Citius Pharmaceuticals, Inc.

(NASDAQ: CTXR)

Corporate Summary

FEBRUARY 2024

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INVESTMENT HIGHLIGHTS

1 Diversified Pipeline: Building a Biotech Platform

- LYMPHIR™: purified reformulation of IL-2 diphtheria toxin fusion protein for CTCL[1] **(P3 completed)**
- Mino-Lok®: potential to be **first and only** FDA-approved product to salvage infected CVCs causing CRBSI/CLABSI **(P3 completed)**
- Halo-Lido: potential to be **first and only** FDA-approved Rx therapy for hemorrhoids **(P2b completed)**

2 Attractive Multi-billion $ Global Market Opportunities

- CTCL market est. $300-$400+M with larger potential in PTCL and immuno-oncology (I/O)
- CRBSI/CLABSI market est. >$1.8B worldwide
- Rx hemorrhoid market est. >$2B US

3 Healthy Financial Platform

- $20.3M cash as of 12/31/23 with runway through August 2024
- $26.5 million invested by insiders

4 Anticipated Value Driving Catalysts

- Mino-Lok Phase 3 trial topline results expected 2Q 2024
- LYMPHIR BLA resubmitted February 2024; 2H 2024 commercialization expected if approved

1. LYMPHIR™ has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed brand name for I/ONTAK (E7777).

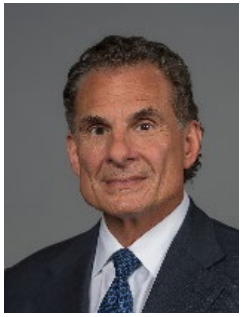
MANAGEMENT TEAM WITH PROVEN TRACK RECORD

LEONARD MAZUR
CHAIRMAN, CEO & CO-FOUNDER

MYRON HOLUBIAK
VICE CHAIRMAN & CO-FOUNDER

JAIME BARTUSHAK
EVP, CFO & CBO

DR. MYRON CZUCZMAN
EVP, CHIEF MEDICAL OFFICER



GARY TALARICO
EVP, OPERATIONS

KELLY CREIGHTON
EVP, CMC

CATHERINE KESSLER
EVP, REGULATORY AFFAIRS

NIK BURLEW
EVP, QUALITY ASSURANCE

JAY WADEKAR
SVP, BUSINESS STRATEGY

DR. ALAN LADER
SVP, CLINICAL OPERATIONS

MINO-LOK

Phase 3

MINO-LOK OVERVIEW

Phase 3 Trial topline data anticipated in 2Q 2024

- First and Only antibiotic lock therapy under investigation to sterilize and salvage infected Central Venous Catheters (CVCs)
- Mino-Lok seeks to address the complications, discomfort and cost of CVC removal and replacement
- Positive Phase 2 data indicated strong safety and efficacy signal
- Phase 3 Trial: multi-center, randomized, open label, blinded assessor, active control superiority study
  - Enrollment completed December 2023; data analysis underway
  - Topline results expected 2Q 2024
  - 241 patients enrolled; 109 catheter failure events observed
  - Clinical sites in US and India
  - Primary Endpoint: Comparison of Time to Catheter Failure Event (TOC = 6 weeks)

LATE-STAGE PRODUCT CANDIDATE: MINO-LOK

First and Only antibiotic lock therapy under investigation to sterilize and salvage infected Central Venous Catheters (CVCs)

7 Million

Central Venus Catheters (CVCs) used annually in the U.S.*

4 Million

Long-term CVCs (>1 month) in the U.S.

