

Drug Master File Submitted to FDA for Citius' Ethanol

Manufacturer Provides Exclusivity to Citius Pharmaceuticals, Inc.

Ethanol is an Active Component of Mino-Lok™

CRANFORD, N.J., Dec. 19, 2016 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius") (OTC BB: CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical care drug products, announced that it has assisted the manufacturer of the active ethanol component of Mino-Lok™, in filing a Type II drug master file (DMF) with FDA. Mino-Lok is being developed as an adjunctive therapy for the treatment of catheter-related or central line associated bloodstream infection (CRBSI/CLABSI) in combination with appropriate systemic antibiotic(s), to salvage infected central venous catheters (CVCs), to preserve central venous access, and to avoid the complications and morbidities associated with catheter removal and reinsertion.

A Type II DMF is reserved for products intended for use as active pharmaceutical ingredients, and such products must meet strict FDA manufacturing and testing standards. It was determined that ethanol is an active component of Mino-Lok, not just an excipient. The DMF allows Citius to cross-reference all manufacturing information related to the ethanol production in their regulatory applications associated with Mino-Lok therapy.

Mr. Myron Holubiak, President and CEO stated, "We have learned that the ethanol level is a vital component to the effectiveness of Mino-Lok therapy providing enhanced antimicrobial coverage and potency to the minocycline/EDTA combination. We believe the proper dose of ethanol is a factor that allows for the relatively short 2 hour dwell times for Mino-Lok, and also avoids the coagulopathies that have been reported with higher dose ethanol locks that have previously been tested. The two hour lock times are a significant benefit as this allows the catheter to be used for its intended purpose the remaining 22 hours throughout the day as needed."

There are currently no approved therapies to salvage infected CVCs.

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

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

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 thirdparty 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.

Contact:
Andrew Scott
Vice President, Corporate Development
(O) 908-967-6676
ascott@citiuspharma.com

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