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Citius Announces The Notice Of Allowance From The USPTO On The Advanced Stability Patent Application For Mino-Lok®

MINO-LOK FDA PHASE 3 TESTING IS CURRENTLY UNDERWAY AT OVER A DOZEN LEADING MEDICAL CENTERS IN THE U.S.

CRANFORD, N.J., July 24, 2018 /PRNewswire/ -- Citius Pharmaceuticals Inc. ("Citius") ("Company") (NASDAQ: CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical care drug products, received notice from MD Anderson Cancer Center ("MDACC") that the US Patent and Trademark Office ("USPTO") has reviewed and examined the patent application US 2017/051373 A1 and that it is allowed for issuance as a patent.

The new invention overcomes limitations in mixing antimicrobial solutions in which components have precipitated because of physical and/or chemical factors, thus limiting the stability of the post-mix solutions. The scientists and technologists at MDACC have been able to improve the stability of the post-mixed solutions through adjustments of the post-mixed pH of the solution. This may allow for longer storage time of the ready-to-use solution.

Citius holds the exclusive worldwide license which provides access to this patented technology for development and commercialization of Mino-Lok.

"The stability of the Mino-Lok solution post-mixing was limited to a time period of about 24 hours prior to use," said Myron Holubiak, president and CEO of Citius Pharmaceuticals. "It would be beneficial for product acceptance and make it easier for Mino-Lok preparation if improvement in the post-mix stability could be achieved. This would enable standard pharmacy process to be employed in the delivery of Mino-Lok to the patient and would allow for several days' storage of ready-to-use Mino-Lok. This patent would also strengthen the intellectual property protection through November of 2036."

Mino-Lok is currently being studied in phase 3 in over a dozen medical centers in the United States. There are currently no approved therapies to salvage infected central venous catheters (CVCs).

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 CRBSIs 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.

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.

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 Hospitals" 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).

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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