~500,000

CRBSI/CLABSI infections annually in the U.S.**

12-25%

CRBSI/CLABSI associated mortality & morbidity**

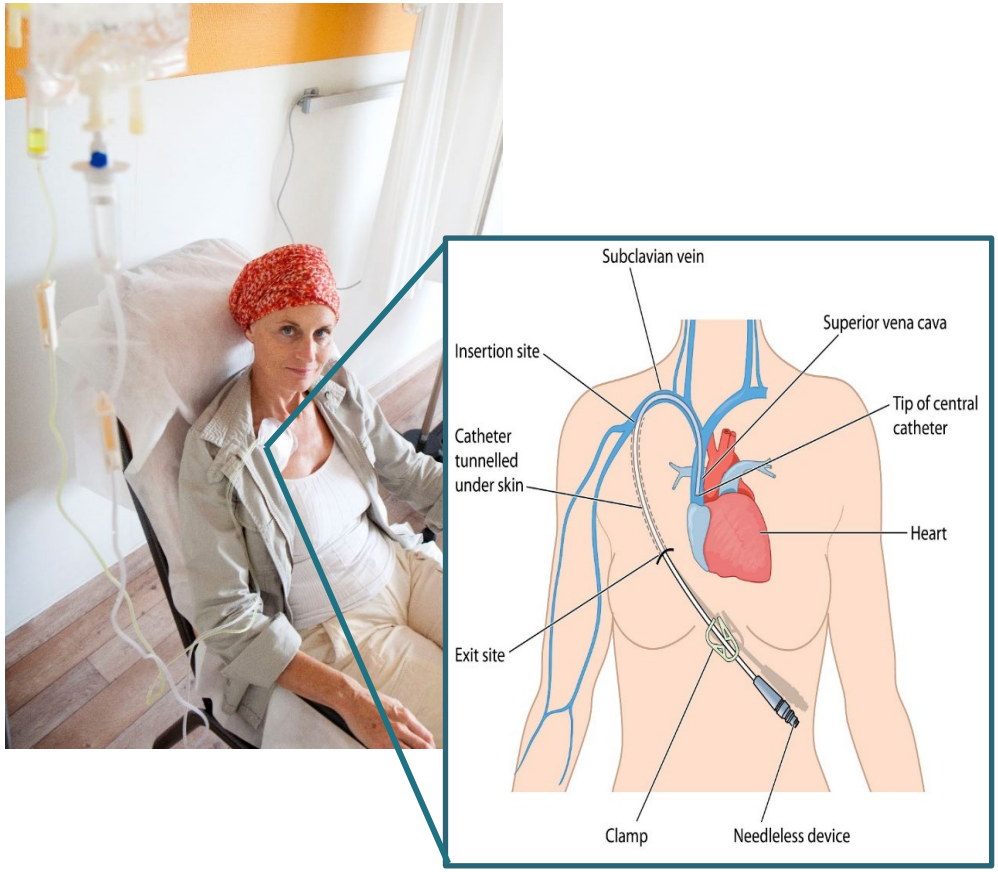
* Shah H., Bosch W., Hellinger W. C., Thompson K. M. (2013). Intravascular catheter-related bloodstream infection. Neurohospitalist 3, 144–151. doi: 10.1177/1941874413476043.

** Antoňáková Němčíková A, Bednárovská E. Catheter-related bloodstream infections: do we know all of it? Klin Onkol. 2017;30(6):405–411. doi: 10.14735/amko2017405.

CURRENT STANDARD OF CARE IS A POOR OPTION

Multiple challenges to removing and replacing infected CVCs

- Limited availability of other vascular sites
- Infusion therapy interrupted
- Potential for complications
  - infectious, thrombotic and mechanical
- 57%-67% of patients experience adverse physical and psychological symptoms from catheter R&R*
- High cost
  - ~$10K cost of R&R procedure
  - $46K-$65K cost of CRBSI/CLABSI episode



* Chaftari, AM et al,. Unnecessary Removal of CVCs in Cancer Patients with CRBSI: Impact on Symptom Burden. Poster presentation at ID Week 2017, Infectious Diseases Society of America (IDSA)Oct 04 - 08, 2017

POTENTIAL GOLD STANDARD IN CLABSI TREATMENT

Mino-Lok addresses the complications, discomfort and cost of CVC removal and replacement

- ✓ Limited duration IV therapy

2 HRS × 5-7 DAYS

- ✓ Limits disruption of infusion therapy
- ✓ Ease of Administration: Locking a catheter is a well-known standard operating procedure
- ✓ Not flushed into the venous system
- ✓ Lowers risks to patient
- ✓ Lower cost alternative: significantly less than removal and replacement

