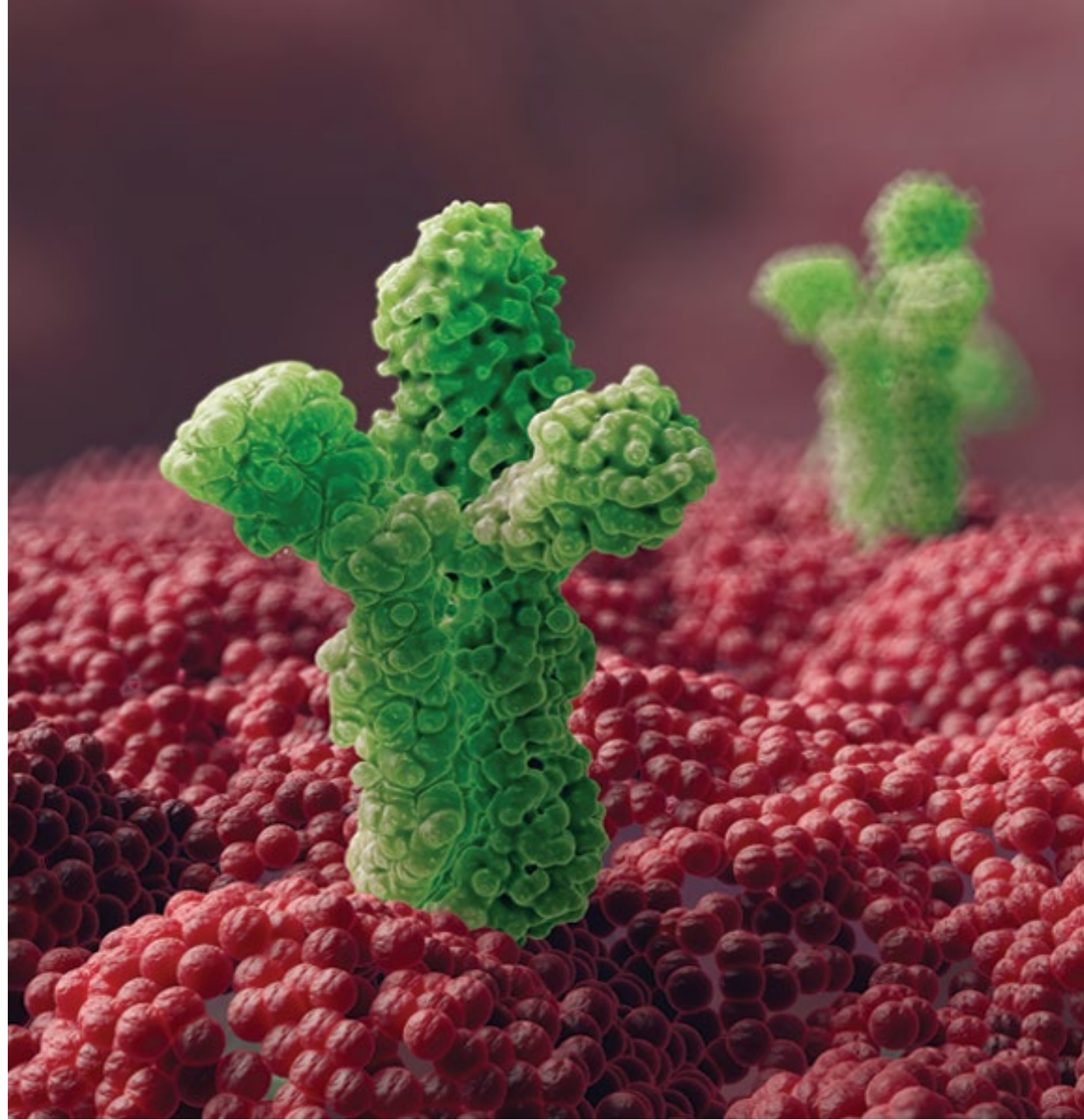




## **CORPORATE OVERVIEW**

**NASDAQ: CTOR**

**FEBRUARY 2025**



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 also includes express and implied forward-looking statements regarding the current expectations, estimates, opinions and beliefs of the Company that are not historical facts. Such forward-looking statements may be identified by words such as “believes”, “expects”, “endeavors”, “anticipates”, “intends”, “plans”, “estimates”, “projects”, “should”, “objective” and variations of such words and similar words. The accuracy of such statements is dependent upon future events, and involves known and unknown risks, uncertainties and other factors beyond the Company’s control that may cause actual results to differ materially from what is presented herein. 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.

## Biopharmaceutical company focused on developing and commercializing innovative targeted oncology therapies

- Majority-owned (~92%) publicly-traded subsidiary of Citius Pharmaceuticals, Inc. (NASDAQ: CTXR)
- Lead product, LYMPHIR™, received FDA approval in August 2024 for the treatment of adult patients with relapsed or refractory Stage I-III cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy
- Orphan indication with 12-year BLA exclusivity
- First new systemic CTCL therapy since 2018
- Estimated \$400M+ addressable U.S. market with significant growth opportunities<sup>1</sup>



1. Internal estimates based on IQVIA market research.

## Commercial launch readiness nearing completion through disciplined financial strategy

- Citius has invested approximately \$90 million in LYMPHIR to date
  - \$40 million          upfront purchase
  - \$43 million          development and precommercial efforts
  - \$5 million          spinout to form Citius Oncology
- Significant pre-commercial activities completed
  - ✓ Manufactured inventory for launch
  - ✓ Negotiated supply chain and contract sales organization 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
