

# Citius Oncology Announces Positive Topline Results from Investigator-Initiated Phase 1 Study of LYMPHIR™ in Combination with Pembrolizumab in Relapsed or Refractory Gynecologic Cancers

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Study data from patients with relapsed or refractory gynecologic cancers signals the potential of LYMPHIR to augment immune checkpoint inhibitor efficacy

Topline data of University of Pittsburgh-led trial to be presented at an upcoming international cancer conference later this year

CRANFORD, N.J., March 10, 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 announced positive topline results from a completed investigator-initiated Phase 1 clinical trial conducted by University of Pittsburgh investigators. This study evaluated the direct T-regulatory (Treg) cell depletion activity of LYMPHIR™ (denileukin diftitox-cxdI) in combination with the PD-1 immune checkpoint inhibitor pembrolizumab (KEYTRUDA®) in patients with recurrent or refractory gynecologic cancers, including ovarian and endometrial malignancies.

Patients with relapsed or refractory gynecological cancer have poor prognoses and very limited treatment options. This dose-escalation Phase 1 non-chemotherapy based clinical study aimed to establish a recommended dose of LYMPHIR in combination with pembrolizumab for a Phase 2 study. In 25 evaluable patients, no unexpected safety signals or serious immune-related adverse events were observed at any dose level.

"We are encouraged by the favorable safety profile and sustained disease control observed in this heavily pretreated patient population. Evidence from the study suggests augmented anti-tumor activity when LYMPHIR is combined with KEYTRUDA and warrants further exploration in Phase 2 settings," stated Dr. Myron Czuczman, Executive Vice President and Chief Medical Officer of Citius Oncology and Citius Pharma.

The trial explored efficacy and demonstrated a 24% objective response rate (ORR) and a 48% clinical benefit rate (CBR, defined as complete response, partial response and/or stable disease for six months or greater) among 21 evaluable patients. Full safety and clinical efficacy results are expected to be presented at an international cancer conference later this year.

"The efficacy signal shown by this combination is incredibly exciting considering the minimal impact immunology has made in ovarian cancer thus far. If these findings are confirmed in subsequent studies, we may have a transformational therapy on our hands," said Dr. Alexander Olawaiye, principal investigator of the study.

## About the Study

This open-label, dose-escalation, investigator-initiated Phase 1 study (NCT05200559), led by Dr. Alexander B Olawaiye at UPMC Magee-Women's Hospital, enrolled patients with recurrent or metastatic solid tumors who had received at least one prior line of therapy. LYMPHIR was administered intravenously on Days 1–3 of each 21-day cycle at escalating doses (3, 6, 9, and 12 mcg/kg), along with pembrolizumab (200 mg IV) on Day 1. Patients who completed eight cycles of combination therapy were continued on pembrolizumab monotherapy until disease progression.

The use of LYMPHIR in this study was investigational and outside of its FDA-approved indication. The Phase 1 study was not designed or powered to evaluate clinical efficacy, and no conclusions can be drawn regarding comparative effectiveness or long-term outcomes.

## About Gynecologic Cancers

Recurrent or metastatic ovarian and endometrial cancers are two of the most common gynecologic malignancies in the United States. Endometrial cancer is the most frequently diagnosed gynecologic cancer, with an estimated 70,000 new cases expected in 2026<sup>1</sup>, while ovarian cancer remains the deadliest with approximately 12,700 deaths per year (51.6% 5 year survival) and approximately 20,000 new diagnoses each year<sup>2</sup>. These cancers are often detected at advanced stages, and although many patients initially respond to platinum-based chemotherapy, most experience relapse and develop resistance. Survival rates in the recurrent setting remain poor, and responses to current immunotherapies such as PD-1 inhibitors are limited, highlighting a significant unmet need for novel

treatment approaches. LYMPHIR's transient depletion of regulatory T-cells may enhance anti-tumor immune responses and help overcome immunotherapy resistance in these difficult-to-treat tumors.

## About LYMPHIR™ (denileukin diftitox-cxdI)

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-cxdI 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, 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-cxdI) 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 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](http://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: 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 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; the estimated markets for LYMPHIR and our product candidates and the acceptance thereof by any market; our ability to secure strategic partnerships and expand international access to LYMPHIR; our ability to maintain Nasdaq's continued listing standards; 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 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; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; market and other conditions; 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. 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](http://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.

#### REFERENCES:

American Cancer Society. Cancer Facts & Figures 2026 (projected). Atlanta: American Cancer Society; 2026. <https://www.cancer.org/cancer/types/endometrial-cancer/about/key-statistics.html>

National Cancer Institute. Surveillance, Epidemiology, and End Results Program (SEER). Cancer Stat Facts: Uterine and Ovarian Cancer. <https://seer.cancer.gov/statfacts/html/ovary.html>

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LYMPHIR™ (denileukin diftitox-cxdI)

## 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-cxdI 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](http://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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