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Citius Files Addendum to Mino-Lok Phase 3 Trial Record Keeping Protocol to Advance Trials with COVID-19 Compliance

-Mino-Lok trial continues to progress despite challenges of conducting clinical trials in COVID-stressed sites

-Interim efficacy review with Drug Monitoring Committee planned for end of this month

CRANFORD, N.J., Sept. 15, 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 filed an amendment to its Mino-Lok phase 3 protocol. This amendment was designed to allow for more efficient follow-up and record-keeping of required clinical trial documentation given COVID-19 restrictions. With personal visits having been severely restricted, Citius issued instructions in the form of file notes to sites in April and has now formalized these instructions. The FDA released guidance on conduct of clinical trials of medical products during COVID-19 in March 2020, updated in July 2020.

"In these challenging times we are working closely with our Principle Investigators (PIs) and their staff to keep the enormous amount of record-keeping associated with any clinical trial as simple and accurate as possible," said Myron Holubiak, Chief Executive Officer of Citius. Holubiak continues, "We have been pleased with the responsiveness of our partners and internal team to today's ever-changing situation. Like all other companies, Citius is facing significant challenges in maintaining progress in its clinical trials. We are especially affected since our site-of-care is frequently the ICU, which is the most resource-stressed site in the hospital because of COVID-19. We expect to be able to conduct our Drug Monitoring Committee meeting as planned at the end of the month, and we look forward to our discussions with these independent experts."

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 associated with conducting clinical trials and drug development; patent and intellectual property matters; market and other conditions; our ability to attract, integrate, and retain key personnel; our need for substantial additional funds; the risk of successfully negotiating within the option period a license agreement with Novellus, Inc. for our planned NoveCite therapy for ARDS; risks associated with conducting clinical trials and drug development; 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; government regulation; 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
(M) 646-522-8410
ascott@citiuspharma.com

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