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Citius Pharmaceuticals, Inc. Receives "Fast Track" Designation By FDA For Mino-Lok™ Investigational Trial

CRANFORD, N.J., Oct. 31, 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 official notice from the U. S. Food and Drug Administration ("FDA") that the investigational program for Mino-Lok™ is designated "Fast Track". Mino-Lok is a catheter lock solution that has entered phase 3 trials for an adjunctive treatment for catheter related blood stream infection ("CRBSI"). Fast Track is a designation by the FDA of an investigational drug to expedite review to facilitate development of drugs which treat a serious or life-threatening condition and fill an unmet medical need.

A drug that receives Fast Track designation is eligible for the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- More frequent written correspondence from FDA about the design of the clinical trials;
- Priority review to shorten the FDA review process for a new drug from ten months to six months; and,
- Rolling Review, which means Citius can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the application is completed before the entire application can be reviewed.

There are currently no approved therapies to salvage infected central venous catheters ("CVCs"), a potential \$750 million sector in the US alone. CRBSIs are responsible for mortality rates up to 25% in some patients, and contribute to significant morbidities. Citius is currently starting up sites for a phase 3 trial of Mino-Lok in the United States.

Mr. Myron Holubiak, Chief Executive Officer of Citius, commented "We are extremely pleased to receive Fast Track designation from the FDA. The agency has been very supportive and helpful in developing the trial design for Mino-Lok as salvage therapy for infected CVCs in CRBSI. We look forward to our continuing collaboration in developing Mino-Lok."

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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