- 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

## Ideal market dynamics support significant value creation

- Concentrated prescriber base: small number of oncologists generate significant sales volume
  - Approximately 10% of providers, or 427 physicians, treat  $\geq 3$  patients
- Penetration into the market believed to be achievable with a targeted salesforce of approximately 25 reps
- Compelling clinical profile and market dynamics expected to drive rapid market penetration and significant growth in sales
  - Current CTCL treatments are non-curative
  - LYMPHIR is the only therapy for CTCL with a unique MOA targeting the IL-2 receptor
  - Market research indicates physicians view LYMPHIR favorably as a treatment option
- Substantial upside potential driven by expanded indications, immuno-oncology opportunities, and international markets

## 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



CATHERINE KESSLER  
EVP, REGULATORY AFFAIRS



KELLY CREIGHTON  
EVP, CMC





# **CLINICAL OVERVIEW**

**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**



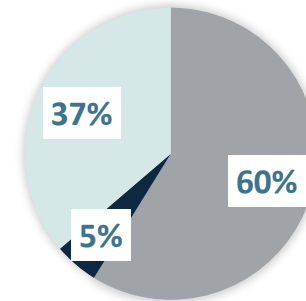
CTCL is a general term for T-cell lymphoma that involves the skin, but may also involve the blood, lymph nodes, and internal organs



CTCL accounts for approximately 4% of all non-Hodgkin lymphoma (NHL)<sup>1</sup>



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



- Mycosis Fungoides
- Sezary Syndrome
- Other CTCL

**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: <https://my.clevelandclinic.org/health/diseases/17940-cutaneous-t-cell-lymphoma> 4. Hristov AC, et al. *Am J Hematol*. 2019;94(9):1027-1041.

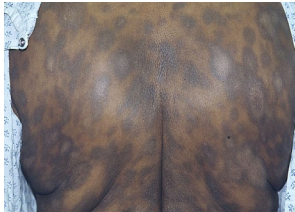


# CTCL PATIENTS HAVE A HIGH DISEASE BURDEN

T1



T2

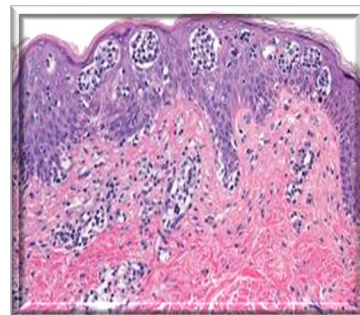


Skin Stage	Description	10-Yr Relative Survival, %
T1	Patches, papules, or plaques covering < 10% of the skin surface	100
T2	Patches, papules, or plaques covering ≥ 10% of the skin surface	67.4
T3	Tumors (≥ 1)	39.2
T4	Generalized erythroderma	41.0