MINO-LOK PHASE 2B TRIAL RESULTS

Mino-Lok® demonstrated a strong safety and efficacy signal

100% Effective in salvaging CVCs in all patients treated with Mino-Lok

100% Patients treated with Mino-Lok all had complete microbiologic eradication with no relapse

0% No SAEs in patients treated with Mino-Lok®

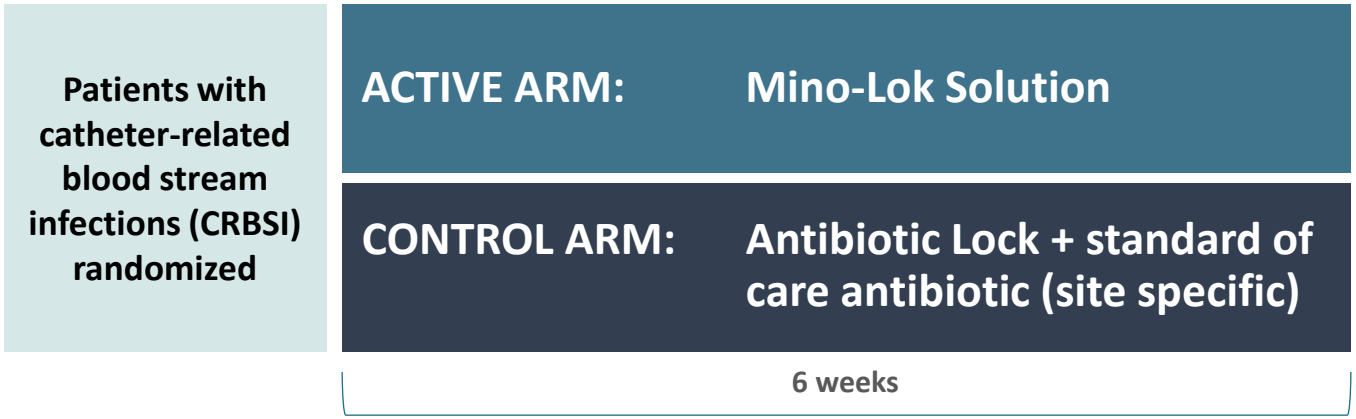
0% Complication rate for Mino-Lok patients was 0% vs. 18% for control arm patients

Parameter	Mino-Lok Arm		Control Arm	
	N	%	N	%
Patients	30	100%	60	100%
Cancer Type				
- Hematologic	20	67%	48	80%
- Solid tumor	10	33%	12	20%
ICU Admission	4	13%	4	7%
Mech. Ventilator	3	10%	-	0%
Bacteremia				
- Gram+	17	57%*	32	53%
- Gram -	14	47%*	28	47%
Neutropenia (<500)	19	63%	36	60%
Microbiologic Eradication	30	100%	60	100%
- Relapse	-	0%	3	5%***
Complications	-	0%	8	13%
SAEs related to R&R	-	0%	6	10%
Overall Complication Rate	**-**	**0%**	**11****	**18%**

*1 polymicrobial patient had Gr+ and Gr – organism cultured; ** 6 patients had >1 complication; ***all 3 CVCs were removed within 1 month.

MINO-LOK PHASE 3 PIVOTAL TRIAL COMPLETED

Multi-center, randomized, open label, blinded assessor, active control superiority study



- Primary Endpoint: Comparison of Time to Catheter Failure Event (TOC = 6 weeks)
- Interim Analyses: DMC recommended proceeding with trial without modification following 3 reviews
- Clinical trial sites in the U.S. and India
- Trial completed with 241 patients enrolled; 109 catheter failure events observed

IP & REGULATORY PROTECTIONS

Robust intellectual property portfolio with protection through 2036

Qualified Infectious Disease Product (US)

- Priority Review reduces NDA review time from 12 to 6 months
- Additional 5 years of market exclusivity upon approval, combined with Hatch-Waxman

