UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) October 23, 2025

Citius Oncology, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-41534	99-4362660
(Commission File Number)	(IRS Employer Identification No.)
11 Commerce Drive, 1st Floor, Cranford, NJ	07016
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (908) 967-6677

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	CTOR	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On October 23, 2025, Citius Oncology, Inc. posted an updated Corporate Presentation on its website. A copy of the Corporate Presentation is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 7.01 (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit is filed herewith:

Exhibit No.	Description
99.1	Corporate Presentation of October 2025.
104	Cover Page Interactive Date File (embedded within the Inline XBRL document).

SIGNATURE

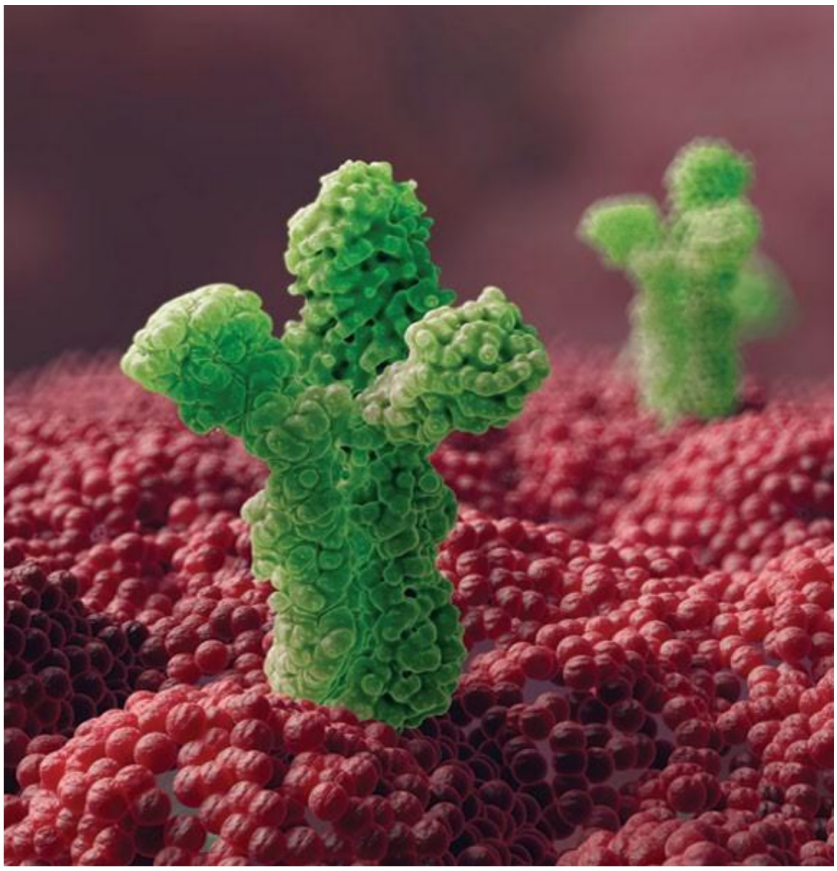
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CITIUS ONCOLOGY, INC.

Date: October 23, 2025

/s/ Leonard Mazur
Leonard Mazur
Chairman and Chief Executive Officer

Exhibit 99.1



CORPORATE OVERVIEW

NASDAQ: CTOR

OCTOBER 2025

FORWARD LOOKING LANGUAGE

This presentation has been prepared by Citius Oncology, Inc. (the "Company") for informational purposes only and not for any other purpose. Nothing contained in this presentation is, or should be construed as, a recommendation, promise or representation by the Company or any director, employee, agent, or adviser of the Company. This presentation does not purport to be all-inclusive or to contain all of the information you may desire. The information contained in this presentation and the comments and remarks of the representatives of the Company made during any presentation to which this presentation relates are integrally related and, as such, are intended to be delivered and understood together. Information provided in this presentation speaks only as of the date hereof. The Company assumes no obligation to update any statement after the date of this presentation as a result of new information, subsequent events or any other circumstances. This presentation does not constitute an offer or invitation for the sale or purchase of securities or to engage in any other transaction with the Company or its affiliates. The information in this presentation is not targeted at the residents of any particular country or jurisdiction and is not intended for distribution to, or use by, any person in any jurisdiction or country where such distribution or use would be contrary to local law or regulation.

