Citius Pharmaceuticals, Inc.

(NASDAQ: CTXR)

CORPORATE PRESENTATION

JUNE 2024

FORWARD-LOOKING STATEMENTS

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INVESTMENT HIGHLIGHTS

Late-stage biopharmaceutical company with multiple advanced development programs

Diversified Pipeline with late-stage assets

Mino-Lok® to salvage infected catheters causing CLABSI; Phase 3 trial completed in 2024

LYMPHIR™ [1] for the treatment of cutaneous T-cell lymphoma (CTCL); BLA under review by the FDA

Halo-Lido, the only Rx therapy under development for hemorrhoids; Phase 2b trial completed in 2023

Attractive Multi-billion $ Global Market Opportunities

CRBSI/CLABSI market est. >$1.8B worldwide

CTCL market est. $300-$400+M with larger potential in PTCL and immuno-oncology (I/O)

Rx hemorrhoid market est. >$2B US

2024 Momentum

Achieved primary and secondary endpoints in Mino-Lok Phase 3 trial

LYMPHIR BLA accepted with PDUFA August 13, 2024

LYMPHIR Q4 2024 commercialization expected, if approved

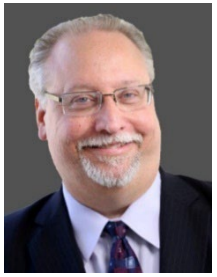
Planned spin-off of oncology subsidiary to form stand-alone publicly traded company

MANAGEMENT TEAM WITH PROVEN TRACK RECORD

LEONARD MAZUR
CHAIRMAN
CEO & CO-FOUNDER

MYRON HOLUBIAK
VICE CHAIRMAN
& CO-FOUNDER

JAIME BARTUSHAK
EVP, CFO & CBO



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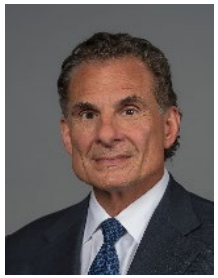
EVP, CHIEF MEDICAL
OFFICER



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CATHERINE KESSLER
EVP, REGULATORY AFFAIRS

NIK BURLEW
EVP, QUALITY ASSURANCE

JAY WADEKAR
SVP, BUSINESS STRATEGY

DR. ALAN LADER
SVP, CLINICAL OPERATIONS

MIKE MCGUIRE
VP, COMMERCIAL

ILANIT ALLEN
VP, INVESTOR RELATIONS

MINO-LOK

Phase 3 Completed

MINO-LOK OVERVIEW

- A novel antibiotic lock solution designed to salvage catheters in patients with catheter-related bloodstream infections
- Mino-Lok addresses the complications, discomfort and cost of catheter removal and replacement
- No drugs currently approved to salvage catheters in patients with central-line associated bloodstream infections (CLABSI) or catheter-related bloodstream infections (CRBSI)
- Phase 3 Trial completed: multi-center, randomized, open label, blinded assessor, active control superiority study
- Estimated global market exceeds $2 billion

Achieved primary and secondary endpoints of Phase 3 Trial

Time to catheter failure exceeded expectations

Majority of patients in the Mino-Lok group achieved overall treatment success

Well tolerated with no drug-related serious adverse events

CLINICAL NEED: CATHETER IS A LIFELINE

Catheter access is essential to patient care

Significance in a clinical setting

CVCs are crucial for severely ill patients to provide medication, pain management, and nutritional support

Infections in CVCs can lead to life-threatening bloodstream infections (CLABSI or CRBSI)

Challenges of current anti-infective lock solutions results in catheter removal and replacement

Bacteria in CVCs form biofilms, making them difficult to sterilize with current antibiotics