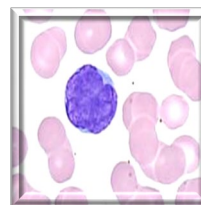
T3



T4



Sézary cell



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

Slide credit: [clinicaloptions.com](http://clinicaloptions.com)

## 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



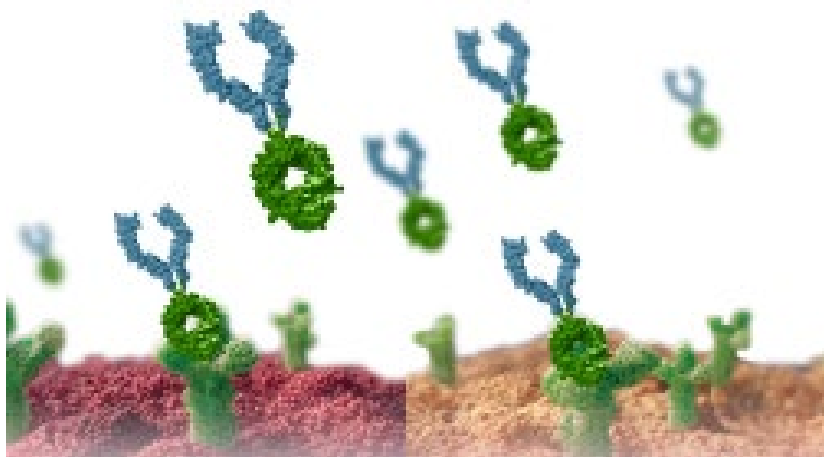
IL-2 receptor offers a unique treatment opportunity in CTCL

### 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



## LYMPHIR addresses CTCL's heavy Quality of Life burden

**OBJECTIVE RESPONSE RATE<sup>1</sup>**

**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  $\geq 50\%$   
reduction in skin tumor burden<sup>2</sup>

**RAPID RESPONSE TIME**

**1.4 months**



Median number of months to  
response among patients who  
experienced clinical benefit  
(complete or partial response)

**DURABLE RESPONSE**

**6.5 months**

Median months of disease  
control among patients who  
responded to E7777<sup>3</sup>

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  $\geq 50\%$  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).

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)

<b>CAPILLARY LEAK SYNDROME</b>	<b>6%</b>	<b>Grade <math>\geq 3</math></b>
--------------------------------	-----------	----------------------------------

<b>INFUSION REACTION</b>	<b>6%</b>	<b>Grade <math>\geq 3</math></b>
--------------------------	-----------	----------------------------------

<b>VISUAL IMPAIRMENT</b>	<b>0%</b>	<b>Grade <math>\geq 3</math> loss in visual acuity</b>
--------------------------	-----------	--

