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Citius Pharmaceuticals Addresses Problem That Affects 10 Million People in the U.S.: Hemorrhoids

The Company's Hydrocortisone-Lidocaine Cream Completed Phase 2a and the Company Looks to Accelerate Commercialization Utilizing FDA's 505(b)(2) Pathway for New Drug Approvals

CRANFORD, N.J., July 25, 2016 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius") (OTC BB: CTXR), a specialty pharmaceutical company dedicated to acquiring, developing and commercializing adjunctive cancer care and critical care drug products, announced significant progress in its development efforts of its Hydro-Lido cream to treat hemorrhoids. In February, the Company reported results from the Phase 2a trial of its Hydrocortisone and Lidocaine Combination Cream in patients with Grade I and II hemorrhoids, and the data suggest that the Hydro-Lido combination may show faster onset of relief of symptoms and reduction in disease severity as compared to its active components or the cream vehicle.

Citius' topical Hydro-Lido product is 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 hemorrhoidal disease in their lifetime. The estimated market in the U.S. is over \$1.2 billion, and over 25 million units of topical products for hemorrhoids are 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. But, 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, "As expected, our Phase 2a trial provided insights into optimizing the formulation for our Hydro-Lido hemorrhoid cream. The trial also helped us identify how and when these therapies help patients. Additionally, our recently conducted market research has informed us as to the symptoms that matter most to patients. This data is helping us generate study endpoints that should be both meaningful to the patients and provide a basis for approval by the FDA. This is a large market opportunity; Hydro-Lido would be the first FDA-approved prescription product to treat hemorrhoids in the U.S. We are extremely pleased with our progress."

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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Contact:

Andrew Scott

Vice President, Corporate Development

646-522-8410; ascott@citiuspharma.com

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