Biofilms act as barriers, preventing antibiotics from reaching bacteria

CURRENT STANDARD OF CARE IS A POOR OPTION

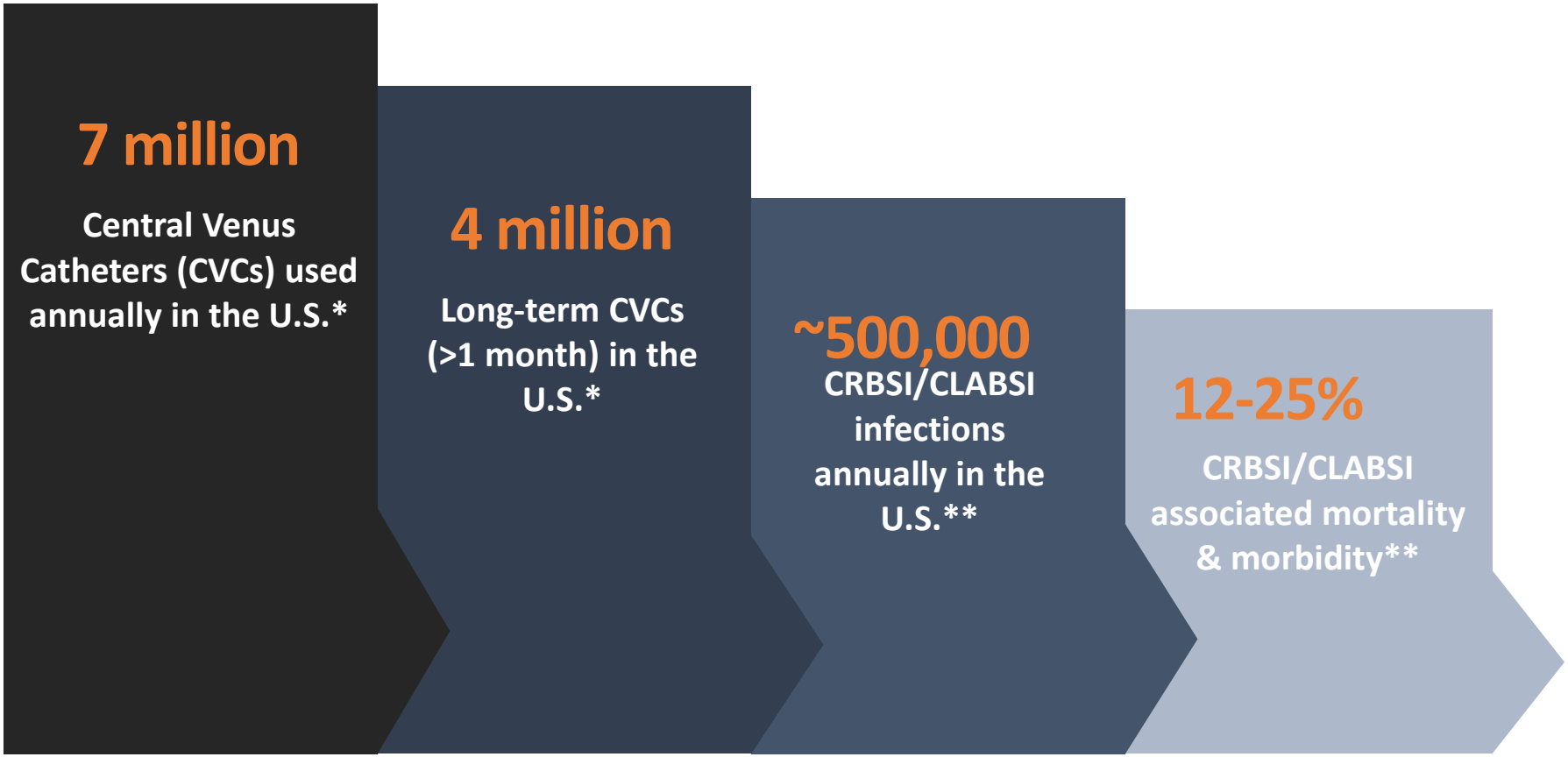
Catheter removal and replacement (R&R) presents multiple challenges

Limited availability of other vascular sites	Infusion therapy interrupted Delayed treatment
Delayed treatment	Especially for unstable patients or those with sepsis
Potential for complications	Infectious, thrombotic and mechanical
Adverse physical and psychological symptoms from catheter R&R*	57%-67% of patients
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