# COMPETITIVE LANDSCAPE



Generic Name	Brentuximab vedotin	Mogamulizumab	Romidepsin
Mechanism of Action	Antibody-drug conjugate that binds to CD30 target, is internalized, and results in tumor cell death	Monoclonal antibody against CC chemokine receptor type 4 (CCR4) that induces antibody-dependent cellular toxicity (ADCC) after binding tumor cells	Histone deacetylase (HDAC) inhibitor (epigenetic MOA; not fully characterized)
Efficacy	<p><b>CR 10%, PR 51.6%, ORR4** 50%; ORR 65%</b></p> <p><b>PFS 16.7 months</b></p> <p><b>DOR 15.1 months</b></p> <p>Median Time to Response: Not Reported</p> <p>Skin Compartment Response: 77%</p> <p>Clinical stage IIB* response: 63%</p>	<p><b>CR 2%, PR 25%, ORR 28%</b></p> <p>PFS 7.7 months</p> <p>DOR 14.1 months</p> <p>Median Time to Response: 3.3 months</p> <p>Skin Compartment Response: 42%</p> <p><b>Clinical stage IIB* response: 17%</b></p>	<p>CR 6%, PR 29%, ORR 35%</p> <p>PFS 8.0 months</p> <p>Median DOR ~ 13 months</p> <p>Median time to CR: 4-6 months</p> <p>Median duration of Rx: 5.6 months</p>
Most Common AEs	Neutropenia, anemia, peripheral sensory neuropathy, fatigue, nausea, pyrexia, rash, diarrhea, and pain in >= 20% subjects	Rash (r/o disease), <b>infusion-related reactions</b> , fatigue, diarrhea, musculoskeletal pain, and upper respiratory tract infection in >= 20% subjects	<b>Nausea, asthenia, myelosuppression, transaminitis, EKG changes, infections in &gt;20%</b> ; Drug dc'ed due to AEs in ~ 15% of patients
Administration/Dosing	IV, 30 min. x 3 weeks <b>up to 12 cycles</b>	IV, 60 min. on days 1, 8, 15, 22 first 28-day cycle; days 1 & 15 of next cycles, up to 12m	IV, 4 hours on days 1, 8, 15 every 28 days until POD or toxicity (significant dose modification needed)
Pros	Highest ORR amongst treatments	High durable responses in Sezary syndrome (<5% of CTCL subtypes)	Moderately active agent
Cons	<p><b># of cycles administered is limited largely by peripheral neuropathy (cumulative toxicity)</b></p> <p><b>Tumor biopsy must be CD30-positive (&gt;=10%)</b></p>	<p>Least effective Rx in Mycosis Fungoides</p> <p>Skin rash (typically with 1<sup>st</sup> cycle); drug rash vs POD may be difficult to discern</p> <p>Cannot be used as a bridge prior to alloSCT</p>	<b>Treatment limited by significant toxicity profile</b> (see AEs above); Cumulative toxicity seen

\*Clinical stage IIB = "Tumor stage" disease (at least one of the skin lesions is a tumor that is 1 cm across or larger)

\*\*ORR4 = ORR lasting = 4 months

ADCETRIS and its logo are US registered trademarks of Seagen Inc.

Prescribing Information: <https://labeling.pfizer.com/ShowLabeling.aspx?id=20629>

POTELIGEO is a registered trademark of Kyowa Kirin Co., Ltd.

Prescribing Information: <https://www.poteligeohcp.com/assets/files/full-prescribing-information.pdf>

©ISTODAX is a registered trademark of Celgene Corporation used under license by Bristol-Myers Squibb Canada.

Prescribing Information: [https://packageinserts.bms.com/pi/pi\\_istodax.pdf](https://packageinserts.bms.com/pi/pi_istodax.pdf)

## Expanded indication potential in peripheral T-cell lymphoma (PTCL)

- First logical label expansion potential would be in PTCL where there is a high unmet need
  - No curative therapies
- Denileukin diftitox has historically shown promising results in PTCL
- Denileukin diftitox-cxdI approved in 2021 for the treatment of PTCL in Japan (Remitorio®)
- PTCL indication could be achieved via a single-arm pivotal trial in the in U.S. for inclusion in NCCN guidelines

## Potential upside opportunity in immuno-oncology

- Differentiated and complementary MOA allows for potential combination with other breakthrough cancer treatments
- Temporarily depleting Tregs is a unique contribution of LYMPHIR for combination with checkpoint inhibitors like KEYTRUDA (the leading drug worldwide) and CAR T therapies
- Two investigator-initiated I/O trials are underway to evaluate LYMPHIR for potential use as an immuno-oncology combination therapy:
  - 1. University of Pittsburgh:** LYMPHIR in combination with KEYTRUDA® in patients with recurrent or metastatic solid tumors (NCT05200559)
    - Phase 1 portion of study nearing completion in patients with solid tumors focusing on gynecological malignant tumors such as ovarian, endometrial, and cervical
    - Highly encouraging preliminary results
    - Well-tolerated chemotherapy-free immunomodulatory regimen with no documented serious immune-related AEs
    - The data supports further research to evaluate this combination across a broader range of solid tumor types
  - 2. 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



