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Citius Provides Developmental Plans for Mino-Wrap

Mino-Wrap to be Developed Through an IND Process

CRANFORD, N.J., July 30, 2019 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius") ("Company") (NASDAQ: CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical care drug products, today reported the Company's decision to develop Mino-Wrap as a drug through the Investigational New Drug ("IND") process. The FDA's IND program is the means by which a pharmaceutical company obtains permission to start human clinical trials and to ship an experimental drug across state lines before a marketing application for the drug has been approved.

"Mino-Wrap is a combination product that is designed to provide both a cushioning element between the tissue expander ("TE") and surrounding tissue reducing post-surgical inflammation, and to prevent colonization of the surgical pocket and the TE device following mastectomy," said Mr. Myron Holubiak, President and CEO of Citius Pharmaceuticals. "We have had extensive interactions with the FDA's Center for Devices and Radiological Health Devices ("CDRH") and have decided that we should follow the Center for Drug Evaluation and Research ("CDER") IND route. This decision was made based on the Mino-Wrap's primary mode of action ("PMOA") which is to reduce microbial colonization and infection. We plan to communicate further developments in the Mino-Wrap program after we secure and have a pre-IND meeting with FDA."

The target patient population in the U.S. is approximately 100,000 women. Citius will also be exploring a designation as an "Orphan Drug" with the Office of Orphan Products Development ("OOPD"). The Company also intends to apply for a Qualified Infectious Disease Product ("QIDP") designation for antibacterial drug candidates intended to treat serious or life-threatening infections and to take advantage of expediting mechanisms (e.g., fast-track and priority review).

About Mino-Wrap

Mino-Wrap is a novel approach to reducing post-operative infections associated with surgical implants. Mino-Wrap is a liquefying gel-based wrap containing minocycline and rifampin for reducing tissue expander (TE) infections following breast reconstructive surgeries. It is a laminate film comprised of porcine gelatin plasticized with glycerol. Mino-Wrap also contains the antibiotics minocycline and rifampin to reduce bacterial bioburden on implantable devices preventing colonization over a sustained period of time. In the setting of breast reconstruction, Mino-Wrap provides more durable antimicrobial protection of the implant-tissue interface than peri-operative irrigation with antibiotic solutions (the current standard of care). Both porcine gelatin (and collagen) as well as the combination of minocycline and rifampin have long histories of successful medical use in implantable devices in multiple anatomical settings.

Tissue Expanders and Infection Risk
A common breast reconstruction technique is tissue expansion, which involves expansion of the breast skin and muscle using a temporary tissue expander. After a few months, the expander is removed and the patient receives either microvascular flap reconstruction, or the insertion of a permanent breast implant. This type of breast reconstruction requires two separate operations. A breast tissue expander is an inflatable breast implant designed to stretch the skin and muscle to make room for a future, more permanent implant. Through a tiny valve mechanism located inside the expander, saline is periodically injected to gradually fill the expander over several weeks or months. The process usually begins three to four weeks after mastectomy. After the skin over the breast area has stretched enough, the expander is removed in a second operation and either flap reconstruction or a permanent implant is inserted. Infection is one of the most common complications of tissue expanders and implants during breast reconstruction, with an infection rate ranging from 2.5 to 24 percent.

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 associated with developing Mino-Wrap, including that preclinical results may not be predictive of clinical results and our ability to file an IND; the estimated markets for our product candidates and the acceptance thereof by any market; risks related to our growth strategy; risks associated with conducting our Phase 3 trial for Mino-Lok, including completing patient enrollment and opening study sites; 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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