This presentation contains forward-looking statements that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words "may", "might", "will", "could", "would", "should", "expect", "intend", "plan", "goal", "objective", "anticipate", "believe", "estimate", "predict", "potential", "continue" and "ongoing", or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements and opinions contained in this presentation are based upon estimates and information available to us as of the date of this presentation. While we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Factors that could cause actual results to differ from those discussed in the forward-looking statements include, but are not limited to: our ability to commercialize LYMPHIR and any of our other product candidates that may be approved by the FDA; our need for substantial additional funds; future financial and operating results, including revenues, income, expenditures, cash balances and other financial items; our ability to execute our growth, expansion and acquisition strategies; current and future economic and political conditions; expected changes in our revenues, costs or expenditures; our expectations regarding demand for and market acceptance of our services; our expectations regarding our customer base; our ability to obtain, maintain or procure all necessary government certifications, approvals, and/or licenses to conduct our business, and in the relevant jurisdictions in which we operate; competition in our industry; relevant government policies and regulations relating to our industry; our capital requirements and our ability to raise any additional financing which we may require; our ability to hire and retain qualified management personnel and key employees in order to enable us to develop our business; overall industry, economic and market performance; and other assumptions described in this presentation underlying or relating to any forward-looking statements Investors are strongly encouraged to carefully review the Company's SEC filings for a listing of the risks that could cause actual results to differ from these forward-looking statements. These forward-looking statements speak only as of the date of this presentation and should not be construed as statements of facts.

As a matter of course, we do not make public projections as to our expected sales or profitability due to, among other reasons, the inherent uncertainty of the underlying assumptions and estimates. Similarly, as a matter of course, we do not comment on ongoing or potential partnership discussions, the expected timing of future financial raises or potential long-term strategic plans.

ABOUT CITIUS ONCOLOGY, INC.

Biopharmaceutical company focused on developing and commercializing innovative targeted oncology therapies

- Lead product, LYMPHIR™, FDA approved August 2024
  - Orphan Indication: treatment of adult patients with relapsed or refractory Stage I-III cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy
  - 12-year BLA exclusivity
  - First new systemic CTCL therapy since 2018
- Commercialization planned for Q4 2025
- Estimated $400M+ addressable U.S. market with growth opportunities[1]
- Publicly traded on NASDAQ since August 2024 (Ticker: CTOR)
  - Majority-owned (~79%) subsidiary of Citius Pharmaceuticals, Inc. (NASDAQ: CTXR)
  - Shared management services agreement with CTXR

1. Internal estimates based on IQVIA market research.

CITIUS IS PREPARING TO LAUNCH LYMPHIR IN Q4 2025

Commercial launch readiness nearing completion through disciplined financial strategy

Citius has invested ~$90 million in LYMPHIR to date

$40M	Upfront purchase
$43+M	Development and precommercial efforts
$5M	Spinout to form Citius Oncology

Significant pre-commercial activities have been completed

- Manufactured inventory for launch (12-18 month supply; 5-year shelf life)
- Negotiated supply chain and CSO agreements
- Secured new permanent J-code (HCPCS Level II code – J9161) and inclusion of LYMPHIR in NCCN guidelines
- Developed targeted machine learning trigger system for salesforce to identify potential patients
- Initiated marketing strategy to raise brand awareness
- Hired key sales force management team

Additional pre-commercial activities underway

- Hire and onboard salesforce to initiate sales
- Ship product to wholesalers
- Implement digital media plan and ad campaign
- Launch Patient Services Hub
- Named Patient Program expansion to ex-US markets

LYMPHIR™ (denileukin diftitox-cxdl) Injection 300 mcg

EXPERIENCED MANAGEMENT TEAM

Shared management services agreement with Citius Pharmaceuticals mitigates execution risk, maximizes capital efficiency and leverages industry expertise

LEONARD MAZUR
CHAIRMAN & CEO

JAIME BARTUSHAK
EVP, CFO & CBO

MYRON HOLUBIAK
EXECUTIVE VICE CHAIRMAN

DR. MYRON CZUCZMAN
EVP, CHIEF MEDICAL OFFICER

MICHAEL MCGUIRE
VP, COMMERCIAL

OMAR LANSARI
DIR, MARKETING

WHAT IS CUTANEOUS T-CELL LYMPHOMA (CTCL)?

