NEWS RELEASE

# Citius Oncology Announces U.S. Commercial Launch of LYMPHIR™, a Novel Cancer Immunotherapy for Cutaneous T-Cell Lymphoma (CTCL)

2025-12-01

LYMPHIR now available nationwide

CRANFORD, N.J., Dec. 1, 2025 /PRNewswire/ -- Citius Oncology, Inc. ("Citius Oncology") (Nasdaq: CTOR), the oncology-focused subsidiary of Citius Pharmaceuticals, Inc. ("Citius Pharma") (Nasdaq: CTXR), today announced the commercial launch of LYMPHIR™ (denileukin diftitox-cxdl). LYMPHIR is a novel IL-2 receptor-directed fusion protein approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with relapsed or refractory (r/r) Stage I–III cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy.

"LYMPHIR is an important new treatment option for the CTCL community, and its launch marks the beginning of a new chapter for Citius Oncology. With a median time to response of 1.4 months in the Phase 3 trial, we believe LYMPHIR may offer rapid skin relief, among other benefits, to patients suffering from severe and debilitating itching common with the disease," said Leonard Mazur, Chairman and CEO of Citius Oncology and Citius Pharmaceuticals. "This is our first marketed product and the culmination of years of development work and commercial preparation. LYMPHIR addresses a clear clinical need in a disease with limited treatment options. Ultimately, we expect LYMPHIR to be a meaningful addition to the treatment paradigm for CTCL and a value-driving catalyst for Citius Oncology shareholders. We estimate that LYMPHIR is entering a growing U.S. market valued at over $400 million, with further upside opportunities through international market access and potential expanded indications in the future. Our focus now is on execution to ensure that LYMPHIR reaches the patients who need it," added Mazur.

The FDA approval of LYMPHIR was based on data from Pivotal Study 302 (**NCT01871727**), which evaluated the efficacy and safety of LYMPHIR in patients with Stage I–III CTCL who had received at least one prior systemic treatment. The study demonstrated an Objective Response Rate (ORR) of 36.2%, with 84% of evaluable patients experiencing a reduction in skin tumor burden. Moreover, LYMPHIR demonstrated meaningful activity on severe pruritus (itchiness), a significant quality of life issue for CTCL patients. Median time to response was 1.4 months. Importantly, LYMPHIR was not associated with cumulative toxicity.

"LYMPHIR is an important new tool in the fight against CTCL. It is the only FDA-approved systemic therapy for CTCL in more than seven years," said Dr. Myron Czuczman, Executive Vice President and Chief Medical Officer of Citius Oncology and Citius Pharma. "LYMPHIR's direct tumoricidal activity and transient T-regulatory cell depletion offer a powerful new approach to disease control without cumulative toxicity. As such, LYMPHIR's clinical profile makes it a compelling treatment option for physicians and patients facing the burden of relapsed or refractory CTCL."

## Commercial Access and Distribution

LYMPHIR is now available in the U.S. through specialty distributors nationwide. Healthcare providers can access treatment resources and prescribing information via the dedicated portal: **www.lymphirhcp.com**. The product has been assigned a permanent J-code (J9161), effective April 1, 2025, to facilitate reimbursement and streamline claims processing.

The launch is supported by medical education and payer access programs, alongside a field engagement strategy. LYMPHIR has also been included in the National Comprehensive Cancer Network (NCCN) Guidelines® for CTCL with a Category 2A recommendation.

Outside the U.S., Citius Oncology holds exclusive rights to develop and commercialize LYMPHIR in all global markets except India, Japan, and certain parts of Asia. The company recently announced a distribution agreement with Integris Pharma S.A. to initiate named-patient access programs in Greece, Cyprus, and other Southern European and Balkan countries. This partnership marks the first pillar in Citius Oncology's international strategy and supports efforts to provide patients worldwide with access to LYMPHIR.

## Patient and Provider Resources

To support informed treatment decisions and facilitate access to care, Citius Oncology has developed clinical, administrative and educational resources for healthcare providers, available at **www.lymphirhcp.com**. The site includes prescribing information, reimbursement support materials, and product ordering guidance. Additionally, the site features information about Citius Advantage, a dedicated patient assistance program that includes reimbursement and benefits support, prior authorization assistance, and coordination with specialty pharmacies

for eligible patients to help reduce out-of-pocket costs and improve access to treatment.

## About LYMPHIR™ (denileukin diftitox-cxdl)

LYMPHIR is a targeted immune therapy for relapsed or refractory cutaneous T-cell lymphoma (CTCL) indicated for use in Stage I-III disease after at least one prior systemic therapy. It is a recombinant fusion protein that combines the IL-2 receptor binding domain with diphtheria toxin (DT) 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. After uptake into the cell, the DT fragment is cleaved and the free DT fragments inhibit protein synthesis, resulting in cell death. Denileukin diftitox-cxdl demonstrated the ability to deplete immunosuppressive regulatory T lymphocytes (Tregs) and antitumor activity through a direct cytocidal action on IL-2R-expressing tumors.