MARKET POTENTIAL: $1B+ IN US AND $2B+ GLOBALLY

High incidence of catheter-related infections support need for effective treatment options



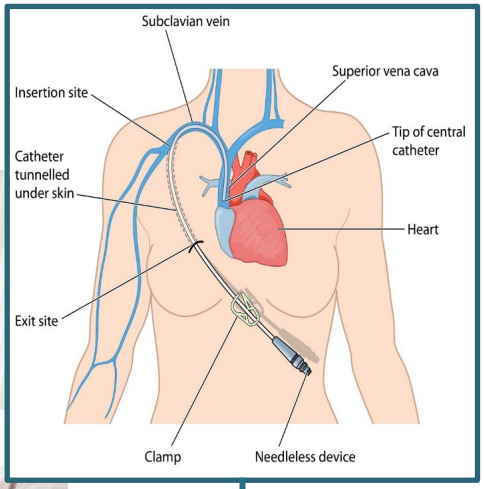
* Shah H., Bosch W., Hellinger W. C., Thompson K. M. (2013). Intravascular catheter-related bloodstream infection. Neurohospitalist 3, 144–151. doi: 10.1177/1941874413476043.

** 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.

POTENTIAL TO CHANGE STANDARD OF CARE

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

- Limited duration IV therapy designed to eradicate bacterial colonization with a short 2-hour dwell time
- Limits disruption of infusion therapy allowing continued use of the catheter for intended treatments
- Ease of Administration: Locking a catheter is a well-known standard operating procedure
- Non-invasive and adjunct to systemic therapy
- Lowers risks to patient
- Lower cost alternative: significantly less than removal and replacement



MINO-LOK PHASE 3 PIVOTAL TRIAL COMPLETED

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

241 Patients with catheter-related bloodstream infections were randomized

ACTIVE ARM:	**Mino-Lok solution + systemic antibiotic**
CONTROL ARM:	**Site-specific antibiotic lock solution + systemic antibiotic**

6 weeks

- 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

MINO-LOK PHASE 3 TRIAL TOPLINE RESULTS

Mino-Lok significantly outperforms hospital-specific anti-infective lock solutions

Kaplan Meier Analysis demonstrated clear separation between Mino-Lok and control arms, illustrating Mino-Lok's superiority in extending time to catheter failure

Primary Endpoint: Median Time to Failure	Control arm: 33 days Mino-Lok arm: exceeded the trial period (6 weeks) (p-value = 0.0006)
Key Secondary Endpoint: Overall Treatment Success	A greater percentage of patients in the Mino-Lok arm achieved overall treatment success compared to the control arm (p-value = 0.0025)
Safety Profile	Mino-Lok was well-tolerated with no drug-related serious adverse events Comparable adverse events between Mino-Lok (45.1%) and control (46.1%) arms, as expected in very ill patients Mino-Lok is instilled into the catheter and never enters the patient

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

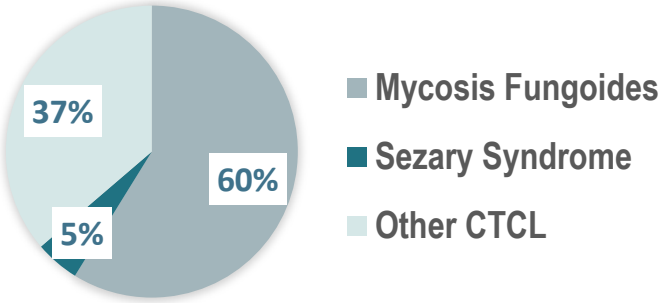
LYMPHIR (I/ONTAK, E7777)

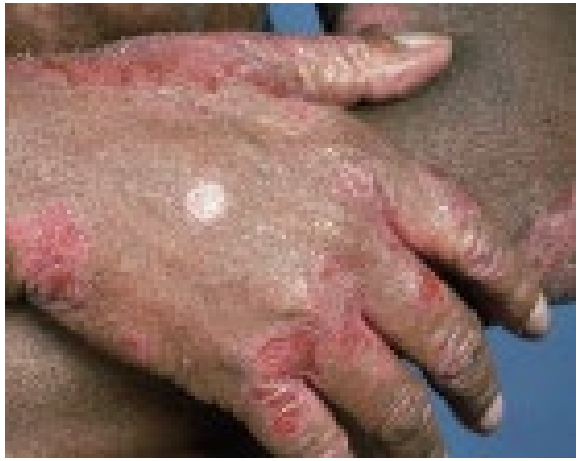
WHAT IS CUTANEOUS T-CELL LYMPHOMA (CTCL)?

