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Citius Pharmaceuticals Announces Results from Phase 2a Trial of Hydrocortisone and Lidocaine Combination Cream in Patients with Grade I and II Hemorrhoids

-- Company advances commercialization of product into $1 billion industry

-- Combination product demonstrates positive directional improvement compared to placebo in Global Score of Disease Severity and the onset of symptom relief

-- Data demonstrate an excellent safety profile

-- Company plans to conduct future studies

MAYNARD, Mass., Feb. 1, 2016 /PRNewswire/ -- Citius Pharmaceuticals, Inc. (OTCQB: CTXR) today announced top line data from the first Phase 2a clinical trial of hydrocortisone acetate (HC) and lidocaine hydrochloride (L) as single agents and in combination (HC+L) in patients with grade I and II hemorrhoids. Citius' hydrocortisone and lidocaine cream is targeting to become the first FDA –approved prescription product to treat hemorrhoids in the U.S.

In this randomized, double blind study of topical formulations of hydrocortisone, lidocaine and hydrocortisone + lidocaine were tested in patients with Grade I and II hemorrhoids. There have been no historical randomized, placebo-controlled studies of these two drugs used either individually or in combination to treat hemorrhoids. Therefore, this study's objective was to obtain data to inform the design of future studies. In this study, 210 patients were treated twice daily for 14-days with either placebo or one of the six active drug treatments (i.e., two concentrations of each HC, L and HC+L). Patients kept a diary of their symptoms. Additionally, there were 4 physician assessments during which patients were evaluated on the Global Score of Disease Severity (GSDS) scale as well as on the individual signs and symptoms of hemorrhoids such as bleeding, pruritus and overall pain and discomfort, and time to the onset of symptom relief.

Within the first few days of treatment the highest concentration of the hydrocortisone + lidocaine product was directionally superior to the placebo as measured by the number of subjects experiencing a minimum of 2 levels improvement from baseline according to the GSDS scale. This study was not powered to obtain statistical significance; however the data

suggest that the combination product may also perform better than the HC or L alone. The trend of HC+L superiority over placebo was also generally consistent for the treatment of individual signs and symptoms of hemorrhoidal disease – bleeding, itching, pain and overall discomfort. In addition, no safety signal of note was recorded in the trial.

"We are pleased with the results of this study which was intended to test the hypothesis that a steroid and anesthetic drug combination can be an effective way to reduce the symptoms of hemorrhoids," said Mr. Leonard Mazur, Chairman and Chief Executive Officer of Citius Pharmaceuticals, Inc. "As expected, the data provides a positive directional signal and also indicate early reduction of symptoms. We look forward to submitting these results to the FDA as we move toward commercialization of our product within this $1 billion market with unmet need. "

About Hemorrhoids

Hemorrhoids are a common gastrointestinal disorder, characterized by itching, pain, swelling and tenderness and bleeding. In the U.S., hemorrhoids affect nearly 5% of the population, with approximately 10 million persons annually admitting to having symptoms of hemorrhoidal disease. Of these afflicted persons, approximately one third visit a physician for evaluation and treatment of their hemorrhoids. The data also indicate that for both sexes a peak of prevalence occurs from age 45 to 65 years with a subsequent decrease after age 65. Caucasian populations are affected significantly more frequently than African Americans, and increased prevalence rates are associated with higher socioeconomic status in men but not women. Development of hemorrhoids before age 20 is unusual. In addition, between 50% and 90% of the general U.S., Canadian and European population will experience hemorrhoidal disease at least once in life. Although hemorrhoids and other anorectal diseases are not life-threatening, individual patients can suffer from agonizing symptoms which can limit social activities and have a negative impact on the quality of life. We believe that currently there are no FDA approved products for the treatment of hemorrhoids.

About Citius Pharmaceuticals, Inc.

Citius is a specialty pharmaceutical company dedicated to the development and commercialization of therapeutic products for large and growing markets using innovative, patented or proprietary formulations of previously approved pharmaceutical products. We seek new and expanded indications for previously approved pharmaceutical products as a means to achieving leading market positions or potential market exclusivity. By using previously approved drugs with substantial safety and efficacy data, we seek to reduce the risks associated with pharmaceutical product development. We seek to achieve these objectives by utilizing the U.S. Food and Drug Administration's, or FDA's, 505(b)(2) pathway for our new drug approvals. We believe this pathway is comparatively faster, lower risk and less expensive than the FDA's traditional new drug approval pathway. In addition, we focus on obtaining intellectual property protection with the objective of listing relevant patents in the FDA Orange Book in order to limit generic competition.

Safe Harbor

This release may contain certain forward-looking statements regarding our prospective performance and strategies within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We

intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995, and are including this statement for purposes of said safe harbor provisions.

Forward-looking statements, which are based on certain assumptions and describe future plans, strategies, and expectations of our company, are generally identified by use of words "anticipate," "believe," "estimate," "expect," "intend," "plan," "project," "seek," "strive," "try," or future or conditional verbs such as "could," "may," "should," "will," "would," or similar expressions. Our ability to predict results or the actual effects of our plans or strategies is inherently uncertain. Accordingly, actual results may differ materially from anticipated results. Some of the factors that could cause our actual results to differ from our expectations or beliefs include, without limitation, the risks discussed from time to time in our filings with the Securities and Exchange Commission.

Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Except as required by applicable law or regulation, we undertake no obligation to update these forward-looking statements to reflect events or circumstances that occur after the date on which such statements were made.

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/citius-pharmaceuticals-announces-results-from-phase-2a-trial-of-hydrocortisone-and-lidocaine-combination-cream-in-patients-with-grade-i-and-ii-hemorrhoids-300212340.html

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