



NEWS RELEASE

Citius Oncology Reports Strong Commercial Momentum for its Cancer Treatment

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New institutional accounts ordering LYMPHIR increased 78% quarter over quarter

LYMPHIR's near-universal payer coverage expands market access

Initial cutaneous T-cell lymphoma (CTCL) market for LYMPHIR currently exceeds \$400 million

CRANFORD, N.J., Aug. 5, 2026 /PRNewswire/ -- Citius Oncology, Inc. ("Citius Oncology") (Nasdaq: CTOR), an oncology-focused biopharmaceutical company and majority-owned subsidiary of Citius Pharmaceuticals, Inc. ("Citius Pharma") (Nasdaq: CTXR), today provided an update on the expanding base of institutions ordering LYMPHIR® (denileukin diftitox-cxdl) through wholesalers, continued formulary progress at priority U.S. treatment centers, and other key indicators supporting the product's commercial launch.

"Our commercial progress is reflected in two closely connected measures: growth in the number of institutions ordering LYMPHIR and continued expansion of the formulary approvals that enable additional institutions to begin ordering the product and treating patients," said Leonard Mazur, Chairman and Chief Executive Officer of Citius Oncology. "I am pleased to report that the number of new institutions ordering LYMPHIR rose, total institutional vial orders increased, formulary reviews and approvals grew, and wholesalers are reordering LYMPHIR to reflect this growth. Formulary inclusion is a key gateway to institutional ordering and patient access. The success of our targeted launch, so far, was accomplished by a small yet focused internal launch team. Together with our recently expanded commercial and medical affairs teams, we believe Citius Oncology is well positioned to broaden engagement with over 250 priority treatment centers, support continued adoption, and accelerate topline growth

through the balance of the year."

LYMPHIR is now available in 42 institutions including academic oncology centers, leading National Comprehensive Cancer Network (NCCN) institutions and community infusion centers. During the quarter ended June 30, 2026, the number of new institutions increased 78% compared with the prior quarter. Vials ordered by institutions from wholesalers rose 31% during the quarter. Subsequent to the quarter ended June 30, 2026, following an increase in both the number of ordering institutions and vial demand, orders from wholesalers have begun to reflect this incremental demand. Citius revenue is recognized when wholesale orders for LYMPHIR are placed and filled.

LYMPHIR's growing institutional footprint consists of leading academic and cancer treatment centers with recognized CTCL expertise. Formulary inclusion is an important step in the commercial adoption process. Once approved, an institution can order the product through a nationwide wholesaler network and make the therapy available for prescribing to eligible adult patients with relapsed or refractory cutaneous T-cell lymphoma (CTCL). Review times vary by institution and may range from several weeks to several months. Based on Company experience to date, institutions that add LYMPHIR to formulary have generally placed their first patient order within approximately two to six weeks. Citius Oncology anticipates more than 20 additional institutions during the current quarter, and is targeting formulary inclusion with 100 priority institutions by year-end.

The Company continues to engage leading CTCL experts through scientific exchange and educational initiatives designed to increase understanding of LYMPHIR's clinical profile and support institutional evaluation of the therapy. At the Sixth World Congress of Cutaneous Lymphomas in Montreal, the Company met with many U.S. and international CTCL key opinion leaders. The expanded medical affairs team is expected to increase the frequency and breadth of the Company's scientific engagement with the CTCL community.

According to Company tracking, LYMPHIR has secured near-universal payer coverage. Formulary inclusion and payer coverage address complementary requirements for market access. Together, these indicators reflect continued progress in building LYMPHIR's commercial foundation.

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 cytotoxic action on IL-2R-expressing tumors.

In 2021, reformulated 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 reformulated denileukin diftitox in all markets except for India, Japan and certain parts of Asia. LYMPHIR (denileukin diftitox-cxdl) was approved by the FDA and subsequently launched in the U.S. in December 2025.

About Citius Oncology, Inc.

Citius Oncology, Inc. (Nasdaq: CTOR) is a platform to develop and commercialize novel targeted oncology therapies. In December 2025, Citius Oncology launched LYMPHIR, 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 CTCL 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.

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 are: our ability to successfully commercialize LYMPHIR and establish a sustainable revenue stream; the estimated markets for LYMPHIR and our product candidates and the acceptance thereof by any market; our ability to use the latest technology to support our commercialization efforts for LYMPHIR; physician and patient acceptance of LYMPHIR in a competitive treatment landscape; our ability to raise additional money to fund our operations; our ability to regain compliance with Nasdaq's continued listing standards; our ability to obtain, perform under and maintain third party agreements and relationships, including obtaining a new bulk drug substance supplier; risks relating to the results of research and development activities, including those from our existing and any new pipeline assets; early-stage clinical data may not be predictive of results from larger or later-stage studies; our ability to secure and maintain strategic partnerships and expand international access to LYMPHIR; 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; the ability of LYMPHIR and our product candidates to impact the quality of life of our target patient populations; our ability to procure cGMP commercial-scale supply; risks related to our growth strategy; patent and intellectual property matters; government regulation; as well as other risks described in our Securities and Exchange Commission ("SEC") filings. 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, 2025, filed with the SEC on December 23, 2025. 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.

LYMPHIR (denileukin diftitox-cxdl)

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 ($\geq 20\%$), 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-cxdI 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.

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