



Citius Pharmaceuticals, Inc.
(NASDAQ: CTXR)

Corporate Overview
JANUARY 2025





FORWARD-LOOKING STATEMENTS

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INVESTMENT HIGHLIGHTS

Biopharmaceutical company with multiple advanced development programs

- Led by management team with successful pharma/biotech track record
- \$26.5 million invested by founders



Diversified Portfolio

- **LYMPHIR™** (denileukin diftitox-cxdl)
 - **NOW APPROVED** for the treatment of cutaneous T-cell lymphoma (CTCL)
- **Mino-Lok®**
 - Only treatment designed to salvage infected catheters causing CLABSI
 - Phase 3 trial completed in 2024
 - Positive Topline data – met primary and secondary endpoints
- **Halo-Lido**
 - Only Rx therapy under development for hemorrhoids
 - Phase 2b trial completed



Key Recent Developments

- LYMPHIR FDA approval August 2024; commercialization planned 1H 2025
- Spin-off to form Citius Oncology, Inc. (NASDAQ: CTOR) completed August 2024
- Achieved primary and secondary endpoints in Mino-Lok Phase 3 trial

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



MIKE MCGUIRE
VP, COMMERCIAL



ILANIT ALLEN
VP, INVESTOR RELATIONS



Biopharmaceutical company focused on developing and commercializing innovative targeted oncology therapies



- Majority-owned (~90%) publicly-traded subsidiary of Citius Pharma
- NASDAQ listed August 2024
- LYMPHIR approved by the FDA in August 2024
- ~\$400+M estimated addressable U.S. market with additional growth opportunities; historically, new market entrants have expanded the size of the market

Program	Investigational Indication	Preclinical	Phase I	Phase II	Phase III
UNIVERSITY OF PITTSBURGH MEDICAL CENTER, HILLMAN CANCER CENTER	COMBINATION WITH PD-1 INHIBITOR (KEYTRUDA®) ¹	Prelim data published			
UNIVERSITY OF MINNESOTA, MASONIC CANCER CENTER	COMBINATION WITH CAR-T (KYMRIAH®) ¹	Prelim data expected in 2025			
LYMPHIR-P ²	PERIPHERAL T-CELL LYMPHOMA				

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

WHAT IS CUTANEOUS T-CELL LYMPHOMA (CTCL)?



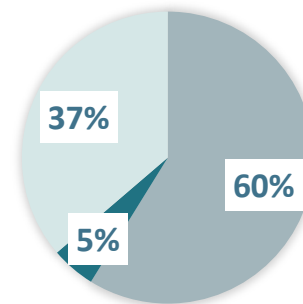
Considered to be incurable, CTCL is a general term for T-cell lymphoma that involve the skin, but may also involve the blood, lymph nodes, and internal organs



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)*



- Mycosis Fungoides
- Sezary Syndrome
- Other CTCL



Plaque Stage



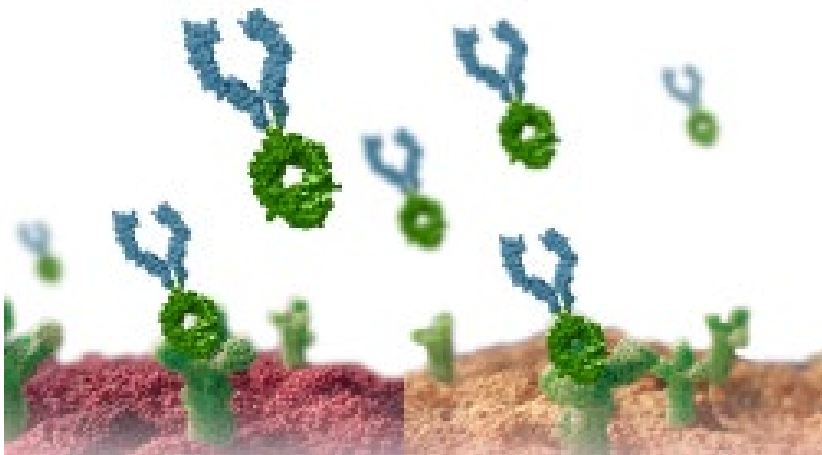
Tumor Stage

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

LYMPHIR: APPROVED AUGUST 2024

Commercialization anticipated 1H 2025

- Added to National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology, supporting adoption and reimbursement



NOW FDA APPROVED

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.

