



**Citius Oncology, Inc.**  
**SPAC Business Combination Overview**

**October 2023**



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# TRANSACTION OVERVIEW

## Transaction Summary

- On October 23, 2023, Citius Pharmaceuticals, Inc. (Nasdaq: CTXR) (“Citius Pharma”) signed a Definitive Agreement to merge its wholly owned subsidiary with TenX Keane Acquisition (Nasdaq: TENK) (“TenX”) to form publicly listed Citius Oncology, Inc. (“Citius Oncology”)
- Anticipated closing in 1H 2024

## Ownership Structure<sup>1</sup>

- 100% of the shares of Citius Pharma’s subsidiary will be rolled into Citius Oncology in exchange for \$675mm in equity
- Citius Pharma expected to own ~90% and TenX expected to own ~10% of Citius Oncology

## Transaction Rationale

- Creates standalone publicly-traded oncology company with improved access to the U.S. capital markets and an attractive platform for an investor base with specific interest in LYMPHIR™
- Enables resources to be focused on the commercialization of LYMPHIR and other pipeline initiatives
- Public company-ready management and board

## Capitalization

- At closing, Citius Oncology capitalized with \$10M in cash from Citius Pharma, in addition to any remaining cash from TenX’s trust
- Commercialization of lead licensed drug candidate LYMPHIR and development of pipeline
- Working capital and general corporate purposes

## Attractive Entry Point

- Anticipated 2024 commercial launch supports potential for significant value creation
- Opportunity to be valued in line with commercial stage oncology peers



1. TenX and Citius Pharma negotiated and set the Base Exchange Ratio based on their assumptions about the value of Citius Oncology following the merger. Assumes de minimis redemptions by TenX public holders and \$10m from Citius Pharma’s balance sheet.

# CITIUS ONCOLOGY HIGHLIGHTS

## Unique Oncology Platform

- LYMPHIR formulation developed by Eisai and marketed in Japan as Remitorio® since 2021; Citius Oncology to control global marketing rights excluding certain East Asian countries
- If approved, LYMPHIR offers a unique mechanism of action for the treatment of cutaneous T-cell lymphoma (CTCL)
- Potential for follow up indication in Peripheral T-cell lymphoma (PTCL); Investigator-led studies ongoing in combination with CAR-T (Kymriah®) and PD-1 Inhibitor (Keytruda®)

## Public Ready, Funded Opportunity

- LYMPHIR licensed by Citius Pharma in 2021; \$40mm upfront payment and an additional \$15mm funded to date
- Upon closing of the business transaction, Citius Oncology to be funded with \$10mm of cash by Citius Pharma, in addition to any cash remaining in TenX trust at closing

## Anticipated Commercial Launch in 2H 2024

- Anticipated positive cash flow commencing within first year of product launch
- 2018 launch of competitive product Poteligeo by Kyowa Kirin indicates unmet need in CTCL given existing therapies are non curative

## Significant Opportunity

- CTCL market estimated to be \$300-\$400+ million
- Potential for substantial growth via additional indications including PTCL and combinations with immunotherapy
- Multiple potential future product in-licensing opportunities identified

## Robust IP Portfolio

- Assuming approval, BLA exclusivity + Orphan drug designation + complex technology + trade secrets provide IP protections
- Patents pending for immuno-oncology use as a combination therapy with checkpoint inhibitors

## Seasoned Management

- Citius Oncology management has extensive expertise in developing and marketing oncology products
- Track record of successfully bringing pharmaceuticals to market
- Services agreement between Citius Pharma and Citius Oncology to maintain continuity in execution of clinical and commercial program



## ATTRACTIVE PRODUCT PROFILE



- LYMPHIR is a recombinant engineered fusion protein that combines interleukin-2 and diphtheria toxin
- Phase 3 Pivotal trial results are consistent with the prior formulation, and clinical profile supports the potential for rapid adoption
- Filed as an original BLA, LYMPHIR may be eligible for reference product exclusivity (12 years marketing exclusivity)
- Manufacturing & distribution agreements with leading global players



1. See slide 11, payment to be made by Citius Pharma (parent) prior to closing of the business combination.

# OVERVIEW OF TENX KEANE ACQUISITION

Over 80+ years of global professional investing, capital markets, M&A, life sciences and operating experience