In 2021, denileukin diftitox received regulatory approval in Japan for the treatment of relapsed or refractory CTCL and peripheral T-cell lymphoma (PTCL). Subsequently, in 2021, Citius acquired an exclusive license with rights to develop and commercialize denileukin diftitox in all markets except for India, Japan and certain parts of Asia. LYMPHIR (denileukin diftitox-cxdl) was approved by the FDA in August 2024.

## 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 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 Oncology, Inc.

Citius Oncology, Inc. (Nasdaq: CTOR) is a platform to develop and commercialize novel targeted oncology therapies. In August 2024, its primary asset, LYMPHIR, was approved by the FDA for the treatment of adults with relapsed or refractory Stage I–III CTCL who had had at least one prior systemic therapy. Management estimates the initial market for LYMPHIR currently exceeds $400 million, is growing, and is underserved by existing therapies. Robust

intellectual property protections that span orphan drug designation, complex technology, trade secrets and pending patents for immuno-oncology use as a combination therapy with checkpoint inhibitors would further support Citius Oncology's competitive positioning. For more information, please visit **www.citiusonc.com**.

## About Citius Pharmaceuticals, Inc.

Citius Pharmaceuticals, Inc. (Nasdaq: CTXR) 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 adults with relapsed or refractory Stage I–III CTCL who had had at least one prior systemic therapy. Citius Pharma's late-stage pipeline also includes Mino-Lok®, a catheter 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. Citius Pharma owns 79% of Citius Oncology. For more information, please visit **www.citiuspharma.com**.

## INDICATION

LYMPHIR is an IL2-receptor-directed cytotoxin indicated for the treatment of adult patients with r/r Stage I-III cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy.

## IMPORTANT SAFETY INFORMATION

## BOXED WARNING: CAPILLARY LEAK SYNDROME

Capillary leak syndrome (CLS), including life-threatening or fatal reactions, can occur in patients receiving LYMPHIR. Monitor patients for signs and symptoms of CLS during treatment. Withhold LYMPHIR until CLS resolves, or permanently discontinue based on severity.

## WARNINGS AND PRECAUTIONS

### Capillary Leak Syndrome

LYMPHIR can cause capillary leak syndrome (CLS), including life-threatening or fatal reactions. CLS was defined in the clinical trials as the occurrence of at least 2 of the following symptoms at any time during LYMPHIR therapy: hypotension, edema, and serum albumin <3 g/dL. These symptoms were not required to occur simultaneously to

be characterized as capillary leak syndrome.

As defined, CLS occurred in 27% of patients in the pooled population across 3 clinical trials, including 8% with Grade 3. There was one (0.8%) fatal occurrence of CLS. Of the patients with CLS, 22% had recurrence. The majority of CLS events (81%) occurred within the first 2 cycles of treatment. The median time to onset from Cycle 1, Day 1 was 6.5 days (range: 1 to 77), the median duration of CLS was 14 days (range: 2 to 40), and 75% of patients had resolution. The most common symptoms included edema, hypoalbuminemia, and hypotension. Pleural effusion, pericardial effusion, and dehydration also occurred.

Regularly assess patients for weight gain, new onset or worsening of edema, dyspnea, and hypotension (including orthostatic changes). Monitor serum albumin levels prior to the initiation of each cycle of therapy and more often as clinically indicated.

Withhold, reduce dose, or permanently discontinue based on severity. If LYMPHIR is withheld, resume LYMPHIR following resolution of CLS and when serum albumin is greater than or equal to 3 g/dL.

## Visual Impairment

LYMPHIR can cause serious visual impairment, including changes in visual acuity and color vision. In the pooled population across 3 clinical trials, visual impairment occurred in 9%, with Grade 1 in 8% and Grade 2 in 1%. The most commonly reported symptom was blurred vision. Of the patients with visual impairment, 67% had resolution of their visual impairment.

Perform baseline ophthalmic examination and monitor as clinically indicated. If patients experience symptoms of visual impairment, such as changes in visual acuity, changes in color vision, or blurred vision, refer for ophthalmologic evaluation.

Withhold LYMPHIR until visual impairment resolves or permanently discontinue based on severity.

## Infusion-Related Reactions

LYMPHIR can cause serious infusion-related reactions. Infusion-related reactions were reported in 69% of patients in the pooled population across 3 clinical trials of patients who received LYMPHIR, with Grade 3 infusion-related reactions in 3.4%. Eighty-three percent of infusion-related reactions occurred in Cycles 1 and 2. The most common symptoms included nausea, fatigue, chills, musculoskeletal pain, vomiting, fever, and arthralgia.

Premedicate patients for the first three cycles prior to starting a LYMPHIR infusion. Monitor patients frequently

during infusion. For Grade 2 or higher infusion reactions, premedicate at least 30 minutes prior to each subsequent infusion with a systemic steroid for at least 3 cycles.