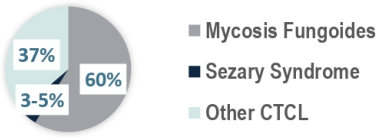
Considered to be incurable, CTCL is a Subgroup of Non-Hodgkin Lymphomas (NHL) that can be Indolent or Aggressive and is Driven by Malignant T Cells

CTCL is a general term for T-cell lymphoma that involves the skin, but may also involve the blood, lymph nodes, and internal organs

More prevalent in men than women and usually appears in patients in their 50s and 60s

CTCL accounts for approximately 4% of all non-Hodgkin lymphoma (NHL)[1]

CTCL Prevalence by Subtype[2]

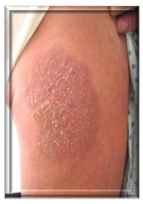


Patients with persistent or recurrent CTCL require systemic therapy

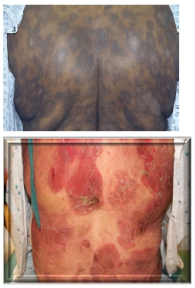
1. Dummer R, et al. *Nat Rev Dis Primers.* 2021;7(1):61. 2. Rangoonwala, HI and Cascella M. 2022, StatPearls Publishing: Treasure Island, FL. 3. Cleveland Clinic. *Cutaneous T-Cell Lymphoma*. 2023. Available from: https0://my.clevelandclinic.org/health/diseases/17940-cutaneous-t-cell-lymphoma 4. Hristov AC, et al. *Am J Hematol.* 2019;94(9):1027-1041.

CTCL PATIENTS HAVE A HIGH DISEASE BURDEN

T1

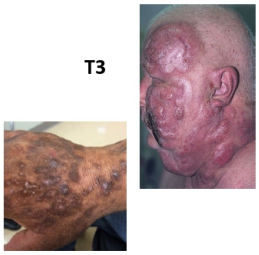


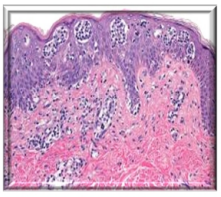
T2



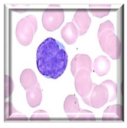
Skin Stage	Description	10-Yr Relative Survival, %
T1	Patches, papules, or plaques covering < 10% of the skin surface	100
T2	Patches, papules, or plaques covering ≥ 10% of the skin surface	67.4
T3	Tumors (≥ 1)	39.2
T4	Generalized erythroderma	41.0

T3

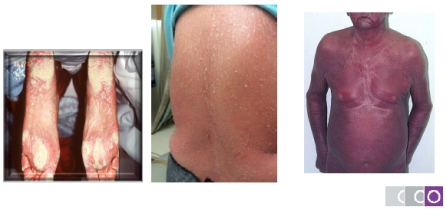




Sézary cell



T4



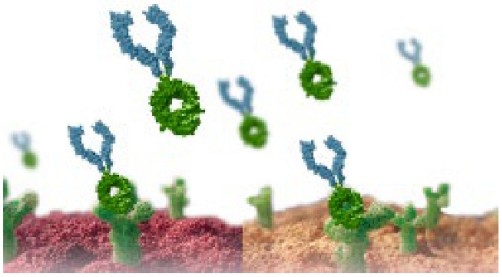
Zackheim. J Am Acad Dermatol. 1999;40:418.