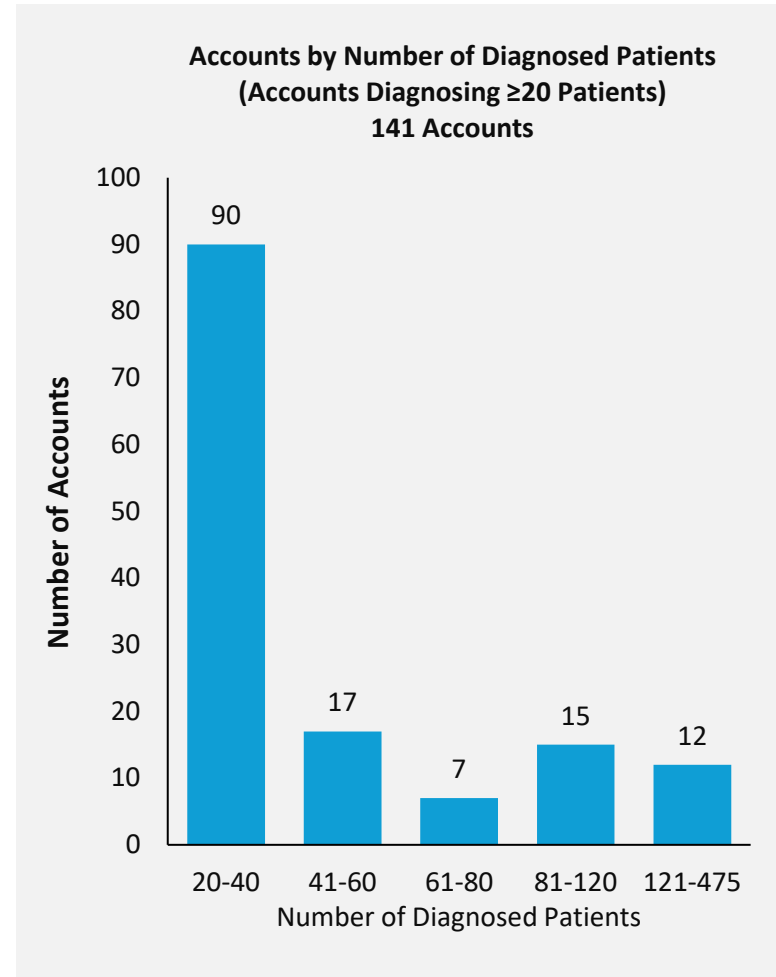
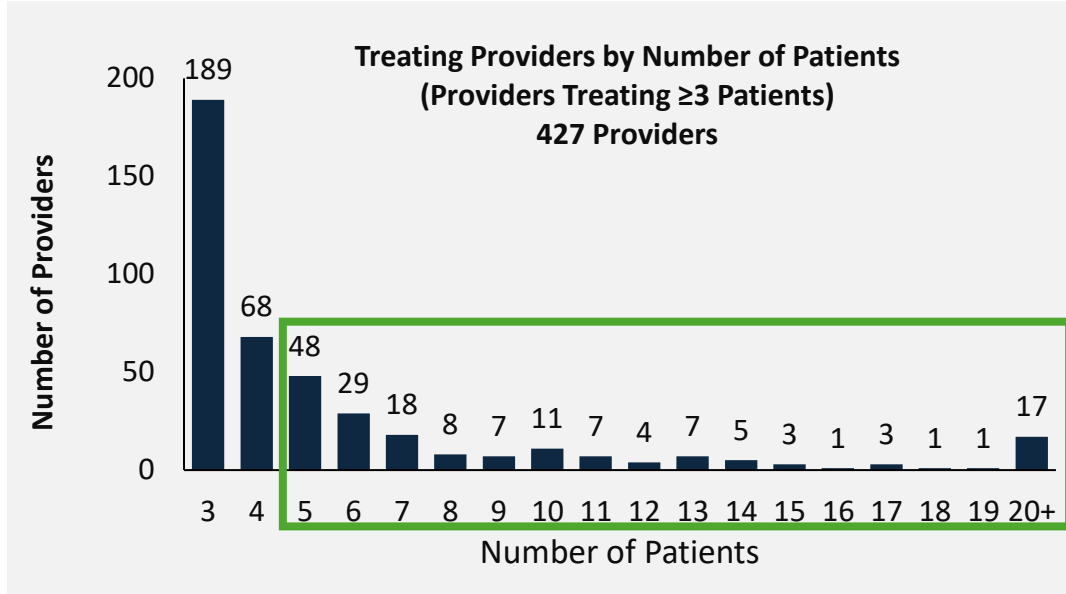
# COMMERCIAL OVERVIEW



