NEWS RELEASE

Citius Oncology Highlights Phase 1 Data in an Investigator-Initiated Study of LYMPHIR® (denileukin diftitox-cxdl) in Combination with Pembrolizumab in Recurrent or Refractory Gynecologic Malignancies

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Investigator-initiated study data presented May 30, 2026, at the American Society of Clinical Oncology (ASCO) Annual Meeting demonstrated durable responses and manageable tolerability in heavily pre-treated patients

20.5 months of median progression-free survival observed among 48% of efficacy-evaluable patients achieving clinical benefit (10 of 21)

Responses were observed in patients previously treated with immune checkpoint inhibitors, including a 33% objective response rate in patients with relapsed or refractory endometrial cancer

CRANFORD, N.J., June 1, 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 highlighted Phase 1 clinical data presented May 30, 2026, at the American Society of Clinical Oncology (ASCO) Annual Meeting evaluating LYMPHIR (denileukin diftitox-cxdl) in combination with pembrolizumab in patients with recurrent or refractory gynecologic malignancies. The poster presentation (Abstract #2564) was presented by investigators from the University of Pittsburgh Medical Center (UPMC) Magee-Womens Hospital.

"LYMPHIR's ability to transiently deplete immunosuppressive regulatory T-cells may help address immune

resistance in the tumor microenvironment and enhance the effect of checkpoint inhibitors. The encouraging clinical signals and tolerability profile observed in this study support continued clinical evaluation of this "chemo-free" immunomodulatory approach, especially in tumors where resistance to checkpoint inhibitors remains a significant challenge," said Dr. Myron S. Czuczman, Chief Medical Officer of Citius Oncology.

The open-label Phase 1 study evaluated LYMPHIR in combination with pembrolizumab in 25 heavily pre-treated patients (21 evaluable for efficacy) with recurrent or metastatic solid tumors, primarily gynecologic malignancies. Enrolled patients had received a median of five prior therapies, and more than half had previously received anti-PD-1 or PD-L1 therapy.

Key Efficacy and Safety findings presented at ASCO included:

- 24% Overall Response Rate (ORR) among the 21 efficacy-evaluable patients (5 partial responses).
- Median duration of response (mDOR) had not yet been reached because only 1 of the 5 partial responders had progressed at the time of analysis (80% of PRs were continuing to experience clinical benefit). The current duration of response times (time since PR was achieved) were 4.2-35 months with a median of 21.1 months.
- 33% ORR in endometrial cancer patients previously treated with checkpoint inhibitors, including one patient with an ongoing response greater than three years.
- 48% of efficacy-evaluable patients (10 of 21) achieved clinical benefit, defined as complete response (CR), partial response (PR), or durable stable disease lasting at least six months:
    - Median progression-free survival (mPFS) of 20.5 months (95% CI: 6.5 – NA) among the 10 patients who achieved clinical benefit; overall mPFS across all 21 efficacy-evaluable patients was 5.8 months (95% CI: 2.2 – NA);
    - 5 patients had a PFS of > 20 months including 1 patient with > 30 months PFS;
- Of the 24/25 pts evaluable for dose limiting toxicities (DLTs), only 1 case of reversible Gr 3 capillary leak syndrome (CLS) was observed at the highest dose level. A maximum tolerated dose was not achieved.
- 16 serious adverse events were observed in seven patients treated at the highest dose level. No new safety signals or grade 3 or greater immune-related adverse events were observed.

Dr. Alexander Olawaiye, a professor and one of the gynecologic cancer researchers at UPMC Magee-Womens Hospital and lead investigator of the study, added, "Patients with recurrent gynecologic malignancies who progress following immunotherapy often have limited treatment options. The clinical activity observed with denileukin diftitox-cxdl plus pembrolizumab, including durable responses and prolonged disease control in heavily pre-treated patients, is notable. Given the lack of effective salvage treatments for these patients, especially those that have failed prior immune-checkpoint inhibition, the novel combination of LYMPHIR plus pembrolizumab provides a potential viable therapeutic option. Importantly, the safety profile observed was manageable in this heavily pre-

treated population, supporting continued evaluation in larger studies."

Ongoing translational studies are evaluating the impact of the combination on regulatory T-cells, immune effector cells, and the tumor microenvironment to help identify potential biomarkers in order to optimize future development strategies. A Phase 2 expansion study is being planned to further evaluate the combination in gynecologic cancers, including less heavily pre-treated and prior immunotherapy-exposed patient populations.

About the Study

This open-label, dose-escalation, investigator-initiated Phase 1 study (**NCT05200559**), led by Dr. Alexander B Olawaiye at UPMC Magee-Womens Hospital, enrolled 25 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. Citius Oncology provided study drug and financial support to the investigator-initiated study; the study was designed, conducted, and analyzed by the UPMC investigators.

Important note on investigational use: The use of LYMPHIR in this study was investigational and outside of its FDA-approved indication of relapsed or refractory Stage I–III cutaneous T-cell lymphoma. LYMPHIR is not approved by the FDA for the treatment of gynecologic malignancies or any solid tumor, and the safety and efficacy of LYMPHIR in this setting have not been established. This 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. Early-stage clinical data may not be predictive of results from larger or later-stage studies.

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 endometrial cancer cases expected in the United States in 2026[1], while ovarian cancer remains the deadliest with approximately 12,700 deaths per year (51.6%) and approximately 20,000 new diagnoses each year in the United States[2]. 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 in combination with anti-PD-1 checkpoint inhibition may potentially enhance host anti-tumor immune responses and help overcome immunotherapy resistance in these difficult-to-treat tumors.

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-associated anti-tumor activity is achieved via a direct cytocidal action on IL-2R-expressing tumors and depletion of host immunosuppressive regulatory T lymphocytes (Tregs).

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 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; 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; 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 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. 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, 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**

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 (≥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.

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