XIAOFENG YUAN  
CHAIRMAN & CEO



TAYLOR ZHANG  
CHIEF FINANCIAL  
OFFICER



CATHY JIANG  
DIRECTOR



JOEL MAYERSOHN  
DIRECTOR



BRIAN HARTZBAND  
DIRECTOR



TenX completed its \$66M IPO in October 2022



# CITIUS ONCOLOGY MANAGEMENT OVERVIEW - SHARED MANAGEMENT AGREEMENT WITH CTXR

## Key management personnel mitigate execution risk and leverage proven industry track record



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



# CITIUS ONCOLOGY BOARD OF DIRECTORS



LEONARD MAZUR  
CHAIRMAN



MYRON HOLUBIAK  
EXECUTIVE VICE CHAIRMAN



SUREN DUTIA  
DIRECTOR



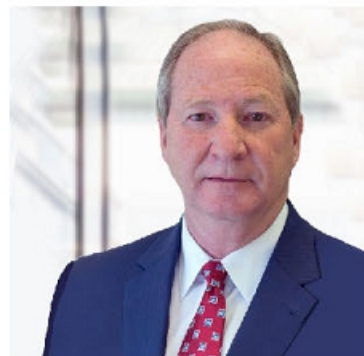
JOEL MAYERSOHN  
DIRECTOR



DR. EUGENE HOLUKA  
DIRECTOR



CAROL WEBB  
DIRECTOR

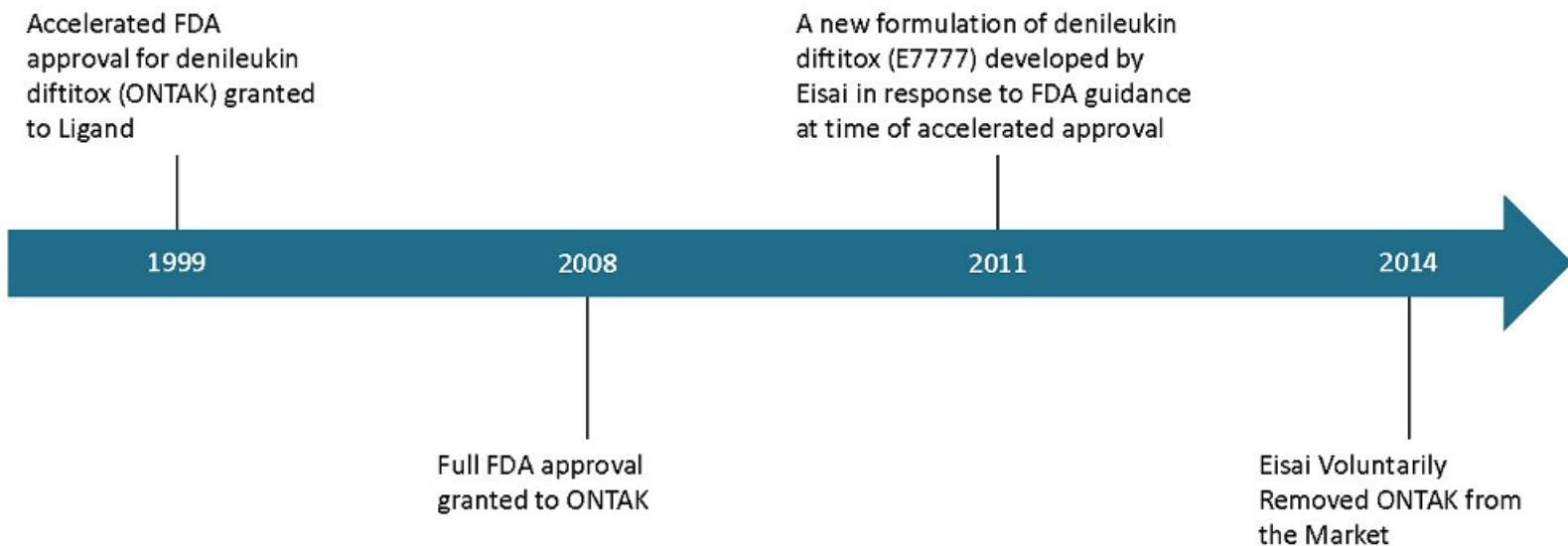


DENNIS MCGRATH  
DIRECTOR



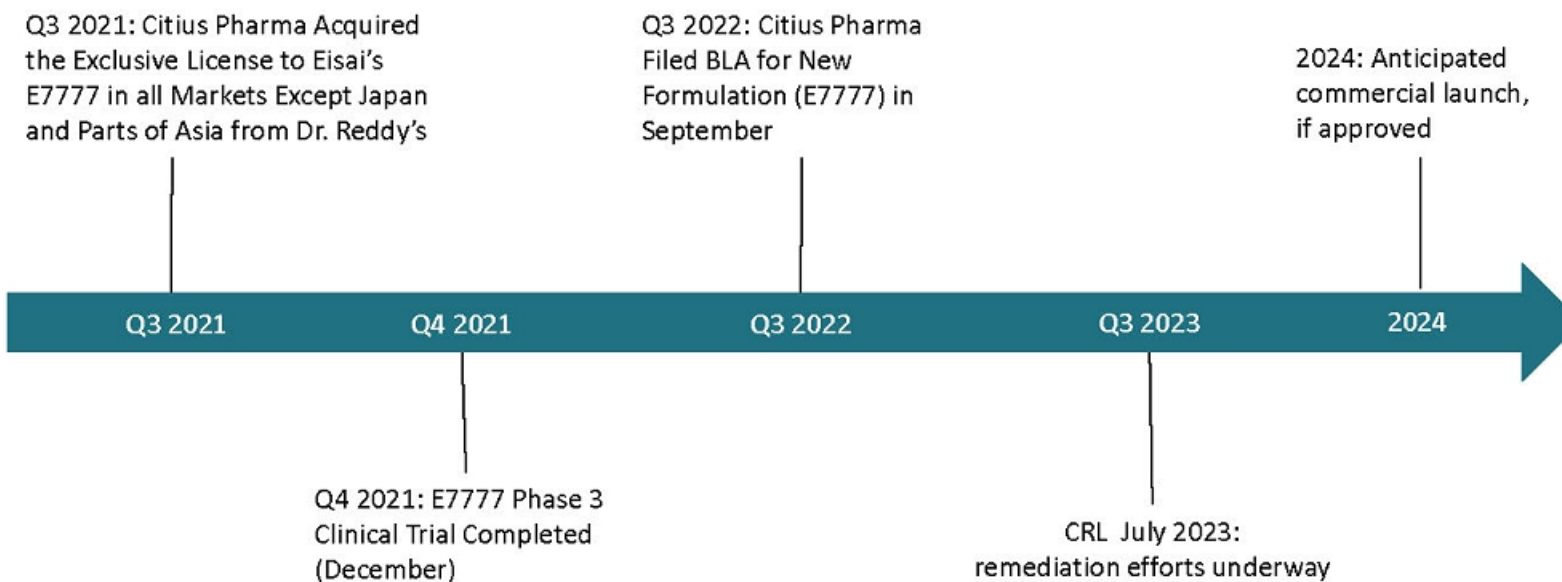
## ORIGINS OF ONTAK

- ONTAK was FDA approved and commercially available in the U.S. between 1999 – 2014
- LYMPHIR (E7777) was developed by Eisai in 2011 as a purified and more bioactive formulation in response to a post marketing commitment agreed to with the FDA upon approval of ONTAK
- Eisai voluntarily removed ONTAK from the market in 2014