Fast Track Designation (US)

- Expedites review of drugs which treat a serious or life-threatening condition and fills an unmet medical need
- Rolling review allows for completed sections of the New Drug Application (NDA) to be submitted when ready

Supplementary Protection Certificate (EU)

- Extends patent protection up to 5 years

LYMPHIR (I/ONTAK, E7777)

LYMPHIR OVERVIEW

IL-2R cancer immunotherapy; recombinant engineered fusion protein that combines interleukin-2 and diphtheria toxin to treat cutaneous T-cell lymphoma (CTCL); Approved for CTCL in Japan

Purified reformulation of denileukin diftitox (ONTAK®), which was previously approved by the FDA for persistent or recurrent CTCL; marketed from 1999-2014 when it was voluntarily removed

In 2021, Citius acquired the exclusive license to Eisai's E7777 (LYMPHIR) in all markets except Japan and parts of Asia from Dr. Reddy's

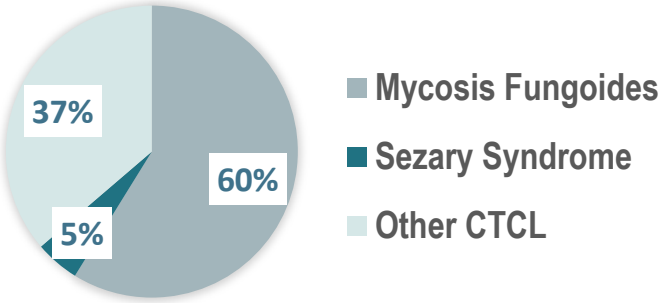
Results from the Phase III clinical trial were consistent with data from ONTAK studies; no new safety concerns were identified

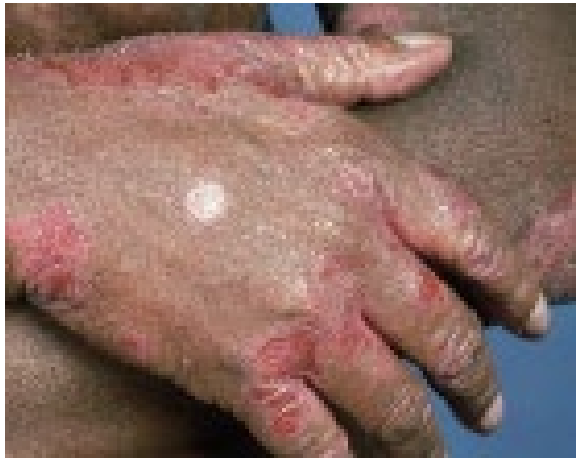
WHAT IS CUTANEOUS T-CELL LYMPHOMA (CTCL)?

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

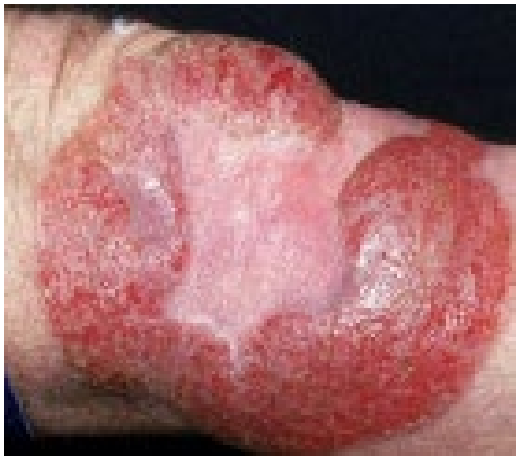
More prevalent in men than women and usually appears in patients in their 50s and 60s

CTCL accounts for approximately 4% of all non-Hodgkin lymphoma (NHL)*





Plaque Stage



Tumor Stage

Source: Company estimates.