CLINICAL DATA MAKES EFFICACY APPARENT

OBJECTIVE RESPONSE RATE¹

36%

9% achieved complete response
27% achieved partial response

RAPID RESPONSE TIME

1.4 months

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

DURABLE RESPONSE

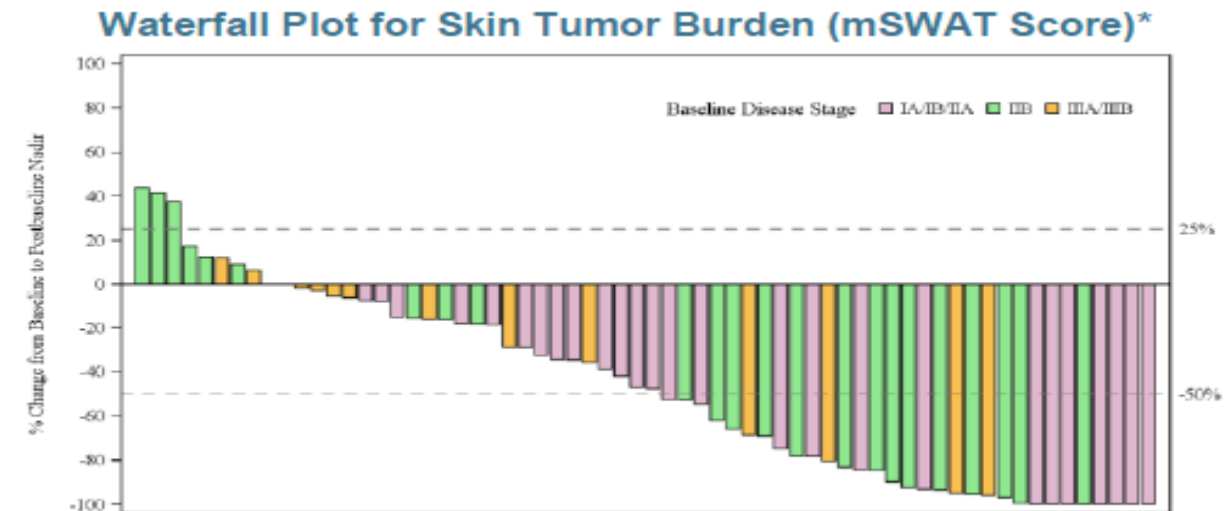
6.5 months

Median months of controlled disease among patients who responded to E7777²

REDUCED SKIN BURDEN

84.4%

- Reduction in skin tumor burden among evaluable patients
- 48.8% of patients with $\geq 50\%$ reduction in skin tumor burden³



1. Objective Response is Complete Response and Partial Response according to the ISCL/EORTC Global Response Score.

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).

3. 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.

SAFETY: WELL-TOLERATED

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 9 μ g

**INFUSION
REACTION**

6%

Limited infusion site reaction

**VISUAL
IMPAIRMENT**

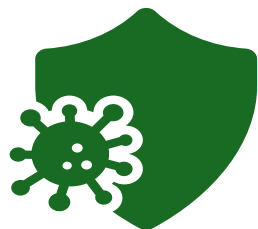
0%

No Grade ≥ 3 loss in visual acuity observed during the trial

COMPETITIVE LANDSCAPE



Generic Name	Denileukin diftitox (E7777)	Brentuximab vedotin	Mogamulizumab	Romidepsin
Mechanism of Action	IL-2-diphtheria fusion protein binds to IL-2 receptors, is internalized, and kills both malignant T-cells and Tregs (unique therapeutic effect)	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	CR 9%, PR 28%, ORR 36% Median DOR 6.5 months, 52% pts >6 months; 20% pts >12months Median Time to Response: 1.4 months (rapid) Skin Compartment Response: 48% Clinical stage IIB* response: 35%	CR 10%, PR 51.6%, ORR4** 50%; ORR 65% PFS 16.7 months DOR 15.1 months Median Time to Response: Not Reported Skin Compartment Response: 77% Clinical stage IIB* response: 63%	CR 2%, PR 25%, ORR 28% PFS 7.7 months DOR 14.1 months Median Time to Response: 3.3 months Skin Compartment Response: 42% Clinical stage IIB* response: 17%	CR 6%, PR 29%, ORR 35% PFS 8.0 months Median DOR ~ 13 months Median time to CR: 4-6 months Median duration of Rx: 5.6 months
Most Common AEs	Increase transaminases, nausea, rash, edema, decrease in albumin, and capillary leak syndrome in >= 20% subjects	Neutropenia, anemia, peripheral sensory neuropathy, fatigue, nausea, pyrexia, rash, diarrhea, and pain in >= 20% subjects	Rash (r/o disease), infusion-related reactions, fatigue, diarrhea, musculoskeletal pain, and upper respiratory tract infection in >= 20% subjects	Nausea, asthenia, myelosuppression, transaminitis, EKG changes, infections in >20%; Drug dc'd due to AEs in ~ 15% of patients
Administration/Dosing	IV, 60 min., 5 days every 21 days until POD or toxicity	IV, 30 min. x 3 weeks up to 12 cycles	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	- Unique and non-cross-resistant MOA - Rapid response - No cumulative toxicity	Highest ORR amongst treatments described above	High durable responses in Sezary syndrome (<5% of CTCL subtypes)	Moderately active agent
Cons	Capillary Leak Syndrome (largely limited to largely grade 1 to 2 in Cycles 1,2; need albumin level >=3)	# of cycles administered is limited largely by peripheral neuropathy (cumulative toxicity) - Tumor biopsy must be CD30-positive (>=10%)	- Least effective Rx in Mycosis Fungoides (of 4 described here) - Skin rash (typically with 1st cycle); drug rash vs POD may be difficult to discern - Cannot be used as a bridge prior to alloSCT	Treatment limited by significant toxicity profile (see AEs above); Cumulative toxicity seen