## LYMPHIR LICENSING AND FDA PATHWAY

- September 2021 Citius Pharma acquired the exclusive license to Eisai's E7777 (LYMPHIR)
- December 2021 Phase 3 clinical trial completed
- September 2022 Citius Pharma submitted a BLA for E7777 (LYMPHIR)
- July 2023 FDA issues complete response letter (CRL);  
Citius Pharma planning resubmission with remediation efforts underway



# LYMPHIR PIPELINE & OPPORTUNITIES BEYOND CTCL

PROGRAM	INVESTIGATIONAL INDICATION	PRECLINICAL	PHASE I	PHASE II	PHASE III
LYMPHIR-P <sup>1</sup>	PERIPHERAL T-CELL LYMPHOMA				

COLLABORATIONS AS IMMUNO-ONCOLOGY THERAPIES

UNIVERSITY OF MINNESOTA, MASONIC CANCER CENTER	COMBINATION WITH CAR-T (KYMRIAH <sup>®</sup> ) <sup>2</sup>				
UNIVERSITY OF PITTSBURGH MEDICAL CENTER, HILLMAN CANCER CENTER	COMBINATION WITH PD-1 INHIBITOR (KEYTRUDA <sup>®</sup> ) <sup>2</sup>				

Multiple potential future product in-licensing opportunities identified

1. We intend to explore a phase 3 clinical development pathway for an indication in PTCL.
2. KYMRIAH is a registered trademark of Novartis Pharmaceuticals Corporation. KEYTRUDA is a registered trademark of Merck & Co., Inc.