Slide credit: clinicaloptions.com

DIFFERENTIATED MECHANISM OF ACTION (MOA)

LYMPHIR targets the IL-2 receptor, working both as a targeted therapy against malignant T-cells AND as an immunotherapy against Tregs

Malignant T-cells and Tregs share a common marker: the IL-2 receptor



IL-2 receptor offers a unique treatment opportunity in CTCL

Targets Malignant Cells

Binds to IL-2 receptors to deliver diphtheria toxin, killing tumor cells directly

Eliminates Immunosuppressive Tregs

Reduces number of Treg cells, subsequently enhancing anti-tumor immunity

COMPELLING CLINICAL DATA

LYMPHIR addresses CTCL's heavy Quality of Life burden

OBJECTIVE RESPONSE RATE[1]
36%

9% achieved complete response
27% achieved partial response

REDUCED SKIN BURDEN
84.4% ✓

Reduction in skin tumor burden among evaluable patients
48.8% of patients with ≥50% reduction in skin tumor burden[2]

RAPID RESPONSE TIME
1.4 months ✓

Median number of months to achieve an objective response (complete or partial response)

DURABLE RESPONSE
6.5 months

Median months of disease control among patients who responded to E7777[3]

1. Objective Response is Complete Response and Partial Response according to the ISCL/EORTC Global Response Score.
2. In the Primary Efficacy Analysis set, 84.4% (54/64) of skin evaluable subjects had a decrease in skin tumor burden, with 48.4% subjects with ≥50% reduction in skin tumor burden. Complete clearing of skin disease (skin CR) was observed in 12.5% (8/64) subjects.
3. The duration of response (DOR) was at least 6 months for 52% of responders and at least 12 months for 20% of responders (25/69 patients).

DEMONSTRATED SAFETY

Overall, LYMPHIR was well-tolerated with the use of pre-medications, close patient monitoring, and prompt initiation of supportive measures and drug management

- No evidence of cumulative toxicity
- Most patients experienced grade 1/2 treatment emergent adverse events (TEAEs)

CAPILLARY LEAK SYNDROME	**6%**	**Grade ≥3**
INFUSION REACTION	**6%**	**Grade ≥3**
VISUAL IMPAIRMENT	**0%**	**Grade ≥3 loss in visual acuity**

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LYMPHIR's full prescribing information: https://www.lymphirhcp.com/prescribing-information.pdf

OPPORTUNITIES FOR GROWTH BEYOND CTCL

- University of Pittsburgh: an investigator-initiated trial is underway to evaluate LYMPHIR for potential use as an immuno-oncology therapy in combination with KEYTRUDA® in patients with recurrent or metastatic solid tumors (NCT05200559)
  - Encouraging preliminary results of interim analysis:
    - 15 evaluable patients showed 27% ORR; 33% Clinical Benefit Rate; median Progression Free Survival of 57 weeks (for patients that achieved a clinical benefit)
  - The data supports further evaluation of this combination across a broader range of solid tumor types
  - Phase 1 Preliminary study data (n=25) anticipated Q4 2025/Q1 2026

- University of Minnesota: LYMPHIR in combination with CAR T therapies (NCT04855253)
  - Phase 1 study to evaluate the potential benefit of LYMPHIR given prior to CAR T therapy in patients with high risk relapsed/refractory B-cell lymphomas
  - Preliminary study results anticipated Q1 2026

- Logical label expansion potential in PTCL where there is a high unmet need and no curative therapies

Program	Investigational Indication	Preclinical	Phase I	Phase II	Phase III
UNIVERSITY OF PITTSBURG MEDICAL CENTER, HILLMAN CANCER CENTER	COMBINATION WITH PD-1 INHIBITOR (KEYTRUDA®) [1]			Prelim Interim data published	
UNIVERSITY OF MINNESOTA, MASONIC CANCER CENTER	COMBINATION WITH CAR-T (KYMRIAH)[1]				
LYMPHIR-P	PERIPHERAL T-CELL LYMPHOMA				

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1. KEYTRUDA is a registered trademark of Merck & Co., Inc. KYMRIAH is a registered trademark of Novartis Pharmaceuticals Corporation.

