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Citius Initiates Mino-Lok™ Phase 3 Trial

Site Recruitment is Underway

CRANFORD, N.J., Sept. 13, 2016 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius") (OTC BB: CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical care drug products, announced today that it has initiated the pivotal Phase 3 clinical trial 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). Mino-Lok in combination with appropriate systemic antibiotic(s), is used to preserve central venous access and to avoid the complications and morbidities associated with catheter removal and reinsertion.

The Phase 3 trial is a multi-center, randomized, double-blind study of 700 subjects. The primary endpoint is the measurement of a significant proportion of subjects having overall success in maintaining the treated CVCs at the test of cure at week 8. Secondary endpoints include the safety and tolerability as described by adverse events, serious adverse events (SAEs), vital signs, clinical laboratory evaluations, and physical examinations.

Citius has begun recruitment of sites for the trial. This pivotal phase 3 clinical trial is expected to take 2 years to complete. The first patient is expected to be enrolled in early 2017. Medpace, (NASDAQ GS: MEDP), based in Cincinnati, OH, has been designated as the trial management clinical research organization (CRO).

Mr. Myron Holubiak, President and CEO stated, "This is a major milestone for Citius as our lead product is entering registration trials. Mino-Lok has the potential to become a standard of care (SOC) for treating CRBSIs."

Central venous catheters (CVCs) are life-saving vascular access ports in many patients requiring long-term intravenous therapy. 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.

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

About Medpace
Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its physician-led, high-science, and disciplined operating approach that leverages regulatory and therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective. Headquartered in Cincinnati, Ohio, Medpace employs approximately 2,300 people across 35 countries.

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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