## LYMPHIR LICENSE AGREEMENT



- Exclusive license of Eisai's cancer immunotherapy LYMPHIR (E7777)
- Initial indication in cutaneous T-cell lymphoma (CTCL)
- Additional potential indications in peripheral T-cell lymphoma (PTCL) and immuno-oncology



- Assigned exclusive license to Citius Pharma for all markets excluding China, Japan and certain parts of Asia; with option for India
- Completed CTCL Pivotal Phase 3 trial work through BLA filing



- \$40 million upfront cash payment to Dr. Reddy's (DRL)
- Development and commercial milestone payments to DRL and Eisai including \$33.5 million FDA approval milestone payment
- Tiered royalties to DRL on net product sales



# WHAT IS CUTANEOUS T-CELL LYMPHOMA (CTCL)?



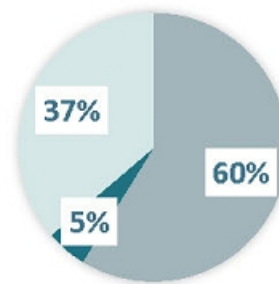
Considered to be incurable, CTCL is a general term for T-cell lymphoma that involves the skin, but may also involve the blood, lymph nodes, and internal organs



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)\*



- Mycosis Fungoides
- Sezary Syndrome
- Other CTCL



Plaque Stage



Tumor Stage



## WHY LYMPHIR?

### Near-term revenue opportunity for an oncology asset with a unique MOA

**Developed for the treatment of cutaneous T-cell lymphoma (CTCL)**

Improved formulation of previously FDA-approved drug (ONTAK); marketed 1999-2014

**Orphan indication with market estimated at \$300-\$400+M**

Market dynamics support new entrant

**No curative therapeutics on the market**

CTCL is a painful disease; current therapies are non-curative and often have limited duration of response or are discontinued early

**Concentrated prescriber base**

Supports targeted launch strategy

**Multi-layered market protections**

Potential marketing exclusivity and complex manufacturing process

**Promising upside potential**

Indicated for PTCL in Japan; 2 investigator-initiated trials in immunology underway (in combination with PD-1 checkpoint inhibitor pembrolizumab (KEYTRUDA®) and CAR-T therapy (KYMRIAH®))



# DIFFERENTIATED MECHANISM OF ACTION (MOA)

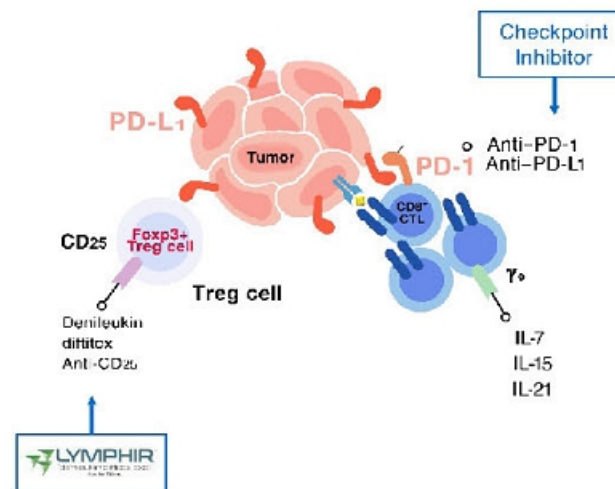
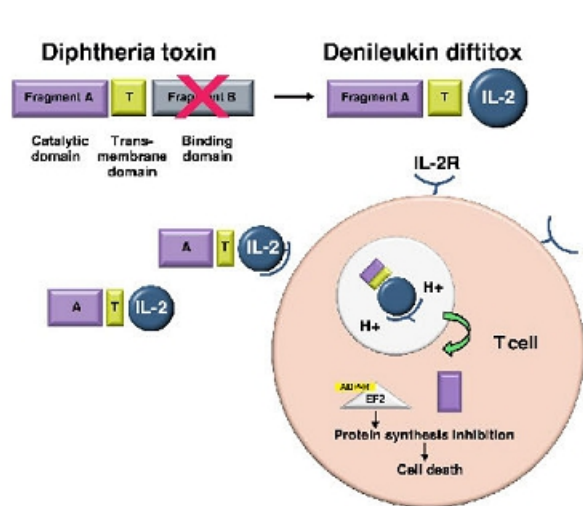
**LYMPHIR (denileukin diftitox) is an engineered IL-2-diphtheria toxin fusion protein with a unique mechanism of action supporting two therapeutic effects**

