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Citius Pharmaceuticals Provides Updates on Mino-Lok® and CITI-002

Proprietary Projects Move Towards Commercialization

CRANFORD, N.J., Dec. 19, 2018 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius") (NASDAQ: CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical care drug products, provided a status report today on Mino-Lok® and CITI-002.

Mr. Myron Holubiak, CEO of Citius, said, "While there are significant challenges involved with studying an adjunctive therapy in patients with underlying serious life-threatening diseases, we are extremely pleased with the progress that has been made in the Phase-3 Mino-Lok® clinical trials. Our investigators confirm that there is a great need for an effective solution to salvaging infected central lines in patients with catheter-related blood stream infections (CRBSIs) so that they can have an alternative to removing and replacing these catheters in these very sick and compromised patients. It is important to have evidence from a controlled trial that an antibiotic lock can be as effective as catheter removal, especially in *Staph.* infections. Also, as it relates to CITI-002, our plans to use a more potent corticosteroid have proceeded well; and, we feel we can be ready to conduct the necessary animal toxicity study that is necessary with that type of change, and quickly move into phase 2b trials. Both treatments have shown significant potential in addressing their respective underserved markets. Additionally, Citius has secured patents for Mino-Lok® in both the US and Europe that protect the product throughout the year 2036, and will be pursuing a patent for CITI-002. Management has successfully raised capital to use toward developing both products and, assuming clinical success and sufficient resources, we look forward to advancing into commercialization stage in the near future."

Mino-Lok®

Mino-Lok® is an antibiotic lock solution used to treat patients with catheter-related bloodstream infections (CRBSIs). 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. The Mino-Lok® Phase 3 Trial is planned to enroll 700 patients in 50 participating institutions, all located in the U.S. There will be interim analyses at the 50% and 75% point of the trial as measured by the number of patients treated. Currently, there are 20 active sites enrolling patients including such academic centers as MD Anderson Cancer Center, Henry Ford Health Center, Georgetown University Medical Center, University of Chicago, and others. There are 15 additional well renowned medical centers in startup mode. When these study centers are activated, site recruitment will have reached 70% of the target institutions planned; and, there are another 30 centers in feasibility stage.

Mino-Lok received notice from MD Anderson Cancer Center ("MDACC") that the US Patent

and Trademark Office ("USPTO") issued United States Patent Number 10/086,114 entitled *"Antimicrobial Solutions with Enhanced Stability"* on October 2, 2018. Protection on Mino-Lok extends to November 4, 2036.

There are currently no approved therapies to salvage infected central venous catheters (CVCs).

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

CITI-002: Hemorrhoid Topical Program

The original topical preparation, CITI-001, was a combination of hydrocortisone acetate and lidocaine hydrochloride. The new formulation, CITI-002, will combine lidocaine with the higher potency corticosteroid for symptomatic relief of the pain and discomfort of hemorrhoids. While not used in combination in currently marketed products, the proposed corticosteroid is included as an FDA-approved topical product to treat a variety of dermatological disorders. The changes in the program are as follows:

- Selection of higher potency corticosteroid for the Phase 2b trial to improve efficacy and faster onset of symptomatic relief;
- Target population to include patients with Grade 2 and 3 hemorrhoids;
- One month dog toxicity study planned prior to initiation of clinical trial;
- Possibility of extended intellectual property as compared to hydrocortisone combination; and,
- Program revised as discussed with the FDA.

In March 2018, Citius held a Type C meeting with the FDA to discuss the results of the Phase 2a study and to obtain the Agency's view on development plans to support the potential formulation change for the planned Phase 2b study. Citius also requested the Agency's feedback on the Phase 2b study design, including target patient population, inclusion/exclusion criteria, and efficacy endpoints. The pre-clinical and clinical development programs for CITI-002 are planned to be similar to those conducted for the development of CITI-001 to support the design for a planned Phase 3 clinical trial.

In August 2018, the Company raised $10 million with the intent to use the capital from the raise towards our Phase 3 clinical Mino-Lok trial for the treatment of catheter related bloodstream infections (CRBSIs), and Phase 2b clinical trial of CITI-002 for the symptomatic treatment of hemorrhoids. More than $23 million has now been invested into the Company privately by the founders and insiders since its inception.

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.

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," "plan" 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: patent and intellectual property matters; risks associated with conducting our Phase 3 trial for Mino-Lok, including completing patient enrollment and opening study sites; 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 need for substantial additional funds; the estimated markets for our product candidates and the acceptance thereof by any market; 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 dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; 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.

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