Interrupt or discontinue LYMPHIR based on severity. Institute appropriate medical management.

### Hepatotoxicity

LYMPHIR can cause hepatotoxicity. In the pooled safety population, elevated ALT occurred in 70% of patients, with Grade 3 ALT occurring in 22%; elevated AST occurred in 64% of patients, with Grade 3 AST elevation occurring in 9%. For Grade 3 events, median time to onset was 8 days (range: 1 to 15 days); median time to resolution was 15 days (range: 7 to 50 days); all cases of Grade 3 ALT or AST elevations resolved. Elevated total bilirubin occurred in 5% of patients, with Grade 3 occurring in 0.9%.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold, reduce dose, or permanently discontinue LYMPHIR based on severity.

### Embryo-Fetal Toxicity

Based on its mechanism of action, LYMPHIR can cause fetal harm when administered to a pregnant woman. Verify the pregnancy status of females of reproductive potential prior to the initiation of LYMPHIR. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment and for 7 days following the last dose of LYMPHIR.

## ADVERSE REACTIONS

The most common adverse reactions (≥20%), including laboratory abnormalities, are increased transaminases, albumin decreased, nausea, edema, hemoglobin decreased, fatigue, musculoskeletal pain, rash, chills, constipation, pyrexia, and capillary leak syndrome.

## USE IN SPECIFIC POPULATIONS

### Pregnancy

Risk Summary

Based on its mechanism of action, LYMPHIR can cause fetal harm when administered to a pregnant woman. There are no available data on the use of LYMPHIR in pregnant women to evaluate for a drug-associated risk. No animal reproductive and developmental toxicity studies have been conducted with denileukin diftitox.

Denileukin diftitox-cxdl causes depletion of regulatory T lymphocytes (Treg), immune activation, and capillary leak syndrome, compromising pregnancy maintenance. Advise pregnant women of the potential risk to a fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies are 2-4% and 15-20%, respectively.

## Lactation

Risk Summary

No data are available regarding the presence of denileukin diftitox-cxdl in human milk, the effects on the breastfed child, or on milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with LYMPHIR and for 7 days after the last dose.

## Females and Males of Reproductive Potential

Based on its mechanism of action, LYMPHIR can cause fetal harm when administered to a pregnant woman.

Pregnancy Testing

Verify the pregnancy status of females of reproductive potential prior to initiating LYMPHIR.

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with LYMPHIR and for 7 days after the last dose.

Infertility

Males

Based on findings in rats, male fertility may be compromised by treatment with LYMPHIR. The reversibility of the effect on fertility is unknown.

Pediatric Use

Safety and effectiveness of LYMPHIR in pediatric patients have not been established.

Geriatric Use

Of the 69 patients with Stage I-III r/r CTCL who received LYMPHIR, 34 patients (49%) were 65 years of age and older and 10 patients (14%) were 75 years of age and older. Clinical studies of LYMPHIR did not include sufficient

numbers of patients 65 years of age and older to determine whether they respond differently from younger adult patients.

You may report side effects to the FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**. You may also report side effects to Citius Oncology at 1-844-459-6744.

Please read Important Safety Information and **full Prescribing Information**, including Boxed WARNING, for LYMPHIR.

## 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 Oncology. 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 Oncology, are: our need for substantial additional funds and our ability to raise additional money to fund our operations for at least the next 12 months as a going concern; our ability to successfully commercialize LYMPHIR and establish a sustainable revenue stream; physician and patient acceptance of LYMPHIR in a competitive treatment landscape; our reliance on third-party logistics providers, distributors, and specialty pharmacies to support commercial operations; our ability to educate providers and payers, secure adequate reimbursement, and maintain uninterrupted product supply; post-marketing requirements and ongoing regulatory compliance related to LYMPHIR; our ability to secure strategic partnerships and expand international access to LYMPHIR; our ability to use the latest technology to support our commercialization efforts; the estimated markets for LYMPHIR and our product candidates and the acceptance thereof by any market; the ability of LYMPHIR and 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 our existing and any new pipeline assets;; our ability to procure cGMP commercial-scale supply; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; our ability to maintain Nasdaq's continued listing standards; 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; as well as other risks described in our Securities and Exchange Commission ("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 SEC filings which are available on the SEC's website at **www.sec.gov**, including in Citius Oncology's Annual Report on Form 10-K for the year ended September 30, 2024, filed with the SEC on December 27, 2024, as amended on January 27, 2025, as 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.

## Investor Contact:

Ilanit Allen
**ir@citiuspharma.com**
908-967-6677 x113

## Media Contact:

STiR-communications
Greg Salsburg
**Greg@STiR-communications.com**

View original content to download multimedia:**https://www.prnewswire.com/news-releases/citius-oncology-announces-us-commercial-launch-of-lymphir-a-novel-cancer-immunotherapy-for-cutaneous-t-cell-lymphoma-ctcl-302627320.html**

SOURCE Citius Oncology, Inc.