NEWS RELEASE

Citius Pharmaceuticals Reports Productive FDA Type C Meeting to Discuss Phase 3 Mino-Lok® Program and Pathway to Approval

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CRANFORD, N.J., Nov. 25, 2024 /PRNewswire/ -- Citius Pharmaceuticals, Inc. (NASDAQ: CTXR) ("Citius Pharma" or the "Company"), a biopharmaceutical company dedicated to the development and commercialization of first-in-class critical care products, today announced that the Company held a constructive in-person Type C meeting with the U.S. Food and Drug Administration (FDA). The meeting followed successful completion of the Company's pivotal Phase 3 clinical trial of Mino-Lok®, a novel catheter lock solution designed to salvage central venous catheters in patients suffering from central line-associated bloodstream infections (CLABSI) or catheter-related bloodstream infections (CRBSI). The primary discussion centered on responses to the FDA's questions related to Mino-Lok's clinical trial data and a pathway to a future submission.

The FDA provided clear, constructive, and actionable guidance during the discussion, underscoring a pathway to support a future New Drug Application (NDA) submission for Mino-Lok. The meeting encompassed an extensive range of topics critical to the NDA process, including in-vitro, clinical efficacy and safety data, and regulatory considerations. Citius Pharma reaffirmed the potential of Mino-Lok to address a critical unmet medical need and its commitment to advancing the program.

"We are highly encouraged by the collaborative and substantive nature of our engagement with the FDA regarding the Mino-Lok program," stated Leonard Mazur, Chairman and CEO of Citius Pharmaceuticals. "The FDA's comprehensive feedback supports our commitment to advancing this novel solution for patients who face life-threatening complications from catheter-related infections. The Agency's guidance provides a strong framework for

completing the remaining steps toward an NDA submission."

"We believe Mino-Lok has demonstrated compelling clinical outcomes in the Phase 3 trial, supporting its potential to significantly enhance the management of catheter-related bloodstream infections. As a groundbreaking alternative to catheter removal, Mino-Lok, if approved, could reduce healthcare costs, mitigate patient risks, and improve clinical outcomes for individuals requiring central venous catheterization. Citius Pharmaceuticals remains committed to advancing the Mino-Lok® program and will continue to provide updates on regulatory and clinical developments as they unfold," added Mazur.

About Mino-Lok®

Mino-Lok is a novel antibiotic lock solution that combines minocycline, ethanol with edetate disodium designed to treat patients with catheter-related blood stream infections. Citius licensed Mino-Lok from an affiliate of The University of Texas MD Anderson Cancer Center. Mino-Lok is designed to offer an alternative to removing and replacing a central venous catheter (CVC), which may lead to a reduction in serious adverse events and cost savings to the healthcare system. If approved, Mino-Lok would be the first and only FDA-approved treatment that salvages central venous catheters that cause central line-related blood stream infections.

About Citius Pharmaceuticals, Inc.

Citius Pharma is a biopharmaceutical company dedicated to the development and commercialization of first-in-class critical care products. In August 2024, the FDA approved LYMPHIR™, a targeted immunotherapy for an initial indication in the treatment of cutaneous T-cell lymphoma. Citius Pharma's late-stage pipeline also includes Mino-Lok®, an antibiotic lock solution to salvage catheters in patients with catheter-related bloodstream infections, and CITI-002 (Halo-Lido), a topical formulation for the relief of hemorrhoids. A Pivotal Phase 3 Trial for Mino-Lok and a Phase 2b trial for Halo-Lido were completed in 2023. Mino-Lok met primary and secondary endpoints of its Phase 3 Trial. Citius Pharma is actively engaged with the FDA to outline next steps for both programs. For more information, please visit **www.citiuspharma.com**.

Forward-Looking Statements

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 Pharma. You can identify these statements by the fact that they use words such as "will," "anticipate," "estimate," "expect," "plan," "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, and, unless noted otherwise, that apply to Citius Pharma and Citius Oncology, are: risks relating to the results of research and development activities, including those from our existing and any new pipeline assets; Citius Pharma's ability to regain compliance with and continue to meet Nasdaq's continued listing standards; our ability to raise additional money to fund our operations for at least the next 12 months as a going concern; risks related to research using our assets but conducted by third parties; our ability to commercialize LYMPHIR and any of our other product candidates that may be approved by the FDA; the estimated markets for our product candidates and the acceptance thereof by any market; the ability of our product candidates to impact the quality of life of our target patient populations; our dependence on third-party suppliers; our ability to procure cGMP commercial-scale supply; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; uncertainties relating to preclinical and clinical testing; the early stage of products under development; market and other conditions; risks related to our growth strategy; patent and intellectual property matters; our ability to identify, acquire, close and integrate product candidates and companies successfully and on a timely basis; government regulation; competition; as well as other risks described in our SEC filings. These risks have been and may be further impacted by any future public health risks. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements. Risks regarding our business are described in detail in our Securities and Exchange Commission ("SEC") filings which are available on the SEC's website at **www.sec.gov**, including in Citius Pharma's Annual Report on Form 10-K for the year ended September 30, 2023, filed with the SEC on December 29, 2023, as updated by our subsequent filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof, and 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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