Upside opportunity in immuno-oncology

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)

2

University of Minnesota: 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)



Expanded indication potential in PTCL

Denileukin diftitox is already approved for the treatment of Peripheral T-Cell Lymphoma (PTCL) in Japan (Remitoro®)

PTCL indication would require a clinical trial in U.S. designed as a single-arm pivotal study

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



MINO-LOK

Phase 3 Trial Completed: Positive Topline Data

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

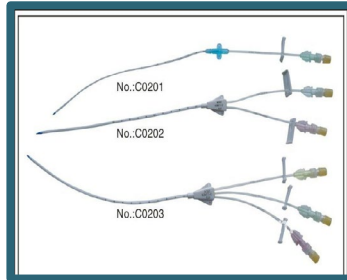
Time to catheter failure exceeded expectations

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

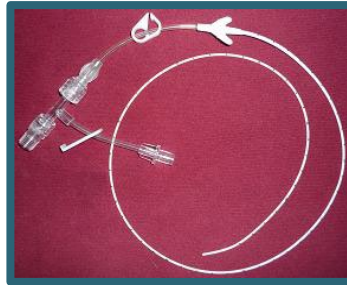
Well tolerated with no drug-related serious adverse events

CENTRAL VENOUS CATHETERS

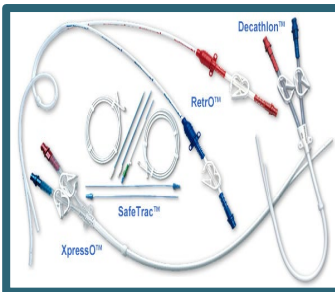
Central Venous Catheters (CVCs), Peripherally Inserted Central Catheter (PICCs), and Hemodialysis