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

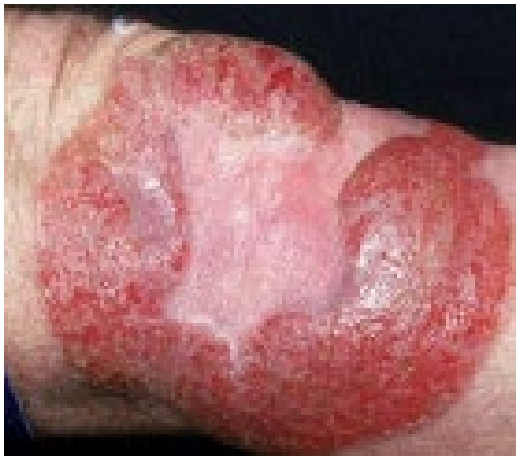
More prevalent in men than women and usually appears in patients in their 50s and 60s

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





Plaque Stage



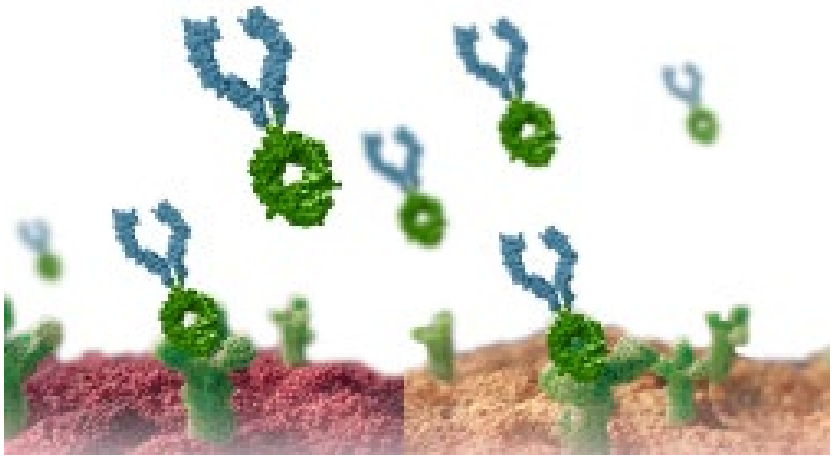
Tumor Stage

Source: Company estimates.

DIFFERENTIATED MECHANISM OF ACTION (MOA)

LYMPHIR 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

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)