DIFFERENTIATED MECHANISM OF ACTION (MOA)

LYMPHIR's differentiated mechanism of action supports 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

COMPETITIVE LANDSCAPE

- Since CTCL treatments are non-curative and often have a limited duration of response and/or are discontinued early, patients are put on multiple alternate therapies
- LYMPHIR's differentiated MOA reinforces rationale for inclusion among the current core therapeutic options in the U.S. market

CITIUS PHARMA

LYMPHIR (E7777)
(denileukin diftitox)

Differentiated MOA targets IL-2 receptor

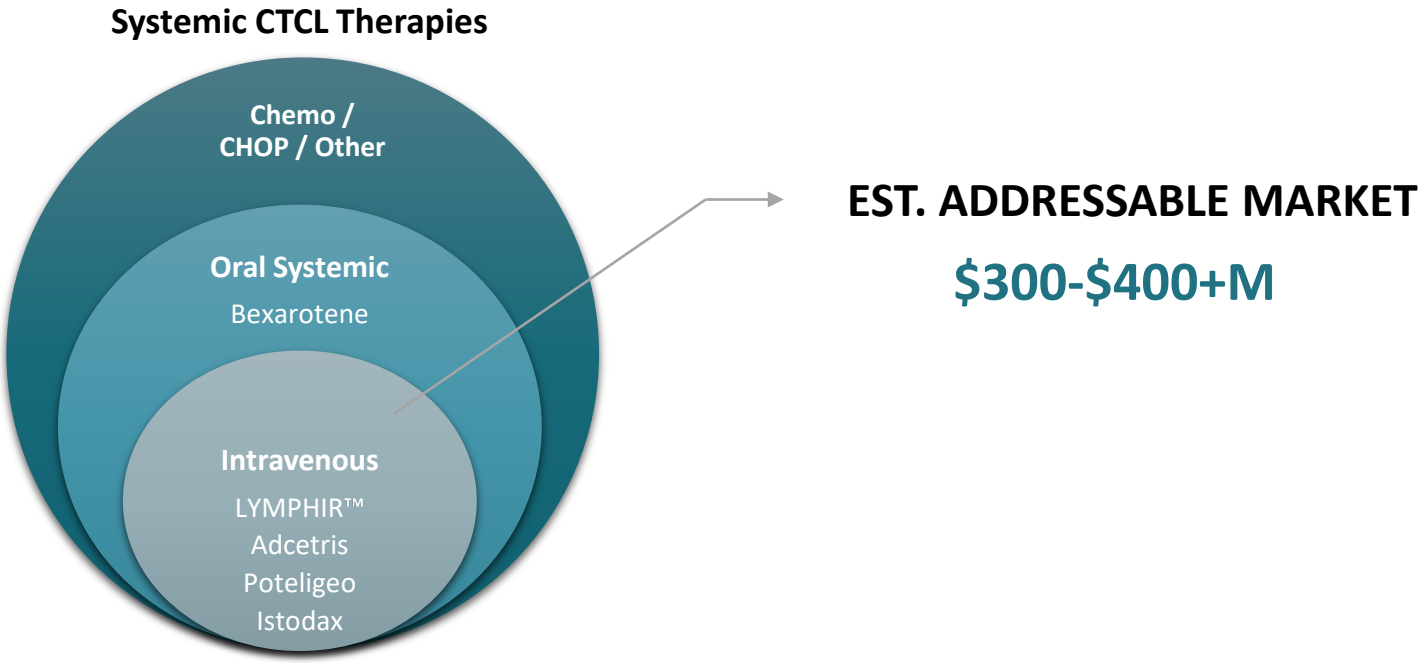
Potential to be additive to market

Brand	Marketed By	MOA
ADCETRIS® brentuximab vedotin for injection	Seagen®	CD30 antigen directed
POTELIGEO® (mogamulizumab-kpkc)	KYOWA KIRIN	CCR4 targeted
ISTODAX® (romidepsin) for injection 10-MG SINGLE-USE VIAL	Bristol Myers Squibb™	HDAC inhibitor

