

September 8, 2016



# Citius Pharmaceuticals, Inc., Initiates Manufacturing of Mino-Lok™

## Two Contract Manufacturing Organizations Engaged to Produce Clinical Trial Material

CRANFORD, N.J., Sept. 8, 2016 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius") (OTC QB: CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical care drug products, announced today that it has initiated manufacturing for the company's clinical trial of Mino-Lok™, an antibiotic lock solution used to salvage central venous catheters (CVCs) and to treat catheter related bloodstream infections (CRBSIs).

Citius Pharmaceuticals has engaged two large contract-manufacturing organizations ("CMOs") to perform the work. The product will be manufactured and packaged in two components, to be mixed and used at patient treatment sites. Minocycline will be manufactured by one of the largest CMOs with global operations. The other two components will be packaged at a US-based CMO with expertise in this area. The work has commenced at both locations and the Company expects the materials to be available for clinical use when the first patient is enrolled in early 2017.

Mr. Myron Holubiak, President and CEO stated, "Manufacturing of the components of Mino-Lok™ for clinical trial purposes marks a significant milestone for Citius. We hope to prove that a simple administration protocol that conforms to everyday work process in hospitals today will be able to salvage infected CVCs that cause devastating bacteremias in very vulnerable patients. There is currently no other solution on the market or in development that is focused on catheter salvage. We are confident that a successful trial will help to establish Citius as a market leader in the industry and allow us to offer an attractive alternative to removing and replacing central lines in very ill and susceptible patients.

Central Venous Catheters (CVCs) are life-saving vascular access ports in many patients requiring long-term intravenous therapy. Approximately 7 million CVCs are used annually and nearly 500,000 of those result in CRBSIs leading serious, life threatening infections and morbidities. Currently, the treatment for patients with a CRBSI is to treat the bacteremia with appropriate systemic antibiotic therapy, and in most cases remove the infected CVC and replace it with a new CVC at a new venous access site. There are currently no approved therapies to salvage infected CVCs. Mino-Lok™ is an antibiotic lock solution that will be studied to treat patients with CRBSIs in combination with appropriate systemic antibiotics(s), to preserve venous access and avoid the complications of morbidities associated with catheter removal and reinsertion. Mino-Lok™ penetrates biofilm, eradicates bacteria and provides anti-clotting properties to salvage infected indwelling CVCs.

### **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 using 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. We focus on developing products that have intellectual property protection and competitive advantages to existing therapeutic approaches. [www.citiuspharma.com](http://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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