LYMPHIR IS COMPETITIVELY POSITIONED

Clinical profile and market dynamics supports market entry

- **Differentiated MOA** targeting the IL-2 receptor reinforces rationale for inclusion among the current core therapeutic options in the U.S. market
- CTCL treatments are **non-curative**, often have a limited duration of response and/or are discontinued early
- Patients are put on multiple alternate therapies and **cycle to 2nd line treatments within 5 months**, on average
- Key growth drivers expected to **increase overall market size** and facilitate market penetration
  - Evolving treatment paradigm; incremental therapeutic option for pre-treated patients
  - Historically, market growth has followed introduction of new therapeutics
  - Competitively priced
  - No new therapy approved since 2018

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COMPETITIVE LANDSCAPE: WHY CHOOSE LYMPHIR?

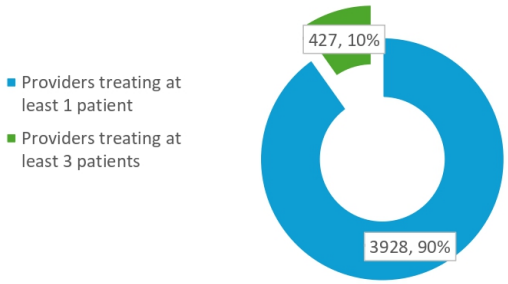
Today's CTCL treatments are non-curative

LYMPHIR excels where current therapies are limited

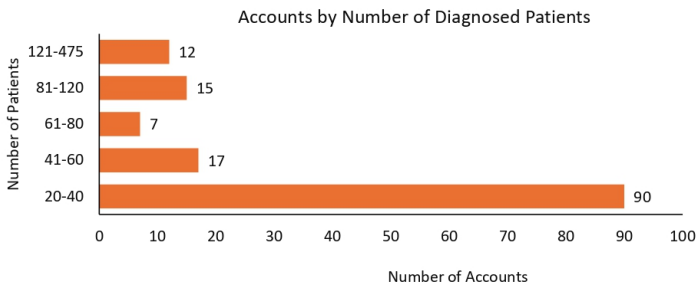
	Limitations	LYMPHIR (denileukin diftitox-cxdl) Injection 300 mcg
ADCETRIS® brentuximab vedotin for injection	• Requires CD30+ biomarker • Peripheral neuropathy may limit use	• No biomarker needed • Broad label • No cumulative toxicity
POTELIGEO® (mogamulizumab-kpkc)	• Most effective in SS subsegment of CTCL (<5%) • Acts on blood disease rather than skin disease • ORR 21% in MF	• Skin relief • Rapid response • No cumulative toxicity
ISTODAX® (romidepsin) for injection 10-MG SINGLE-USE VIAL	• Use limited by cumulative bone marrow toxicity • Quality of life issues	• No cumulative toxicity • Refined patient profile
LYMPHIR™ (denileukin diftitox-cxdl) Injection 300 mcg		

CONCENTRATED PRESCRIBER BASE

10% of Providers (Physicians) Treat ≥3 Patients



141 Accounts Diagnose ≥20 Patients



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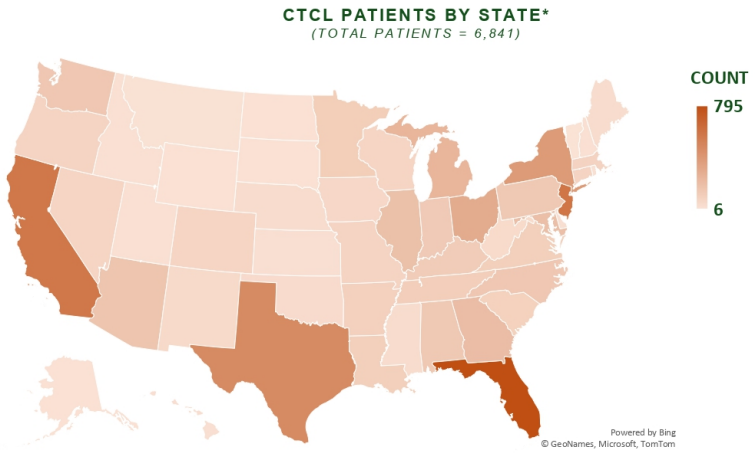
Source: IQVIA Medical (Dx) & Pharmacy (Rx) Claims Data
IQVIA Citius CTCL HCP Targeting Report – September 2022

Patients may be double counted if treated by multiple providers.
Accounts include institutions with multiple prescribing physicians or centers of care.

