Citius Pharmaceuticals Announces Efficacy and Safety Data for its I/ONTAK (E7777) Phase 3 Study for Treatment of Cutaneous T-Cell Lymphoma to be Presented at the 64th American Society of Hematology (ASH) Annual Meeting

Oral and Poster Presentations to Highlight Clinical Data for I/ONTAK (E7777) Study in Relapsed or Refractory Cutaneous T-cell Lymphoma on December 11, 2022

CRANFORD, N.J., November 9, 2021 -- Citius Pharmaceuticals, Inc. ("Citius" or the "Company") (Nasdaq: CTXR), a biopharmaceutical company dedicated to the development and commercialization of first-in-class critical care products today announced that abstracts for I/ONTAK (E7777) for the treatment of relapsed or refractory cutaneous T-cell lymphoma (CTCL) have been accepted for presentations at the prestigious 64th American Society of Hematology (ASH) Annual Meeting, to be held in New Orleans, December 10-13, 2022.

Dr. Francine Foss, Professor of Medicine in the Section of Medical Oncology at the Yale Cancer Center, and world-renowned expert in T-cell lymphomas, will deliver an oral presentation reviewing the efficacy and safety results of the completed I/ONTAK (E7777) Phase 3 study.

Dr. Christiane Querfeld, Professor of Dermatology and Dermatopathology at City of Hope Cancer Center, and Director of City of Hope's multidisciplinary Cutaneous Lymphoma Program will present a poster highlighting the safety and tolerability data of I/ONTAK (E7777) in patients with relapsed or refractory cutaneous T-cell lymphoma from Study 302. Dr. Querfeld is one of the world's foremost experts in the diagnosis and management of cutaneous lymphomas.

Oral Presentation:	**Efficacy and Safety of E7777 (improved purity denileukin diftitox [ONTAK]) in Patients with Relapsed or Refractory Cutaneous T-Cell Lymphoma: Results from Pivotal Study 302**
Publication Number:	618
Session Name:	624. Hodgkin Lymphomas and T/NK cell Lymphomas: Clinical and Epidemiological: Mature T-cell Malignancies: Clinical and Epidemiological
Date:	Sunday, December 11, 2021
Session Time:	4:30 – 6:00 PM ET
Presentation Time:	5:45PM ET
Room:	Ernest N. Morial Convention Center, 393-396
Presenter:	Francine Foss, M.D., Yale Cancer Center, New Haven, CT

Poster Presentation:	**Safety and Tolerability of E7777 (improved purity denileukin diftitox [ONTAK]) in Patients with Relapsed or Refractory Cutaneous T-Cell Lymphoma: Results from Pivotal Study 302**

Publication Number:	2927
Session Name:	624. Hodgkin Lymphomas and T/NK cell Lymphomas: Clinical and Epidemiological: Poster II
Date:	Sunday, December 11, 2021
Session Time:	6:00 – 8:00 PM ET
Location:	Ernest N. Morial Convention Center, Hall D
Presenter:	Christiane Querfeld, M.D., Ph.D., City of Hope Cancer Center, Duarte, CA

"We look forward to sharing additional efficacy and safety data for I/ONTAK with the medical community at this year's ASH meeting. With I/ONTAK's differentiated mechanism-of-action, we believe CTCL patients could benefit from this promising therapeutic option, if approved. Based on the clinical data from our recently completed Phase 3 trial, we submitted a biologics license application (BLA) with the U.S. Food and Drug Administration (FDA) in late September 2022, and look forward to engaging with the FDA during their review process," stated Dr. Czuczman, Chief Medical Officer and Executive Vice President of Citius Pharmaceuticals, Inc.

The oral presentation and poster will be available on Citius' website once the event commences.