LYMPHIR™ expected to be included among core targeted systemic therapy options

MARKET OPPORTUNITY

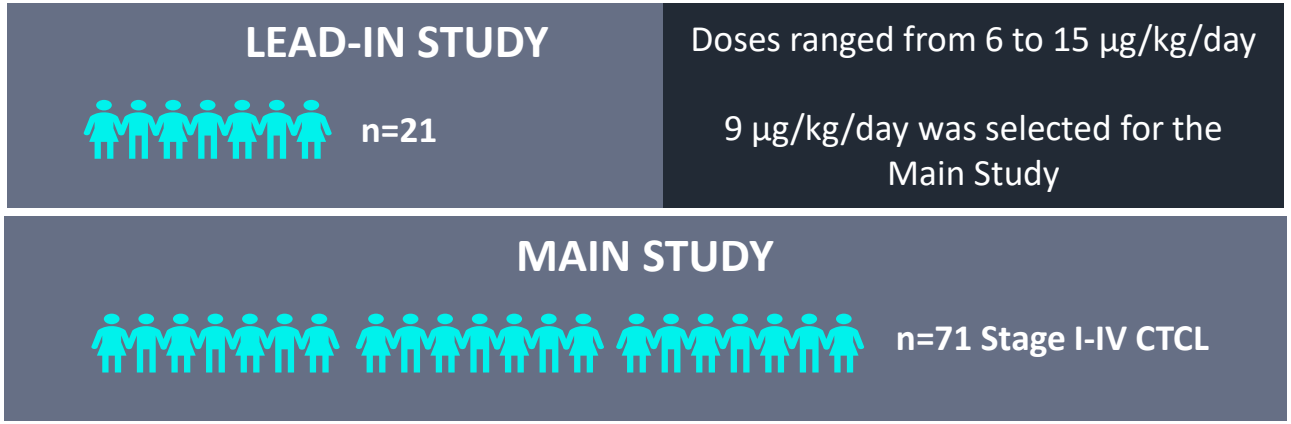
- Estimated U.S. market size for LYMPHIR in CTCL is $300-$400+ million
- Key growth drivers expected to increase overall market size and facilitate market penetration
  - Evolving treatment paradigm; incremental therapeutic option for pre-treated patients
  - Historically, market growth has followed introduction of new therapeutics
  - Competitively priced



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

STUDY 302: PHASE 3 CLINICAL TRIAL RESULTS

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

36.2% 95% CI (25%, 48.7%)	**ORR** (Objective Response Rate)[1,2]
49%	**Nearly half of patients on the trial experienced a complete response, partial response or durable stable disease**
4	**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 previously approved 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 ≥50% reduction in skin tumor burden[1]

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[2]

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 ≥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

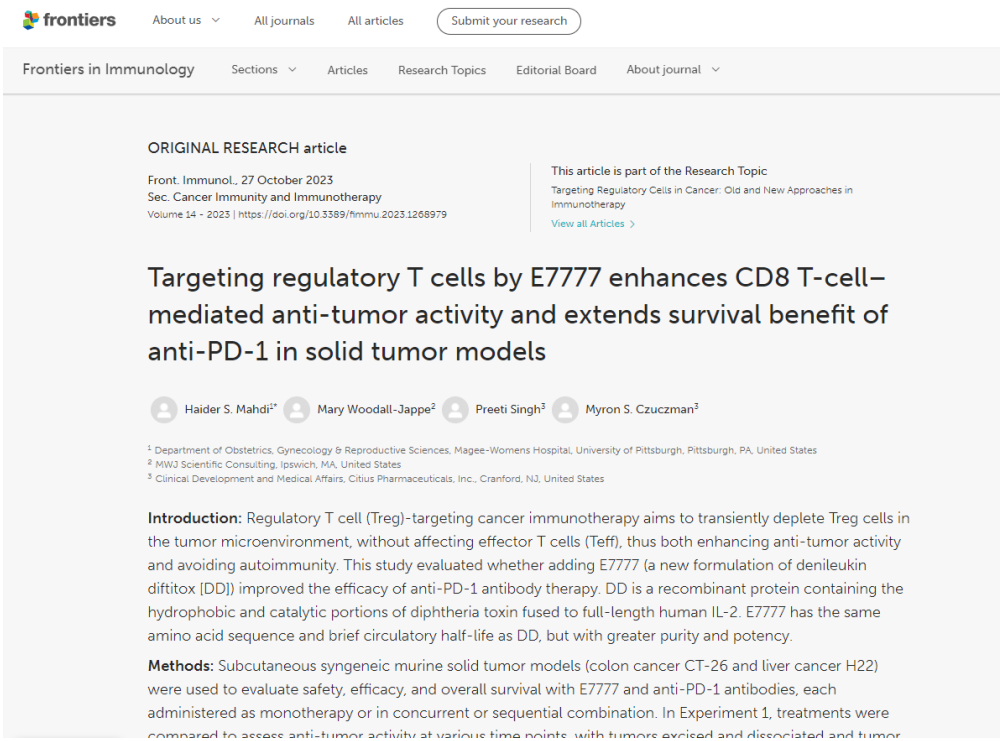
- No evidence of cumulative toxicity
- Most patients experienced low grade 1/2 treatment emergent adverse events (TEAEs)