PATIENT AND HCPS CLUSTERED NEAR MAJOR CANCER CENTERS

60% of CTCL patients are concentrated in 10 states

- Concentration of providers and accounts allows for a focused field force approach (~25 reps)
- AI-driven trigger system will direct the field force to optimize opportunities with providers and patients



* Source: IQVIA Medical (Dx) & Pharmacy (Rx) Claims Data IQVIA Citius CTCL HCP Targeting Report – September 2022. Cumulative Data 2017-2021. Patient State based on patient ZIP 3. US Territories removed from visualization.

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DISTRIBUTION READINESS AND CHANNEL ACCESS

Patient-Centric Distribution Strategy aims to promote timely product availability for eligible CTCL patients across all care settings, reinforcing Citius' commitment to access

- Nationwide U.S. distribution network established
  - All major distribution agreements operational
  - Citius Oncology has executed agreements with Cencora, Cardinal Health, and McKesson to support U.S. distribution of LYMPHIR
  - These partnerships ensure nationwide coverage across academic centers and community clinics
  - Commercial-ready inventory with a 60-month shelf life is in place to meet projected demand 12–18 months post-launch

- Ex-U.S. strategy to leverage country-specific Named Patient Programs
  - Exclusive distribution agreement with Integris Pharma S.A. (Oct 2025)
    - Establishes coverage for 12 markets: Greece, Cyprus, Malta, Bulgaria, Romania, Croatia, Serbia, Albania, Bosnia Herzegovina, Kosovo, Montenegro and North Macedonia
  - Citius Pharma is in active discussions with multiple additional prospective distribution partners across several European Union member states, in South America, and in select Middle Eastern territories

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Solid foundation supporting potential market share ramp in Year 1 with targeted salesforce

Patients

- We plan to target the cohort of U.S. patients with relapsed or refractory CTCL that receive intravenous systemic therapeutics
- Overall U.S. prevalence is estimated to be approximately 3,000[1]

Providers

- Concentrated HCP universe with most prescribers located in major metropolitan centers/major cancer centers
- 427 physicians (10% of providers) treat 3 or more patients

Payers

- Reimbursement expected to be in line with other targeted therapies
- Added to NCCN guidelines
- Unique J-code awarded

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1. JAMA Oncology. 2022 Sep 1;8(11):1690–1692. doi: 10.1001/jamaoncol.2022.3236

MULTI-LAYERED PROTECTION: BARRIERS TO ENTRY

12 years of BLA exclusivity

Complex Proprietary Manufacturing Process

trade secret

2 Patents Pending

LYMPHIR use as combination therapy with check point inhibitors

Orphan Drug Exclusivity (7 years)

ODD designation granted for CTCL and PTCL
(CTCL exclusivity determined upon BLA review)

LYMPHIR is poised for successful launch with potential upside opportunities beyond CTCL

- LYMPHIR is an approved therapy in a rare indication with no curative therapies
- Estimated $400M+ addressable U.S. market1 with potential upside potential driven by expanded indications, immuno-oncology opportunities, and international markets
- Orphan indication with 12-year BLA exclusivity
- First new systemic CTCL therapy since 2018; existing therapies are non-curative
- Concentrated prescriber base: small number of oncologists generate sales volume (~10% or 427 providers treat ≥3 patients)
- Potential market share ramp can be achieved beginning year 1 with a targeted salesforce of ~25 reps
- Launch expected Q4 2025

1. Internal estimates based on IQVIA market research.