The ONLY systemic treatment to target the IL-2 receptor

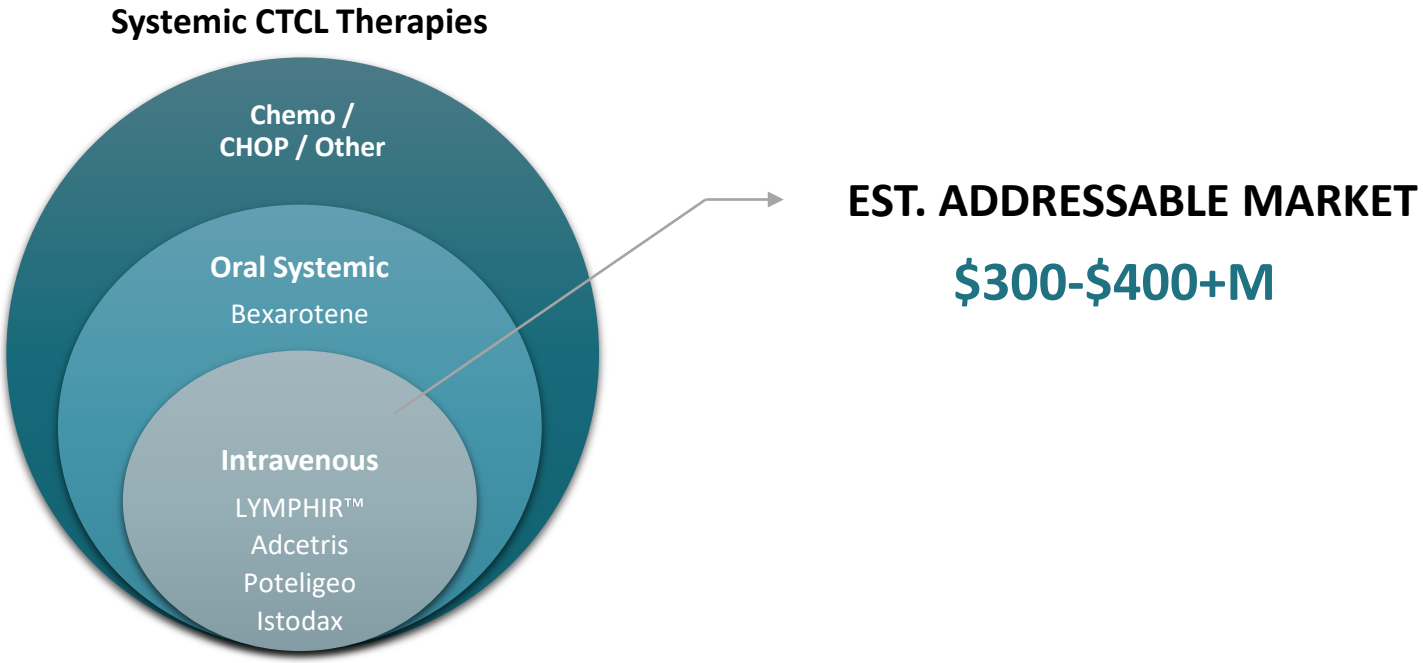
Potential to be additive to market

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

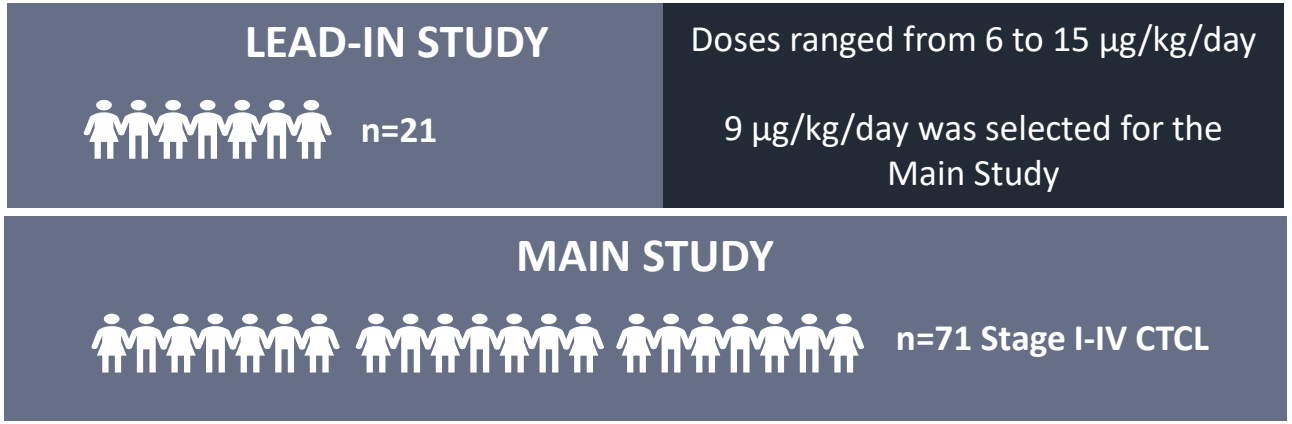
- Estimated U.S. market size for LYMPHIR in CTCL is $300-$400+ million
- Key growth drivers expected to increase overall market size and facilitate market penetration
  - Evolving treatment paradigm; incremental therapeutic option for pre-treated patients
  - Historically, market growth has followed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