## Targets Malignant Cells

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

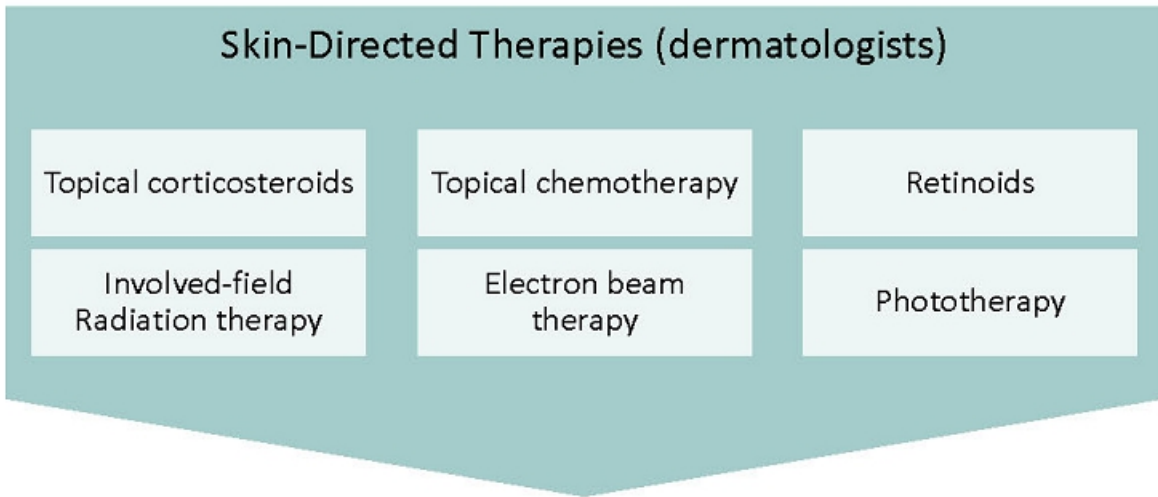
## Eliminates Immunosuppressive Tregs

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

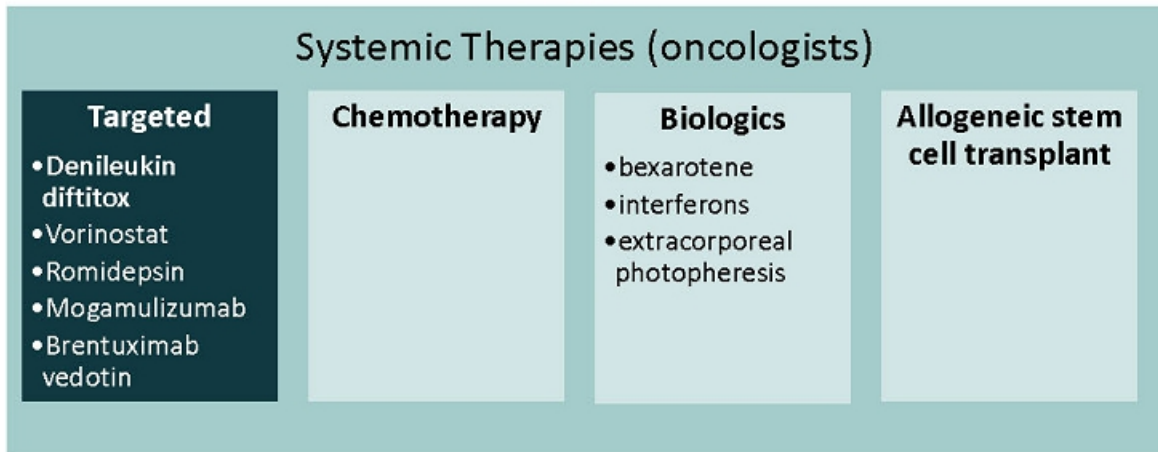


# PATIENT JOURNEY: TOPICAL TO SYSTEMIC TREATMENT







**Early-stage CTCL commonly treated with “skin-directed” therapies by dermatologists**



**Advanced CTCL, typically treated by oncologists, has a limited number of FDA-approved “targeted” therapies**



## COMPETITIVE LANDSCAPE

		MOA	Approval Date
 ADCETRIS® brentuximab vedotin   for injection	 Seagen®	CD30 antigen directed <sup>1</sup>	November 2017
 POTELIGEO® (mogamulizumab-kpkc)	 YOWA KIRIN	CCR4 targeted <sup>2</sup>	August 2018
 ISTODAX® (romidepsin) <sup>for injection</sup> 10-MG SINGLE-USE VIAL	 Bristol Myers Squibb™	HDAC inhibitor <sup>3</sup>	November 2009

- 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 other approved therapy since 2018



1. CD30 - cell membrane protein of the tumor necrosis factor receptor superfamily (TNFRSF) and a tumor marker.
2. CCR4 - C-C chemokine receptor type 4 is a protein that in humans is encoded by the CCR4 gene.
3. HDAC - Histone deacetylase inhibitors are believed to induce death, apoptosis, and cell cycle arrest in cancer cells.

## LYMPHIR PHASE 3 TRIAL (STUDY 302): COMPLETED

**Pivotal, multicenter, open-label, single-arm study of LYMPHIR in subjects with persistent or recurrent CTCL**

All subjects were diagnosed with Mycosis Fungoides or Sézary Syndrome, with tumors assessed as positive for expression of the CD25 subunit of the IL-2 receptor



- A total of 69 subjects with Stage I-III persistent or recurrent CTCL from the Lead-In and Main Studies were included in the Primary Efficacy Analysis Set
- Single trial as agreed to with FDA

## STUDY 302: PHASE 3 CLINICAL TRIAL RESULTS

**LYMPHIR demonstrated meaningful benefits for trial patients who had previously been treated**

<b>36.2%</b> 95% CI (25%, 48.7%)	<b>ORR</b> (Objective Response Rate) <sup>1,2</sup>
<b>49%</b>	Nearly half of patients on the trial experienced a complete response, partial response or durable stable disease
<b>4</b>	Median number of prior therapies of patients participating in the study

