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Citius Submits Mino-Wrap Briefing Package to FDA for Pre-IND Consult

- Mino-Wrap being developed for the reduction of post-operative infections associated with breast reconstruction surgery

- Mino-Wrap is the second major drug development collaboration with MD Anderson Cancer Center

CRANFORD, N.J., Aug. 4, 2020 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius") ("Company") (NASDAQ: CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical care drug products announced progress in the development of Mino-Wrap, a novel approach to reducing post-operative infections associated with surgical implants.

Mino-Wrap is a gel-containing minocycline and rifampin film that is used to wrap the tissue expander ("TE") used in breast reconstructive surgeries. In order to stimulate early consultation and potentially speed the development of Mino-Wrap, the company has submitted a briefing package to the FDA Division of Anti-Infective Products. The briefing package contains information regarding pre-clinical data and a clinical development plan, along with questions for the FDA regarding safety and efficacy data that would be required to advance Mino-Wrap into clinical trials. The company will consider the feedback provided by the FDA in the development of the Pre-IND. There is no set timeline for FDA to respond to a consultation package; however, based on pre-COVID-19 experience, we expect a response from FDA within 60 days.

Mino-Wrap also marks the second collaboration with MD Anderson Cancer Center ("MDACC") who are the inventors of this novel approach to preventing post-mastectomy infections when tissue expanders are used. The Company is currently developing Mino-Lok®, an antibiotic lock treatment for catheter-related bloodstream infections (CRBSIs), in collaboration with MDACC. Mino-Lok is in phase 3 development.

"The published rate of infection for tissue expanders used in breast reconstructive surgery is between 2.5 % and 24%, with an estimated mean at around 12% to 14%. We believe Mino-Wrap has the potential to provide a significant reduction in the incidence of infection, sparing the patient the pain and discomfort of extended hospitalization and further aggressive and lengthy courses of antibiotics in an attempt to salvage the TEs. In many cases the TE is removed leading to a delay in lifesaving chemo-radiation therapy, which can be a devastating consequence for the patient," said Myron Holubiak, President and CEO of Citius Pharmaceuticals. "We also are extremely honored to be working with the doctors and scientists at MD Anderson Cancer Center to develop another much-needed improvement in adjunctive cancer care. The early consultation with FDA allows for the identification of optimal strategies for our preclinical and clinical development programs. We are pleased to

be taking advantage of this collaborative approach with the agency."

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 is designed to provide 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.

About 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. A tissue expander is an empty breast implant that is filled with normal saline over 6 to 8 weeks until it reaches the breast size that is desired. In this type of reconstruction, the surgeon will either make a pocket under a large muscle in the chest and place a tissue expander in that space or place the expander above the large muscle. About 4 to 8 weeks after the tissue expansion is finished, a second surgery is required to remove the tissue expander and insert the permanent breast implant. The patient receives either microvascular flap reconstruction, or the insertion of a permanent breast implant. 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 MD Anderson Cancer Center

The University of Texas MD Anderson Cancer Center in Houston ranks as one of the world's most respected centers focused on cancer patient care, research, education and prevention. The institution's sole mission is to end cancer for patients and their families around the world. MD Anderson is one of only 45 comprehensive cancer centers designated by the National Cancer Institute (NCI). MD Anderson is ranked No.1 for cancer care in U.S. News & World Report's "Best Hospital's" survey. It has ranked as one of the nation's top two hospitals since the survey began in 1990, and has ranked first for 11 of the past 14 years. MD Anderson receives a cancer center support grant from the NCI of the National Institutes of Health (P30 CA016672).

About Citius Pharmaceuticals, Inc.

Citius is a late-stage specialty pharmaceutical company dedicated to the development and commercialization of critical care products, with a focus on anti-infectives and cancer care. For more information, please visit www.citiuspharma.com.

About Mino-Lok®

Mino-Lok® is an antibiotic lock solution being developed as an adjunctive therapy in patients with central line-associated bloodstream infections (CLABSIs) or catheter-related bloodstream infections (CRBSIs). CLABSIs/CRBSIs are very serious, especially in cancer patients receiving therapy through central venous catheters (CVCs) and in hemodialysis patients, for whom venous access presents a challenge. There are currently no approved therapies for salvaging infected CVCs.

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 of FDA response to our pre-IND briefing package for Mino-Wrap and, depending on the response, our ability to successfully undertake and complete clinical trials and the results from those trials; our need for substantial additional funds; the estimated markets for our product candidates, and the acceptance thereof by any market; risks associated with conducting trials for our product candidates, including our Phase III trial for Mino-Lok; risks relating to the results of research and development activities; risks associated with developing our product candidates, including that preclinical results may not be predictive of clinical results and our ability to file an IND for such candidates, including Mino-Wrap; uncertainties relating to preclinical and clinical testing; the early stage of products under development; risks related to our growth strategy; 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 ability to attract, integrate, and retain key personnel; 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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