About I/ONTAK

I/ONTAK is a recombinant fusion protein that combines the interleukin-2 (IL-2) receptor binding domain with diphtheria toxin fragments. The agent specifically binds to IL-2 receptors on the cell surface, causing diphtheria toxin fragments that have entered cells to inhibit protein synthesis. I/ONTAK, a purified version of denileukin diftitox, is a reformulation of previously FDA-approved oncology treatment ONTAK. ONTAK was marketed in the U.S. from 1999 to 2014, when it was voluntarily withdrawn from the market. Manufacturing improvements resulted in a new formulation, which maintains the same amino acid sequence but features improved purity and bioactivity. The new formulation received regulatory approval in Japan in 2021 for the treatment of CTCL and peripheral T-cell lymphoma (PTCL). In 2011 and 2013, the FDA granted orphan drug designation (ODD) to I/ONTAK for the treatment of PTCL and CTCL, respectively.

About Cutaneous T-cell Lymphoma

Cutaneous T-cell lymphoma is a type of cutaneous non-Hodgkin lymphoma (NHL) that comes in a variety of forms and is the most common type of cutaneous lymphoma. In CTCL, T-cells, a type of lymphocyte that plays a role in the immune system, become cancerous and develop into skin lesions, leading to a decrease in the quality of life of patients with this disease due to severe pain and pruritus. Mycosis Fungoides (MF) and Sézary Syndrome (SS) comprise the majority of CTCL cases. Depending on the type of CTCL, the disease may progress slowly and can take anywhere from several years to upwards of ten to potentially reach tumor stage. However, once the disease reaches this stage, the cancer is highly malignant and can spread to the lymph nodes and internal organs, resulting in a poor prognosis. Given the duration of the disease, patients typically cycle through multiple systemic agents to control disease progression. CTCL affects men twice as often as women and is typically first diagnosed in patients between the ages of 50 and 60 years of age. Other than allogeneic stem cell transplantation, for which only a small fraction of patients qualify, there is currently no curative therapy for advanced CTCL.

About Citius Pharmaceuticals, Inc.

Citius is a late-stage biopharmaceutical company dedicated to the development and commercialization of first-in-class critical care products, with a focus on oncology, anti-infectives in adjunct cancer care, unique prescription products, and stem cell therapies. The Company's diversified pipeline includes two late-stage product candidates, Mino-Lok®, an antibiotic lock solution for the treatment of patients with catheter-related bloodstream infections (CRBSIs), which is currently enrolling patients in a Phase 3 Pivotal superiority trial, and I/ONTAK (E7777), a novel IL-2R immunotherapy for an initial indication in cutaneous T-cell lymphoma (CTCL), for which a BLA has been submitted. Mino-Lok® was granted Fast Track designation by the U.S. Food and Drug Administration (FDA). I/ONTAK has received orphan drug designation by the FDA for the treatment of CTCL and peripheral T-cell lymphoma (PTCL). In the first half of 2022, Citius initiated a Phase 2b trial for Halo-Lido, a topical formulation for the relief of hemorrhoids. The Company anticipates completing enrollment in the Halo-Lido trial by the end of 2022. 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 "believe," "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 are: the FDA may find inadequacies and deficiencies in our BLA for I/ONTAK, including in the data we submit, and may decide not to accept the BLA for filing; our need for substantial additional funds; our ability to successfully undertake and complete clinical and non-clinical trials and the results from those trials for our product candidates; the estimated markets for our product candidates and the acceptance thereof by any market; our ability to commercialize our products if approved by the FDA; our dependence on third-party suppliers; the ability of our product candidates to impact the quality of life of our target patient populations; risks relating to the results of research and development activities, including those from existing and new pipeline assets; uncertainties relating to preclinical and clinical testing; the early stage of products under development; market and other conditions; our ability to attract, integrate, and retain key personnel; risks related to our growth strategy; patent and intellectual property matters; 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 procure cGMP commercial-scale supply; government regulation; competition; as well as other risks described in our SEC filings. These risks have been and may be further impacted by Covid-19. 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 our Annual Report on Form 10-K for the year ended September 30, 2021, filed with the SEC on December 15, 2021 and updated by our subsequent filings with the SEC. 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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