NEWS RELEASE

Citius Oncology Announces Preliminary Topline Phase 1 Data from Study of LYMPHIR™ (E7777) Dosing Prior to Commercial CAR-T Therapy in High-Risk Diffuse Large B-Cell Lymphoma

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Topline data of investigator-initiated study at the University of Minnesota and City of Hope demonstrates 86% overall response rate (OR), including 57% complete response (CR) and 29% partial response (PR)

LYMPHIR was well-tolerated with no dose-limiting toxicities observed

CRANFORD, N.J., March 4, 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 safety and efficacy results from an investigator-initiated Phase 1 trial evaluating LYMPHIR™ (E7777, denileukin diftitox-cxdl) administered prior to commercial CD19-directed CAR-T therapy in patients with high-risk relapsed or refractory diffuse large B-cell lymphoma (DLBCL). The trial was conducted by lead investigator, Dr. Veronika Bachanova, at the University of Minnesota and City of Hope. Full results were presented at the 2026 ASTCT® & CIBMTR® Tandem Meetings[1].

The Phase 1 trial was designed to augment the lymphodepletion regimen prior to CAR-T infusion through the administration of LYMPHIR to potentially improve the anti-tumor activity of CAR-T therapies. LYMPHIR, an engineered fusion toxin that preferentially binds to the IL-2 receptor expressed on regulatory T-cells (Tregs), is currently FDA-approved and commercially available for the treatment of relapsed or refractory cutaneous T-cell lymphoma (CTCL) after one prior systemic therapy.

"Enhancing Treg depletion prior to CAR-T infusion with LYMPHIR represents a promising immunomodulatory strategy in patients with high-risk DLBCL, and these Phase 1 data provide an encouraging signal of the potential to enhance current CAR-T regimens," said Dr. Myron Czuczman, Executive Vice President and Chief Medical Officer of Citius Oncology and Citius Pharma. "These positive data support our broader strategy of exploring LYMPHIR's modulatory effect on Tregs in combination with other approved therapies to potentially enhance the body's own immune system to fight cancerous tumors," he added.

Topline Results & Study Design

- All patients (n=14) completed treatment and proceeded to CAR-T infusion;
- LYMPHIR was well tolerated, with no dose-limiting toxicities observed;
- No Grade ≥3 LYMPHIR-related immune adverse events or infusion reactions were reported; and,
- Data demonstrated effective Treg depletion, and promising efficacy signals of enhanced standard lymphodepletion with the use of Treg-targeting LYMPHIR.

The Phase 1, open-label, dose-escalation study (**NCT04855253**), enrolled 14 patients with relapsed or refractory DLBCL exhibiting poor prognostic features, including double/triple hit genetics, primary refractory disease, and extranodal involvement. Participants received one dose of LYMPHIR (E7777) at 5, 7, or 9 µg/kg followed by low dose chemotherapy prior to standard commercial CD19-directed CAR-T cell therapy. All patients received an infusion of one of the following FDA-approved, commercially manufactured CAR-T products: axicabtagene ciloleucel (Yescarta®; Kite Pharma/Gilead Sciences), lisocabtagene maraleucel (Breyanzi®; Bristol Myers Squibb), or tisagenlecleucel (Kymriah®; Novartis).

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.

Key Findings from the Phase 1 Trial

- Overall response rate (ORR) was 86% at one month, including 57% complete responses (CR) and 29% partial responses (PR);
- One-year progression-free survival (PFS) was 77% (95% CI: 43–92%);
- One-year overall survival (OS) was 84% (95% CI: 49–96%);
- A single LYMPHIR dose resulted in depletion of circulating Tregs in all but one patient;
    - Median reduction of 24 Tregs/µL (range 8–65);
    - Treg nadir was observed 24 hours post-LYMPHIR;

- LYMPHIR was well tolerated with no dose-limiting toxicities (DLTs) observed up to 9 µg/kg; and,
- Reported adverse events included manageable Grade 1–2 capillary leak syndrome, fever, and transient liver enzyme elevations; Grade 3 cytopenias were consistent with expected lymphodepletion. CAR-T related cytokine release syndrome (CRS) occurred in 43% of patients (all Grade 1/2), and immune effector cell-associated neurotoxicity syndrome (ICANS) occurred in 21% (primarily low grade).

"In this high-risk population, LYMPHIR showed a favorable safety profile and promising pharmacodynamic effects when administered prior to CAR-T therapies. This data sets the stage for a larger study to assess its potential to enhance CAR-T efficacy through longer duration of LYMPHIR use," said Dr. Veronika Bachanova, Principal Investigator and Professor of Medicine at the University of Minnesota.

Dr. Bachanova presented the topline data at the 2026 Tandem Meetings | ASTCT® CIBMTR®.

Title: E7777 to Enhance Regulatory T-Cell Depletion Prior to CAR-T for High-Risk LBCL
Presentation ID: 677608
Abstract ID: 296369

About Diffuse Large B-Cell Lymphoma (DLBCL)

Diffuse large B-cell lymphoma (DLBCL) is the most common subtype of non-Hodgkin lymphoma (NHL), accounting for approximately 30%–40% of newly diagnosed cases in the United States. DLBCL is an aggressive and rapidly growing cancer of B lymphocytes, a type of white blood cell responsible for producing antibodies. While frontline chemoimmunotherapy regimens such as R-CHOP can be curative for many patients, up to 40% experience relapse or refractory disease. High-risk features are associated with poor outcomes and limited responses to standard therapies, including CAR-T cell therapy. Novel strategies that modulate the tumor microenvironment, such as transient regulatory T-cell depletion, are under investigation to improve treatment efficacy and long-term remission rates in this difficult-to-treat population.

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 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**.

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**, 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:

Tandem Meetings: Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT®) & the Center for International Blood and Marrow Transplant Research (CIBMTR®)
Yescarta® is a registered trademark of Kite Pharma, Inc., a Gilead company.

Breyanzi® is a registered trademark of Bristol Myers Squibb.

Kymriah® is a registered trademark of Novartis.

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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SOURCE Citius Oncology, Inc.