CAPILLARY LEAK SYNDROME	**6%**	**Low rate of Grade ≥3 capillary leak syndrome at 9µg**
INFUSION REACTION	**6%**	**Limited infusion site reaction**
VISUAL IMPAIRMENT	**0%**	**No Grade ≥3 loss in visual acuity observed during the trial**

PRECLINICAL DATA SIGNALS POTENTIAL IN I/O

Preclinical study: adding LYMPHIR to anti-PD-1 treatment augments anti-tumor activity and improves overall survival compared to monotherapy

Published in Peer-Reviewed *Frontiers in Immunology*[1]



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ORIGINAL RESEARCH article

Front. Immunol., 27 October 2023
Sec. Cancer Immunity and Immunotherapy
Volume 14 - 2023 | https://doi.org/10.3389/fimmu.2023.1268979

This article is part of the Research Topic
Targeting Regulatory Cells in Cancer: Old and New Approaches in Immunotherapy
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Targeting regulatory T cells by E7777 enhances CD8 T-cell–mediated anti-tumor activity and extends survival benefit of anti-PD-1 in solid tumor models

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[2] MWJ Scientific Consulting, Ipswich, MA, United States
[3] Clinical Development and Medical Affairs, Citius Pharmaceuticals, Inc., Cranford, NJ, United States

Introduction: Regulatory T cell (Treg)-targeting cancer immunotherapy aims to transiently deplete Treg cells in the tumor microenvironment, without affecting effector T cells (Teff), thus both enhancing anti-tumor activity and avoiding autoimmunity. This study evaluated whether adding E7777 (a new formulation of denileukin diftitox [DD]) improved the efficacy of anti-PD-1 antibody therapy. DD is a recombinant protein containing the hydrophobic and catalytic portions of diphtheria toxin fused to full-length human IL-2. E7777 has the same amino acid sequence and brief circulatory half-life as DD, but with greater purity and potency.

Methods: Subcutaneous syngeneic murine solid tumor models (colon cancer CT-26 and liver cancer H22) were used to evaluate safety, efficacy, and overall survival with E7777 and anti-PD-1 antibodies, each administered as monotherapy or in concurrent or sequential combination. In Experiment 1, treatments were compared to assess anti-tumor activity at various time points, with tumors excised and dissociated and tumor

Key Study Results

- LYMPHIR + anti-PD-1
  - Demonstrated significant anti-tumor activity, and
  - Consistently targeted and transiently depleted Tregs
- Combination treatment was more effective than monotherapy
- Combination therapy was well-tolerated and significantly enhanced long-term survival in solid tumor-bearing animals
- Informed design of investigator-initiated trials at Univ. of Minnesota and University of Pittsburgh

1.Mahdi, H. Woodall-Jappe, M., Singh, P., Czuczman, S., Targeting Regulatory T cells by E7777 enhances CD8 T-cell-mediated anti-tumor activity and extends survival benefit of anti-PD-1 in solid tumor models. *Frontiers in Immunology.* (Published online ahead of print, 2023 October 27).