## Clinical profile and market dynamics supports market entry

- LYMPHIR's **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

# VERY CONCENTRATED PRESCRIBER BASE



Number of Patients	Number of Providers
Providers Treating at Least 1 Patient	3,928
Providers Treating at Least 3 Patients	427

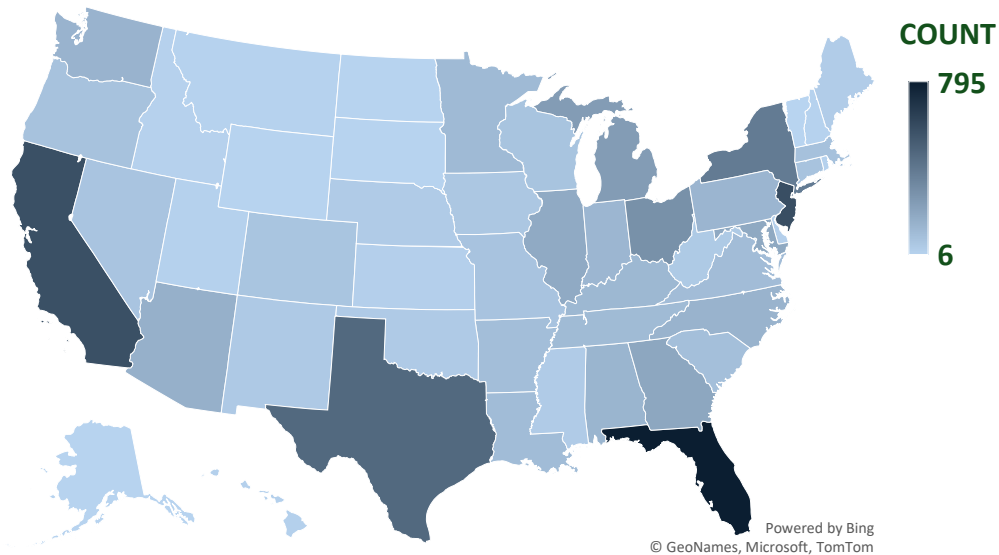
Of all providers who treat patients with CTCL, ~10% treat 3 or more patients

