

May 26, 2020



Citius Announces Expanded Access Program for Investigational Phase 3 Mino-Lok®

-The COVID-19 pandemic has highlighted the need to provide Mino-Lok on a compassionate case basis

-Many patients in hospitals receive medication, chemotherapy and nutrition via central venous catheters that can become infected and may require a removal and replacement procedure

-These catheter replacement procedures are risky for the patients, further tax the healthcare system capacity, and compound the nurse and doctor labor shortage

-The company's Mino-Lok® solution could salvage such infected catheters and eliminate the removal and replacement procedure, thus easing the burden on patients, healthcare professionals and systems

CRANFORD, N.J., May 26, 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 is providing free access to Mino-Lok® for healthcare providers under an Expanded Access protocol to ease the burden associated with the COVID-19 pandemic.

Through the Expanded Access protocol, an infected central venous catheter can now be treated with Citius' Mino-Lok, potentially avoiding the need for the removal and replacement procedure. Given the challenges at today's hospitals, the patients, the hospital staff, and the hospital system at large stand to benefit greatly from free access to the Mino-Lok solution.

"Some of our investigators have told us that if Mino-Lok were approved by the FDA, they would already be using it – particularly in today's environment," commented Myron Holubiak, Chief Executive Officer of Citius. "We clearly must wait for the results of our clinical trial to fully market Mino-Lok, but we do believe that it can benefit patients and help ease the burden on the health care system. In these challenging times, we welcome the opportunity to help in any way we can."

Mino-Lok is an antibiotic lock solution used to treat patients with 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. Mino-Lok is currently in a Phase 3 clinical trial for the

treatment of central line-associated bloodstream infections (CLABSIs). In early February 2020, the Company announced that the trial had reached the halfway point of enrollment.

Mino-Lok 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 catheter-related bloodstream infections (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 providing Mino-Lok under the expanded use program prior to approval for marketing by the FDA; 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.

Contact:

Andrew Scott
Vice President, Corporate Development
(O) 908-967-6677 x105
ascott@citiuspharma.com

🔗 View original content:<http://www.prnewswire.com/news-releases/citius-announces-expanded-access-program-for-investigational-phase-3-mino-lok-301064966.html>

SOURCE Citius Pharmaceuticals, Inc.