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Citius Announces Completion of In-Depth Interviews on Patient-Reported Outcomes: Signs and Symptoms of Hemorrhoids and Treatments

Leading Life Sciences Market Research Firm Conducted Patient Interviews

CRANFORD, N.J., Aug. 23, 2016 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius") (OTC BB: CTXR), a specialty pharmaceutical company dedicated to developing and commercializing adjunctive cancer care and critical care drug products, announced completion of market research with in-depth interviews on patient-reported signs and symptoms of hemorrhoids and treatment outcomes with its Hydro-Lido product.

Citius and the market research group conducted in-depth, in-person and telephonic interviews of patients who were diagnosed with grade II and grade III hemorrhoid disease. The interviews examined patients' experience with multiple concomitant symptoms and varying severity. In its phase 2a study, Citius used both individual signs and symptoms and a composite of these individual symptoms to measure the efficacy of its Hydro-Lido product. The composite of the symptoms, or the Global Score of Disease Severity (GSDS), was scrutinized in the patient survey. This Patient Reported Outcome (PRO) information provides Citius with more specific guidelines for designing the endpoints in its planned phase 2b study.

Citius' topical Hydro-Lido product is being developed to provide anti-inflammatory and anesthetic relief to persons suffering from hemorrhoids. 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. could exceed $1 billion, and over 25 million units of topical products for hemorrhoids are currently sold annually in the U.S.

Both Hydrocortisone and Lidocaine have each been separately approved by the FDA for other indications, and are commercially available and marketed by other companies. Currently, there are no approved prescription products, alone or in combination, for the treatment of hemorrhoids. Citius plans to use FDA's 505(b)(2) pathway for new drug approvals to develop its Hydro-Lido product.

Myron Holubiak, CEO of Citius, said, "This patient-reported outcome study confirms our use of the Global Score of Disease Severity (GSDS) as a reliable measure of the hemorrhoid symptoms that directly affect patient lives, and allows us to differentiate the drug effect in

reducing these symptoms."

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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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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