# PATIENT AND HCPS CLUSTERED NEAR MAJOR CANCER CENTER

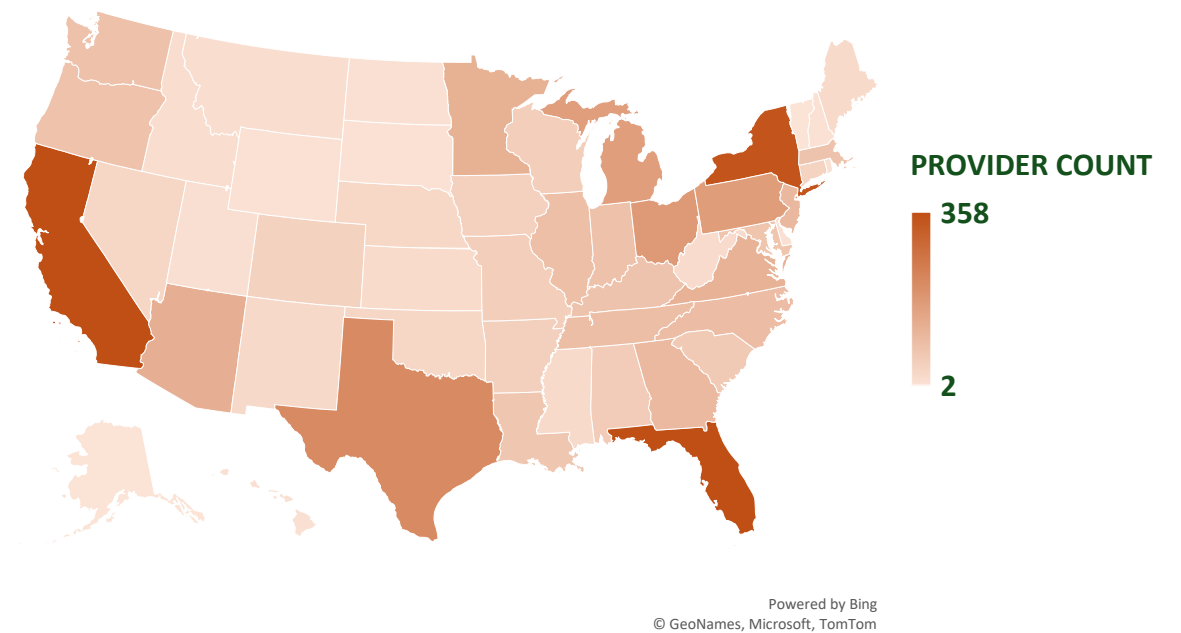
60% of CTCL patients are concentrated in 10 states

Approximately 257 providers treated 4 or more patients with systemic therapy from July 2021 – June 2022

**CTCL PATIENTS BY STATE\***  
(TOTAL PATIENTS = 6,841)



**CTCL PRESCRIBERS BY STATE\***  
(TOTAL HCPS = 3,928)



\* 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.

## IL-2 the Logical Target due to its Dual Mode of Action

**AIM ONCE, STRIKE TWICE**

**LYMPHIR™**  
(denileukin diftitox-cxdl)  
Injection 300 mcg

**MALIGNANT T CELLS**

**EPO**

**IMMUNOSUPPRESSIVE TREGS**

**FDA-approved IL-2R-based immunotherapy for CTCL<sup>1</sup>**

Proven 36% objective response rate (ORR\*) with LYMPHIR in heavily pretreated (median of 4 prior therapies)<sup>†</sup> patients with relapsed or refractory Stage I-III cutaneous T-cell lymphoma (CTCL)<sup>1</sup>

**TARGET THE IL-2 RECEPTOR** ➤ **TREAT CTCL WITH LYMPHIR**

LYMPHIR is indicated for the treatment of adult patients with relapsed or refractory Stage I-III cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy

Achieved a 36% ORR\* in heavily pretreated patients in the pivotal phase III Study 302 (N=69)<sup>1,2,†</sup>

- 68% of responders (n=25) experienced a rapid response within the first 2 treatment cycles (mTTR: 1.4 months)<sup>2</sup>
- 52% of responders maintained their response for ≥6 months<sup>1</sup>
- 84% (54/64) of skin-evaluable patients had a decrease in tumor burden<sup>2</sup>
  - 13% (8/64) saw complete clearing of skin disease
- Displayed no evidence of cumulative toxicity<sup>1</sup>
  - 12% of patients permanently discontinued therapy due to adverse reactions
- Administered as 1-hour IV infusions with an on/off infusion cycle until disease progression or unacceptable toxicity<sup>1</sup>
- 32% of patients (13/41) had pruritus improvement, defined as an absolute decrease of 20 mm from baseline maintained for ≥4 weeks<sup>2</sup>