1. Primary Efficacy Analysis Set includes 69 Stage I-III CTCL subjects from the Lead-In Study and the Main Study who received a dose of 9 ug/kg/day of study drug. Two subjects were considered by the Independent Review Committee to have Stage IV CTCL and excluded from the Primary Efficacy Analysis Set. This dataset matches the patient population used for the ONTAK indication.
2. Objective Response is Complete Response and Partial Response, according to the ISCL/EORTC Global Response Score (Olsen 2011). According to the trial protocol, the treatment would be considered efficacious and demonstrate clinical benefit if the lower limit of the 2-sided 95% exact confidence interval (CI) of the observed ORR exceeds 25.0%, as determined by the Independent Review Committee (IRC). In this study, the IRC determined the study achieved an ORR of 36.2%, 95% confidence interval (25.0%, 48.7%) (25 patients out of 69).



## MEANINGFUL RESPONSE IN CTCL PATIENTS

More than half of responders in the trial had at least six months of improved or controlled disease

### 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>1</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 controlled disease among patients who responded to E7777<sup>2</sup>

1. 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.
2. 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).



## NO NEW SAFETY SIGNALS

**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 low grade 1/2 treatment emergent adverse events (TEAEs)

**CAPILLARY LEAK  
SYNDROME**

**6%**

**Low rate of Grade  $\geq 3$  capillary leak syndrome at 9 $\mu$ g**

**INFUSION  
REACTION**

**6%**

**Limited infusion site reaction**

**VISUAL  
IMPAIRMENT**

**0%**

**No Grade  $\geq 3$  loss in visual acuity observed during the trial**

# MULTI-LAYERED PROTECTION: HIGH BARRIERS TO ENTRY

**Complex Proprietary  
Manufacturing Process**  
trade secret

**May be eligible for BLA  
exclusivity of 12 years  
upon approval**

**2 Patents Pending**  
  
**LYMPHIR use as  
combination therapy with  
check point inhibitors**

**Orphan Drug Exclusivity  
(7 years)**  
  
**ODD designation granted  
for CTCL and PTCL  
(exclusivity determined  
upon BLA review)**



# ROBUST SUPPLY CHAIN

Manufacturing and distribution strategic vendor relationships with leading global providers to support seamless product launch and ongoing commercialization needs

