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Citius Reports Progress in Hemorroid Treatment Program

- Selection of Higher Potency Corticosteroid For Phase 2b Trial to Improve Efficacy and Faster Onset of Symptomatic Relief

- Target Population to include Patients with Grade 2 and 3 Hemorrhoids

- Revised Program Discussed with the FDA

CRANFORD, N.J., March 6, 2018 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("CITIUS") ("Company") (NASDAQ: CTXR), a specialty pharmaceutical company, announced that the Company is selecting a higher potency corticosteroid in its steroid/anesthetic topical formulation program for the treatment of hemorrhoids. The original topical preparation, CITI-001, was a combination of hydrocortisone acetate and lidocaine hydrochloride. The new formulation, CITI-002, will combine lidocaine with the higher potency corticosteroid for symptomatic relief of the pain and discomfort of hemorrhoids. While not used in combination in currently marketed products, the proposed corticosteroid is included as an FDA-approved topical product to treat a variety of dermatological disorders.

The Company held a Type C meeting with the FDA to discuss the results of the Phase 2a study and to obtain the Agency's view on development plans to support the potential formulation change for the planned Phase 2b study. Citius also requested the Agency's feedback on the Phase 2b study design, including target patient population, inclusion/exclusion criteria, and efficacy endpoints. The pre-clinical and clinical development programs for CITI-002 are planned to be similar to those conducted for the development of CITI-001 to support the design for a planned Phase 3 clinical trial.

Myron Holubiak, CEO of Citius, said, "We made this decision to take advantage of the efficacy exhibited with higher potency steroids in reducing inflammation and in the faster onset of relief for hemorrhoid patients. In our planned Phase 2b trial, we will focus our attention on more severe hemorrhoidal disease, Grade 2 and 3, where a prescription strength may be more urgently needed. We will also be using the proprietary formulation we have developed since completing our CITI-001 clinical trial."

Hemorrhoids are a common gastrointestinal disorder characterized by pain, swelling, itching, tenderness, and bleeding. Hemorrhoids affect nearly 5% of the U.S. population, with 10 million patients reporting symptoms and a third seeking treatment from doctors. Between 50% and 90% of the population will experience hemorrhoid disease in their lifetime. The potential prescription market in the U.S. is very large with over 25 million units of topical products for hemorrhoids being sold annually in the U.S."

Currently, there are no approved prescription products, alone or in combination, for the treatment of hemorrhoids. Citius plans to use the FDA's 505(b)(2) pathway for new drug

approvals.

CITI-002 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 relating to the results of research and development activities, including the risk that preclinical results might not be replicated in any subsequent studies or trials and are not indicative of success in clinical trials; 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; risks related to our growth strategy; 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; and 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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