September 29, 2020

Citius Pharmaceuticals Reports Positive Results from Recent Data Monitoring Committee Meeting for Mino-Lok Phase 3 Trial

DMC makes recommendation to continue trial with no modifications and requests an ad hoc meeting in near future

CRANFORD, N.J., Sept. 29, 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 a Data Monitoring Committee (DMC) meeting was held to review the data being generated and analyzed in the Mino-Lok phase 3 trial, and to make recommendations to Citius as to any action that may be necessary regarding the study.

After reviewing these data, the DMC members stated that they did not find any safety signals; and they also recommended continuing the trial without any modifications. The DMC further requested to have an *ad hoc* meeting in the near future.

The Data Monitoring committee is an independent panel of experts that review progress regarding the safety and efficacy of drugs in clinical trials, and to determine if the trial may be futile in achieving its endpoints or if the trial should be modified in any way.

"We are very pleased with the outcome of the DMC's independent review of the Mino-Lok data. This information is very encouraging and supports the confidence that we have long held in the safety and efficacy of Mino-Lok," said Myron Holubiak, Chief Executive Officer of Citius. "Despite challenges in recruiting patients recently due to the COVID-19 pandemic, we have continued to recruit patients and are now approaching the late stage of our pivotal study." Holubiak continued, "I want to thank the DMC committee members for their thoughtful review, and also all of the study investigators and their staff that continue to support our trial in these challenging times."

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 relating to the results of research and development activities; risks associated with conducting clinical trials and drug development; our need for substantial additional funds; our dependence on third-party suppliers; patent and intellectual property matters; market and other conditions; our ability to attract, integrate, and retain key personnel; the risk of successfully negotiating within the option period a license agreement with Novellus, Inc. for our planned NoveCite therapy for ARDS; the estimated markets for our product candidates and the acceptance thereof by any market; risks related to our growth strategy; 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; 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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