**BDS<sup>1</sup>  
Manufacturing**



- Global network with major U.S. presence
- Leading CDMO in biologics
- 30+ years of mfg. expertise

**BDS<sup>1</sup> Storage**



- Experts in cold chain-of-custody logistics
- Commercial biorepository with experience in management of domestic and international shipments

**Drug Product  
Manufacturing**



- Specialize in manufacturing cytotoxic drug products for oncology
- Proven worldwide regulatory compliance record

**Commercial  
Packaging &  
Labeling**



- World renown CDMO
- Experts in commercial packaging
- Experienced in DSCSA compliance

1. BDS = bulk drug substance.



## A LARGER MARKET OPPORTUNITY IN PTCL

### High unmet need with strong KOL and clinical support for indication in PTCL

- Denileukin diftitox approved for PTCL in Japan in 2021
- Only 3 branded FDA–approved therapies in the US – Adcetris, Beleodaq and Fofotyn
- Denileukin diftitox has historically shown promising results in PTCL
- ODD granted by FDA to LYMPHIR for PTCL
- Next steps: engage with FDA to determine optimal regulatory path forward

<b>2006</b>	Phase 2 safety and efficacy of ONTAK in 27 patients	48% ORR 61% ORR in patients with CD25+ tumor Median PFS: 6 months
<b>2013</b>	Multicenter Phase 2 study of ONTAK + CHOP (concept trial in 49 patients at 15 US sites)	65% ORR Median duration of response was 30 months Median PFS: 12 months
<b>2016-2019</b>	Study 205: Pivotal study to support J-NDA (45 patients) NCT02676778	41% ORR Approved for PTCL in Japan in 2021



# MORE OPPORTUNITIES FOR GROWTH

## PTCL expanded indication potential

- Eisai’s E7777 is already approved for the treatment of Peripheral T-Cell Lymphoma (PTCL) in Japan (Remitoro®)
- Would require clinical trial in U.S. designed as a single-arm pivotal study

## Upside opportunity in immuno-oncology

- Two investigator-initiated trials are underway to evaluate LYMPHIR for potential use as an immuno-oncology combination therapy

<p>LYMPHIR in combination with KEYTRUDA® in patients with recurrent or metastatic solid tumors (NCT05200559)</p>	<p>Collaboration with the University of Pittsburgh</p>
<p>LYMPHIR given prior to lymphodepletion chemotherapy and CAR T therapies for the treatment of relapsed/refractory B-cell lymphomas considered at a high risk for failure from KYMRIA® alone (NCT04855253)</p>	<p>Collaboration with the University of Minnesota</p>



KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.  
 KYMRIA® is a registered trademark of Novartis AG, Basel, Switzerland.

## MERGER CONSIDERATION AND PRO FORMA OWNERSHIP

- Citius Pharma to receive \$675 million in equity of Citius Oncology, or 67.5 million shares at an implied value of \$10 per share
- An additional 12.75 million in equity options will be assumed by Citius Oncology
- At closing, \$10 million in cash provided by Citius Pharma and any cash remaining in TenX's trust account would be contributed to Citius Oncology to support operations and planned commercialization efforts
- Pro forma ownership of Citius Oncology<sup>1</sup>:
  - ~90% Citius Pharma
  - ~10% TenX public shareholders and founders



1. TenX and Citius Pharma negotiated and set the Base Exchange Ratio based on their assumptions about the value of Citius Oncology following the merger. Assumes de minimis redemptions by TenX public holders and \$10m from Citius Pharma's balance sheet.

# ACCELERATED GROWTH AS A STANDALONE PUBLIC COMPANY

Citius Oncology is primed for growth as a standalone public entity

- 1 Commercial Launch** → Near-term revenue potential 2H 2024
- 2 Clear Market Opportunity** → High unmet need in CTCL implies rapid adoption
- 3 Drivers for Growth Beyond CTCL** → PTCL, combinations with CAR-T & PD-1s and multiple potential future product in-licensing opportunities