- **Focused Product launch**
  - **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<sup>1</sup>
  - **Providers:** concentrated HCP universe with most prescribers located in major metropolitan centers/major cancer centers
  - **Payers:** reimbursement expected to be in line with other targeted therapies / added to NCCN guidelines / unique J-code awarded
- **Solid foundation supporting meaningful market share ramp beginning Year 1 (>10%)**
  - Existing therapies are non-curative
  - New therapy with differentiated MOA for rare disease
  - Physicians' prior experience with/awareness of ONTAK

**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)**

- CTOR owned by CTXR ~92%
- Shares outstanding: ~71.6 million
- Public Float: ~3.6 million
- Shared services agreement between CTOR and CTXR

## 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. market with substantial upside potential driven by expanded indications, immunology opportunities, and international markets
- Orphan indication with 12-year BLA exclusivity
- First new systemic CTCL therapy since 2018
- Concentrated prescriber base: small number of oncologists generate significant sales volume (~10% or 427 providers treat  $\geq 3$  patients)
- Rapid market share can be achieved with a targeted salesforce of ~25 reps
- Launch expected 1H 2025





# APPENDIX

## Denileukin Diftitox (1999-2019)

- **1999** – Ligand receives accelerated FDA approval for **Ontak** (Denileukin Diftitox) for the treatment of persistent or recurrent cutaneous T-cell lymphoma (CTCL) in patients with CD25-expressing tumors.
- **2006** – Eisai Co., Ltd. , a Japanese pharmaceutical company, **acquires Ontak** from Ligand
- **2008** – **Full FDA approval** granted to ONTAK
- **1999-2014** – Ontak remains one of few systemic CTCL therapies for **15 years**
- **2011** – Eisai develops a new formulation of denileukin diftitox (**E7777**) in response to FDA guidance at time of accelerated approval, addressing manufacturing and purity concerns
- **2013** – Eisai **begins Phase III trial** for E7777
- **2014** – Eisai **voluntarily withdraws** Ontak from the U.S. market
- **2019** – Eisai **licensed E7777 to Dr. Reddy's Laboratories**, granting them development and commercialization rights outside of Japan and Asia

## Citius Commitment to LYMPHIR – Approx. \$90 million invested to date

- **Citius has invested approximately \$90 million in LYMPHIR to date:**
  - \$40 million           upfront purchase
  - \$43 million           development and precommercial efforts
  - \$5 million            spinout to form Citius Oncology
- **2021 (September)** – Citius Pharmaceuticals acquires exclusive license to E7777 from Dr. Reddy's Laboratories
- **2021 (December)** – Eisai completes Phase III clinical trial
- **2022 (September)** – Citius submits BLA for E7777 (LYMPHIR)
- **2023 (July)** – FDA issues complete response letter (CRL)
- **2024 (February)** – Citius resubmits LYMPHIR BLA following remediation of FDA mfg concerns
- **2024 (August)** – Citius receives FDA approval for LYMPHIR; spins out LYMPHIR into Citius Oncology, a stand-alone publicly traded company (Nasdaq: CTOR)
- **2024** – Citius prepares for commercial launch:
  - manufactures inventory for launch and clinical supplies to support ongoing investigator-initiated immuno-oncology clinical studies
  - Negotiates supply chain and contract sales organization agreements
  - Secures new permanent j-code and inclusion of LYMPHIR in NCCN guidelines
  - Develops targeted machine learning trigger system for salesforce to identify potential patients
  - Initiates marketing strategy to raise brand awareness



# THANK YOU

Citius Oncology, Inc.

Nasdaq: CTOR

[www.citiusonc.com](http://www.citiusonc.com)

Investor Relations: [ir@citiusonc.com](mailto:ir@citiusonc.com)

