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Citius Pharmaceuticals, Inc. Provides Phase 3 Update On Mino-Lok™ Clinical Trial Following FDA Meeting

CRANFORD, N.J., Sept. 5, 2017 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius") ("Company") (NASDAQ: CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical care drug products, announced today it has received feedback from the U. S. Food and Drug Administration regarding amendments to the phase 3 study plan for Mino-Lok™, an adjunctive treatment for catheter related blood stream infection. There are currently no approved therapies to salvage infected central venous catheters ("CVCs"). Citius is currently recruiting sites for a phase 3 trial of Mino-Lok in the United States.

The FDA stated that they recognized that there is an unmet medical need in salvaging infected catheters and agreed that an open label, superiority design would address the Company's concerns and would be acceptable. They also reinforced their commitment to work with the Company to revise the trial design to meet the requirements of a new drug application.

Following the discussion with the FDA, Citius amended the phase 3 study design to remove the saline and heparin placebo control arm and to use an active control arm that conforms with today's current standard of care. The Company also noted that the dwell times and dosing schedules of the antibiotic lock therapy ("ALT") active control arm would be changed because there is an extreme level of variability and heterogeneity in how ALTs are dosed and used today.

Mr. Myron Holubiak, Chief Executive Officer of Citius, commented, "We are extremely pleased to work closely with the FDA to design a trial that meets today's need for better information and evidence as it relates to the treatment of infected CVCs and dosing schedules for ALTs. Experts agree that there is a great deal of variability allowed in the Infectious Disease Society of America (IDSA) guidelines with respect to the antibiotic chosen and the dwell times used for ALT's. We are confident that we will be able to demonstrate the superiority of our ready-to-use Mino-Lok over hospital compounded antibiotic solutions for which there have not been any largescale controlled studies or data driven evidence."

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," 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 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; our ability to attract, integrate, and retain key personnel; our need for substantial additional funds; 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.

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