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 as an immuno-oncology combination therapy

LYMPHIR in combination with KEYTRUDA® in patients with recurrent or metastatic solid tumors (NCT05200559)	Collaboration with the University of Pittsburgh
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 KYMRIAH® alone (NCT04855253)	Collaboration with the University of Minnesota

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

ATTRACTIVE MARKET DYNAMICS

NO CURATIVE THERAPEUTICS ON THE MARKET	Current therapies are non-curative and often have limited duration of response
CONCENTRATED PRESCRIBER BASE	Supports targeted launch strategy
MULTI-LAYERED MARKET PROTECTIONS	Potential marketing exclusivity and complex manufacturing process
PROMISING UPSIDE POTENTIAL	Approved for PTCL in Japan; 2 investigator-initiated trials in immuno-oncology underway; ex-US licensing opportunities

CITIUS ONCOLOGY

- Anticipated oncology-focused publicly-traded carve-out of CTXR; led by seasoned executive team from CTXR via shared management agreement

- To be formed via planned merger with TenX Keane Acquisition (SPAC) expected 1H 2024
  - To unlock value of oncology business which we believe is not currently priced into company valuation
  - To facilitate greater access to capital markets for oncology business
  - Citius Pharmaceuticals (Nasdaq: CTXR) to receive $675M in shares of Citius Oncology and retain ~90% equity

- BLA for lead asset, LYMPHIR, resubmitted February 2024; 2H 2024 commercialization planned, if approved

- ~$300-$400+M estimated addressable U.S. market with additional growth opportunities; historically, new market entrants have expanded the size of the market

HALO-LIDO

Halobetasol/Lidocaine

HALO-LIDO OVERVIEW

1

Potentially the first FDA-approved prescription product to treat hemorrhoids

- 10+ Million patients report symptoms of hemorrhoidal disease; 1/3 seek physician treatment[1]
- A cream formulation containing halobetasol propionate (highly potent steroid) and Lidocaine HCl
- Phase 2b enrollment completed April 2023
  - 5 cohorts of 60 subjects each
  - Primary endpoint: reduction in hemorrhoidal symptoms
  - Subject self-reported using proprietary mobile app (PRO)
- Positive Phase 2b results
  - Meaningful reduction in symptom severity when compared to individual components alone
  - Dose for Phase 3 trial selected
  - Trial validates Patient Reported Outcome (PRO) instrument developed to support a pivotal Phase 3 study
  - End of Phase 2 meeting with the FDA expected 2Q 2024

1. Source: https://www.mayoclinic.org/medical-professionals/digestive-diseases/news/hemorrhoidal-disease-diagnosis-and-management/mac-20430067

SUMMARY

WHY INVEST? WHY NOW?

Diversified late-stage pipeline with near-term catalysts

LYMPHIR

- ✓ BLA resubmitted February 2024
- If approve, anticipated launch in 2H 2024
- Spin-out

MINO-LOK

- ✓ Phase 3 trial completion
- Topline results anticipated 2Q 2024

HALO-LIDO

- End of Phase 2 meeting with FDA
- Potential for monetization through partnerships

Healthy Financial Platform with cash runway through August 2024

- $20.3 M cash as of 12/31/23
- $26.5 M invested by founders

PRINCIPAL INSIDER SHAREHOLDERS (1)	
LEONARD MAZUR	11%
MYRON HOLUBIAK	3%

CURRENT CAPITALIZATION(2)	SHARES	% OF FULLY DILUTED
BASIC SHARES OUTSTANDING	158,966,576	70.0%
WARRANTS	50,704,847	22.3%
OPTIONS	17,390,171	7.7%
FULLY DILUTED SHARES OUTSTANDING	**227,061,594**	**100%**

(1) Beneficial stock ownership as calculated under rules of the SEC as filed with the Citius Def 14 A Proxy Statement in January 2024 and based on 158,966,576 shares outstanding as of January 19, 2024.
(2) As of December 31, 2023.