this quarter (Q3 2018)," said Myron Holubiak, President and CEO of Citius. "This will be the largest and most definitive study of its kind conducted to date. Because of the unique properties of Mino-Lok, we believe we will be able to show that Mino-Lok therapy, used in a very manageable dosing regimen, namely two hours of lock time for 5 to 7 days, is superior to any other antibiotic locks that require substantially more dwell time and have not been thoroughly studied. Mino-Lok would be the first approved antibiotic lock for the treatment of CRBSIs. The Company thanks all of its advisors and partners for their help in bringing Mino-Lok to the clinic."

Catheter Related Bloodstream Infections ("CRBSIs") are some of the most difficult infections to treat, and, are a leading cause of healthcare-associated infections (HAIs) with substantial morbidity and mortality. Patients with CRBSI may be at risk for serious complications, including septic thrombosis, endocarditis, and disseminated infection. Many of these patients need to have their central venous catheters removed and subsequently replaced, causing added costs, morbidities and discomfort. Removal and reinsertion of a new CVC may be difficult or even impossible due to the unavailability of other accessible vascular sites.

Furthermore, critically ill patients often have underlying coagulopathy, which may increase the risk of mechanical complications (e.g., hemopneumothorax, misplacement, or arterial puncture with severe hematomas and attendant blood loss) with the reinsertion of a new catheter at a different site.

About the Mino-Lok Trial

The Mino-Lok trial is a Phase 3, Multi-Center, Randomized, Open-Label, Assessor-Blind Study to Evaluate the Efficacy and Safety of Mino-Lok Therapy (MLT) in Combination with Systemic Antibiotics in the Treatment of Catheter-Related Bloodstream Infections.

Subjects with documented CRBSI for whom catheter retention is reasonable or required due to lack of alternative venous access will be included.

The primary endpoint for this study is the proportion of subjects who have Overall Success at the test of cure at week 8.

Overall Success is defined as a subject who does NOT demonstrate ANY of the following:

- All-cause mortality at Week 8;
- Catheter removal for any infection-related reason or inability to administer study drug;
- Worsening of systemic signs and symptoms of infection that result in discontinuation of lock therapy;
- Demonstration that the baseline pathogen is not eradicated from the blood at 48 hours following randomization despite 48 hours of antibiotic therapy to which the infecting organism is susceptible;
- Demonstration that the baseline pathogen has recurred by Week 8 of the study; or,
- Demonstration that the baseline pathogen is part of a newly diagnosed deep-seated infection by Week 8 of the study.

Mino-Lok® is under investigation and not approved for commercial use.

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.

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 and opening study sites; the estimated markets for our product candidates and the acceptance thereof by any market; risks related to our growth strategy; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; the early stage of products under development; 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 dependence on third-party suppliers; our ability to attract, integrate, and retain key personnel; our need for substantial additional funds; 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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