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Citius Moves Forward with Mino-Lok™ Phase 3 Trial

Manufacturing Finalized and Site Recruitment Initiated

CRANFORD, N.J., Dec. 8, 2016 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius") (OTC BB: CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical care drug products, provided details of its phase 3 trial for Mino-Lok™, an antibiotic lock solution used to salvage infected central venous catheters (CVCs) and to treat catheter related bloodstream infections (CRBSIs). 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 CVCs, to preserve central venous access, and to avoid the complications and morbidities associated with catheter removal and reinsertion.

Manufacturing of the clinical trial components which consists of minocycline HCl in the first pre-mix component and a solution of disodium EDTA and ethanol in the second component have been finalized; and, the two components are being assembled for distribution to the clinical trial sites.

Clinical trial startup activities are underway and Citius is recruiting and qualifying sites for the trial. The first patient is expected to be enrolled in early 2017.

Myron Holubiak, President and CEO stated, "We have been working diligently to assure that all of the work streams are coming together at the right time to begin our registration trial in the first quarter of 2017. Mino-Lok is Citius' lead product, and we believe we will be able to show that there is an alternative to subjecting bacteremic patients to the risky CVC removal and replacement procedures. Mino-Lok may improve outcomes in these patients. We are also encouraged to see the passage of the 21st Century Cures Act by Congress last week. The Act amends the Federal Food, Drug, and Cosmetic Act to require the FDA to establish processes under which patient experience data may be considered in the risk-benefit assessment of a new drug. We strongly believe that Mino-Lok therapy improves patient experience as compared to remove and replace procedures. As was reported earlier, Mino-Lok has already received Qualified Infectious Disease Product (QIDP) designation which allows for Fast Track, Priority Review and extended market exclusivity."

In the US, approximately 7 million CVCs are used annually and nearly 500,000 of those result in CRBSIs leading to 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 catheter and replace it with a new one at a new venous access site. This process of removing and replacing the catheter in seriously ill patients with CRBSIs is difficult, costly, and carries significant clinical risks. Salvaging an infected catheter in these settings would be an important clinical advance. This trial will be the largest and most definitive study to date to examine if antibiotic locks can be

used to salvage infected catheters.

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

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