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# Citius Announces Enrollment Of First Patient In The Mino-Lok™ Phase 3 Trial

## **PIVOTAL TRIAL TO ASSESS EFFECTIVENESS AND SAFETY OF MINO-LOK™ IN THE TREATMENT OF INDIVIDUALS WITH CATHETER RELATED BLOOD STREAM INFECTIONS**

CRANFORD, N.J., Feb. 15, 2018 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius") ("Company") (NASDAQ: CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical care drug products, announced that yesterday the first patient was randomized into the Mino-Lok Phase 3 clinical trial for catheter related bacteremias ("CRBSIs") at the Henry Ford Health System in Detroit, Michigan. When fully-recruited, it is planned that there will be 700 patients enrolled in 50 participating institutions, throughout the U.S.

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 ("CVCs") 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, such as hemopneumothorax, misplacement, or arterial puncture, with the reinsertion of a new CVC at different site.

"We are pleased to enroll the first patient in the Mino-Lok™ phase 3 trial, which is designed to further our understanding of the efficacy of antibiotic lock solutions in salvaging infected catheters in the treatment of this serious infection," stated Mr. Myron Holubiak, President and CEO of Citius. "We believe we are at the forefront of providing much needed evidence that antibiotic lock therapy is an attractive alternative to removing and replacing infected central lines. This will be the largest and most definitive study of its kind conducted to date.

### **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 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.

Mr. Holubiak continued, "Because of the unique properties of Mino-Lok, we believe we will be able to show that our proprietary 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, especially M.D. Anderson Cancer Center, for their help in bringing Mino-Lok to this juncture."

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 aims to develop products that have intellectual property protection and competitive advantages to existing therapeutic approaches. For more information, please visit [www.citiuspharma.com](http://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 the Henry Ford Health System**

Henry Ford Health System is committed to improving the health and well-being of a diverse Michigan community. Founded in 1915 by auto pioneer Henry Ford and now one of the nation's leading health care providers, Henry Ford Health System is a not-for-profit

corporation governed by a 17-member Board of Trustees, with volunteer-led advisory and affiliate boards providing additional leadership. It is comprised of hospitals, medical centers and one of the nation's largest group practices, the Henry Ford Medical Group, which includes more than 1,200 physicians practicing in over 40 specialties. The System's flagship, Henry Ford Hospital in Detroit, is a Level 1 Trauma Center recognized for clinical excellence in cardiology, cardiovascular surgery, neurology and neurosurgery, orthopedics, sports medicine, multi-organ transplants and cancer treatment. The Henry Ford Health System provides care to 3.3 million patient visits annually. With more than 30,000 employees, Henry Ford Health System is the fifth-largest employer in metro Detroit, and among the most diverse. Henry Ford Health System was one of only four 2011 recipients of the Malcolm Baldrige National Quality Award and the only organization in Michigan to receive it.

### **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 clinical trials and drug development, including the completion and results of the Mino-Lok trial; 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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