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Citius Pharmaceuticals Achieves Chemical Manufacturing and Control Milestones for Mino-Lok®

- Milestones include manufacturing of 3 registration lots for Mino-Lok

CRANFORD, N.J., Sept. 22, 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 achieved a number of significant milestones over the past several weeks for Mino-Lok®.

Mino-Lok is an antibiotic lock solution being developed as an adjunctive therapy for patients with central line-associated bloodstream infections (CLABSIs) or catheter-related bloodstream infections (CRBSIs). Mino-Lok contains three active drug substances (minocycline, ethanol and EDTA) which are combined into two vials, MLT01 (minocycline) and MLT02 (ethanol and EDTA). Citius has manufactured three registration lots of Mino-Lok using the commercial manufacturing process, which will be filed in the planned New Drug Application (NDA). Citius has placed all registration lots on stability at the appropriate ICH (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) conditions to support the NDA filing. Citius has also developed a new exclusive synthesis process for disodium edetate ("EDTA"), a chelating agent which supplants heparin as the anti-clotting agent in Mino-Lok.

NDAs are applications to request permission to market a drug product in the U.S. for a specific use. Chemistry, manufacturing, and controls (CMC) information is therefore submitted in the NDA to ensure product quality as it relates to the safety and efficacy of the drug product.

"A typical drug approval contains one drug substance, so for all practical purposes our team has developed three products. Mino-Lok is unique in many ways, this being one of them," said Myron Holubiak, Chief Executive Officer of Citius. "It's important to know that we expect to be prepared to immediately move to validation/commercial manufacturing upon the completion of our Phase 3 clinical trial and receiving the required FDA clearance."

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; our dependence on third-party suppliers 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; 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; 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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