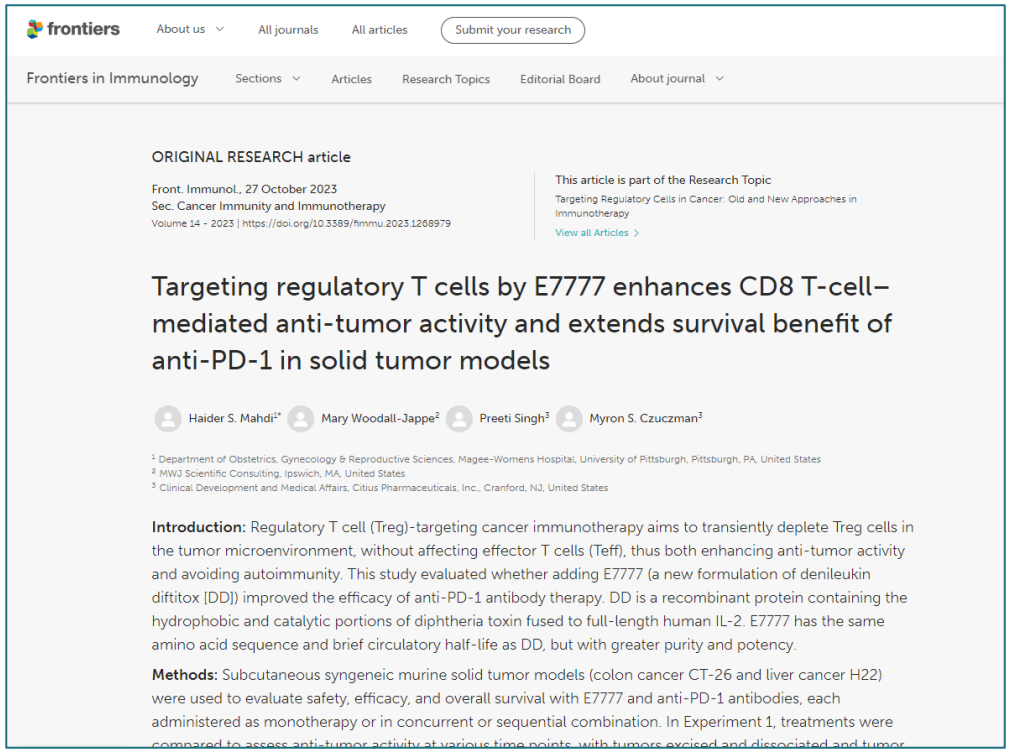
- No evidence of cumulative toxicity
- Most patients experienced low grade 1/2 treatment emergent adverse events (TEAEs)

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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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

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)
  - Unlocks value of oncology business which is not currently priced into company valuation
  - Facilitates greater access to capital markets
  - Citius Pharmaceuticals (Nasdaq: CTXR) to receive $675M in shares of Citius Oncology and retain ~90% equity

- LYMPHIR PDUFA 8/13/2024; Q4 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
  - Ongoing FDA engagement regarding next steps

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 biopharmaceutical company with commercialization anticipated in 2024

- $12.6 M cash as of 3/31/24
- $15 M capital raise April 2024 extends runway
- $26.5 M invested by founders

PRINCIPAL INSIDER SHAREHOLDERS (1)	
LEONARD MAZUR	9.3%
MYRON HOLUBIAK	2.6%

CURRENT CAPITALIZATION(2)	SHARES	% OF FULLY DILUTED
BASIC SHARES OUTSTANDING	180,395,150	66.8%
WARRANTS	72,133,421	26.7%
OPTIONS	17,390,171	6.4%
FULLY DILUTED SHARES OUTSTANDING	**269,918,742**	**100%**

(1) Beneficial stock ownership as calculated under rules of the SEC as filed with the Citius Def 14 A Proxy Statement in December 2023 and based on 180,395,150 shares outstanding as of May 9, 2024.
(2) As of June 11, 2024.