# CITIUS ONCOLOGY HIGHLIGHTS

**A Unique Oncology Platform**

**Anticipated Commercial Launch in 2H 2024**

**Significant Market Opportunity**

**Robust IP Portfolio**

**Seasoned Management**

**Attractive Entry Point With Growth Potential**





# APPENDIX





## TRIALS AND PUBLICATIONS

- A Clinical Study to Demonstrate Safety and Efficacy of LYMPHIR® in Persistent or Recurrent Cutaneous T-Cell Lymphoma [Link to clinicaltrials.gov](#)
- Safety and Tolerability of LYMPHIR® (improved purity Denileukin diftitox [ONTAK]) in Patients with Relapsed or Refractory Cutaneous T T-cell Lymphoma: Results from Pivotal Study 302 [View Poster](#)

# LYMPHIR SINGLE PIVOTAL TRIAL IN CTCL DESIGN

<b>PIVOTAL TRIAL DETAILS</b>	Global, multicenter, open label single arm pivotal clinical trial for the treatment of patients with persistent or recurrent CTCL	<b>Inclusion Criteria:</b> <ul style="list-style-type: none"> <li>- CTCL (MF or SS)</li> <li>- CD25+</li> <li>- Stage IA-IVA</li> <li>- At least 1 prior CTCL therapy</li> <li>- ECOG PS <math>\geq</math>2</li> <li>- Visceral metastasis and prior denileukin diftitox therapy excluded</li> </ul>
<b>2 PHASES</b>	<b>Lead In: Completed</b> FPI: May 2013 LPO: Aug 2015	<b>Subjects: N=21</b> Dose finding by CRM: 6,9,12,15mcg/kg/d IV for 5 consecutive days in 21 day cycle PK and immunogenicity
	<b>Pivotal Study: Completed</b> FPI: Jun 2016 LPO: Dec 2021	<b>Subjects: N=71</b> Dose: <b>9 mcg/kg/d IV</b> for 5 consecutive days in 21 day cycle PK and immunogenicity
<b>OBJECTIVES</b>	<b>Primary:</b> ORR (Olsen 2001) <sup>1</sup>	<b>Secondary:</b> Overall DOR, TTR Skin RR, DOR, TTR ORR (Prince 2010) <sup>2</sup> PK and immunogenicity



1. Objective Response is Complete Response and Partial Response, according to the ISCL/EORTC Global Response Score (Olsen 2001).
2. To assess ORR for LYMPHIR<sup>®</sup> using the alternate response assessment criteria of Prince (2010).

## LYMPHIR AND ONTAK: CTCL CLINICAL TRIAL SUMMARY

Study Design	Dose (µg/kg/d) / N	Product / Study Status (Year)	Result
Phase 1/2 open label, dose-escalation study in CD25 positive subjects with CTCL	3 to 31 IV N=35	ONTAK / Complete (1998)	<ul style="list-style-type: none"> <li>37% ORR (14% CR, 23% PR)</li> </ul>
Phase 3 double blind randomized study to evaluate efficacy, safety and PK in CD25 positive subjects with stage IB to IVA CTCL	9 or 18 IV N=71	ONTAK / Complete (2001)	<ul style="list-style-type: none"> <li>30% ORR (10% CR, 20% PR)</li> <li>36% ORR for 18mcg, 23% ORR for 9mcg</li> <li>Median duration of response: 7 months</li> <li>32% stable disease</li> </ul>
Phase 4 double-blind, placebo-controlled study to evaluate efficacy and safety in CD25 positive subjects with Stage 1a to III CTCL	Placebo Active 9 or 18 IV N=144	ONTAK / Complete (2010)	<ul style="list-style-type: none"> <li>44% ORR (10% CR, 34% PR)</li> <li>38% ORR for 9mcg, 49% ORR for 18mcg and 16% for placebo</li> <li>Progression Free Survival 26 months</li> <li>Stable disease 35%</li> </ul>
Open label, single arm study to demonstrate efficacy and safety in CD25 positive subjects with Stage I to III CTCL	9 Lead in phase N=21 Main phase N=71	LYMPHIR® / Complete (2021)	<ul style="list-style-type: none"> <li>36.2% ORR (8.7% CR, 27.5% PR)</li> <li>9mcg/g does was selected for the main phase by the Protocol Steering Committee based on safety, tolerability and efficacy data</li> <li>No new safety signals identified with LYMPHIR compared to ONTAK</li> </ul>



## Citius Oncology, Inc. SPAC Business Combination Overview

Copies of relevant documents filed or that will be filed with the SEC by Citius Oncology, Inc. may be obtained through the website maintained by the SEC at [www.sec.gov](http://www.sec.gov) or by contacting Citius Pharmaceuticals or TenX