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Citius Reaches First Interim Analysis Milestone for Mino-Lok® Pivotal Trial

- Study Reaches 40% Completion Triggering Data Cutoff for Futility Analysis

CRANFORD, N.J., Oct. 7, 2019 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius") ("Company") (NASDAQ: CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical care drug products, today reported that the data cutoff for the most recent patient treated and completing 8 weeks of observation has been reached. The Company is preparing the submission to the independent Drug Monitoring Committee ("DMC") for review and evaluation.

The objective of the Phase III pivotal trial for Mino-Lok is to evaluate the efficacy and safety of Mino-Lok in salvaging colonized central venous catheters in subjects with catheter-related or central line-associated bloodstream infection (CRBSI/CLABSI) compared to the standard of care using antibiotic locks.

The primary endpoint for the trial is the time to a catheter failure event between randomization and the test of cure (TOC).

The Mino-Lok protocol is based on reaching 92 catheter failure events for the trial, which corresponds to approximately 144 patients treated in both arms combined.

There are 2 interim analyses planned:

- Analysis of futility will be assessed upon reaching 37 catheter failure events (40% of the total number of anticipated events at approximately 58 patients); and
- Analysis for superiority will be performed when 69 catheter failure events (75% of the total number of anticipated events at approximately 108 patients).

"We are extremely pleased to have reached this important milestone in the pivotal trial. With the great work performed at such institutions such as MD Anderson Cancer Center, MedStar Georgetown University Hospital, Henry Ford Hospital, Cleveland Clinic, Carolinas Medical Center, and Massachusetts General Hospital, among others, we have been able to progress to our first analysis of the data. There is a huge medical need for a proven antibiotic lock. We are working hard to provide an alternative to submitting a very sick patient to two surgical procedures to remove and possibly replace a tunneled or implanted venous port. We believe that this pivotal trial will be the largest and best controlled clinical trial evaluating catheter salvage in diagnosed CLABSI patients to date. We are doing everything possible to keep the momentum going," said Myron Holubiak, Chief Executive Officer of Citius Pharmaceuticals, Inc.

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 Mino-Lok®

Mino-Lok® is an antibiotic lock solution used to treat patients with CLABSIs/CRBSIs. CLABSIs/CRBSIs are very serious, especially in cancer patients receiving therapy through central venous catheters (CVCs), and in hemodialysis patients where venous access presents a challenge. There are currently no approved therapies to salvage infected central venous catheters (CVCs).

Mino-Lok® is under investigation and not approved for commercial use.

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, opening study sites and achieving the required number of catheter failure events; the estimated markets for our product candidates and the acceptance thereof by any market; our need for substantial additional funds; risks associated with developing Mino-Wrap, including that preclinical results may not be predictive of clinical results and our ability to file an IND; risks related to our growth strategy; our ability to identify, acquire, close and integrate product candidates and companies successfully and on a timely basis; 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 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

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