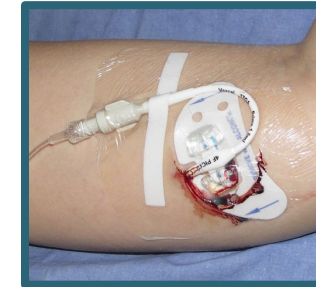
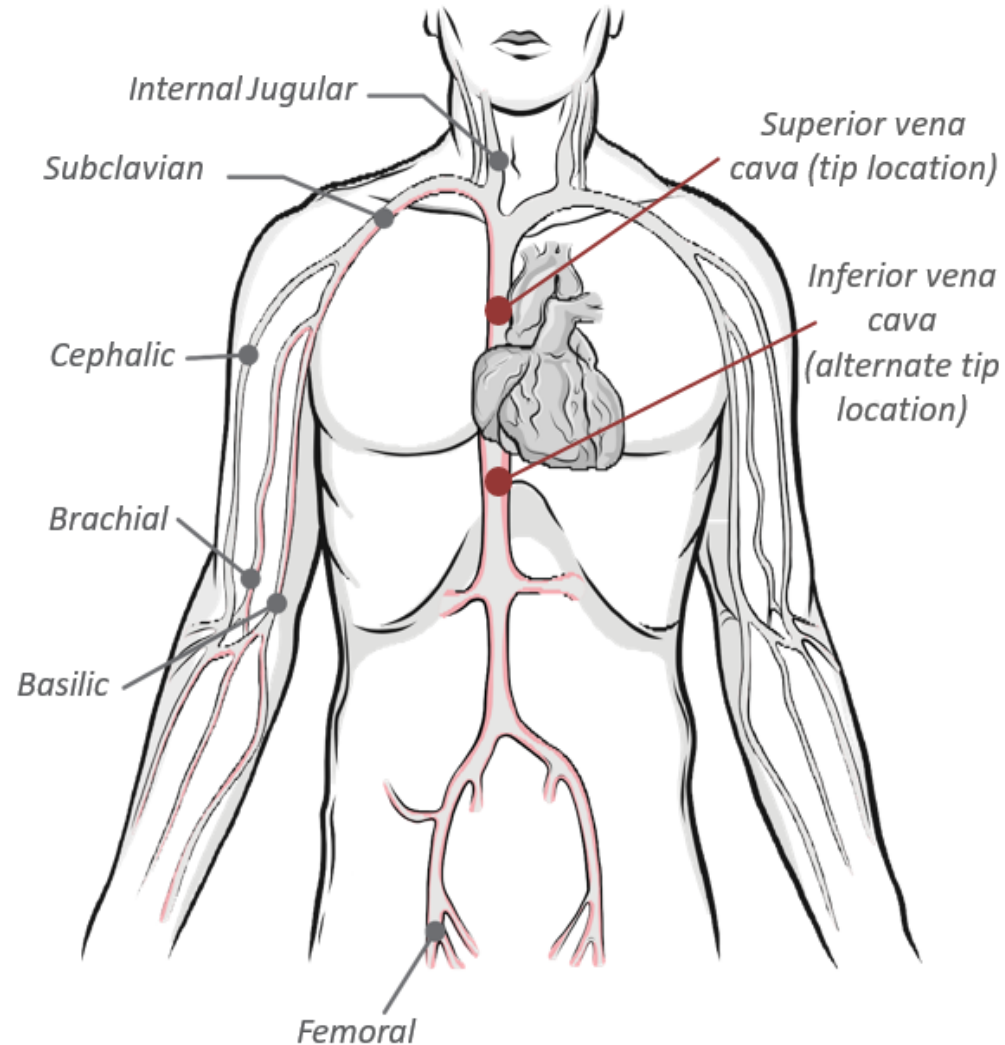
Central Venous Catheter



PICC

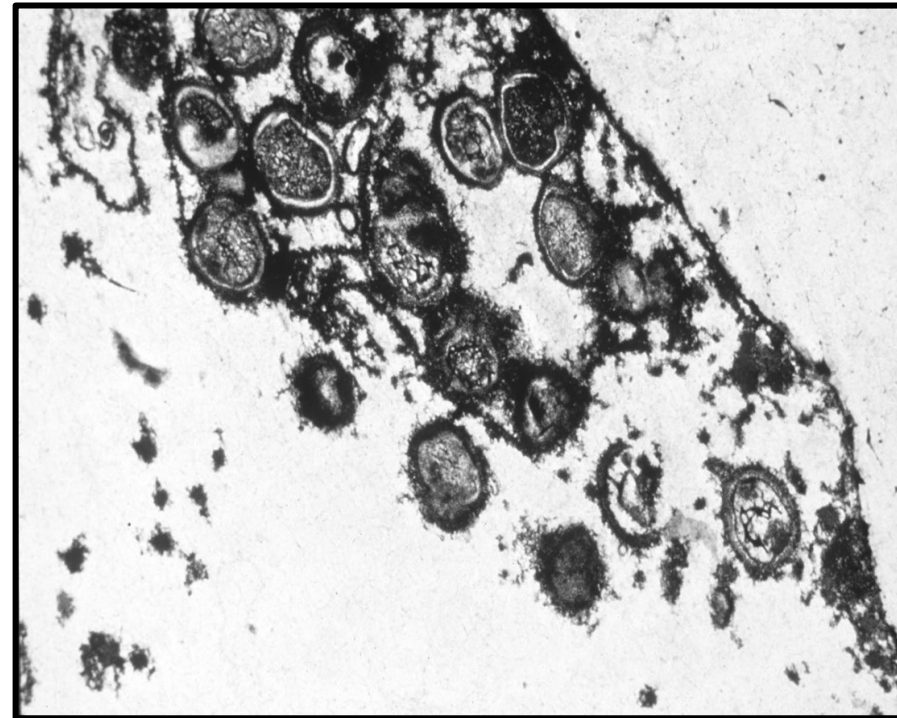
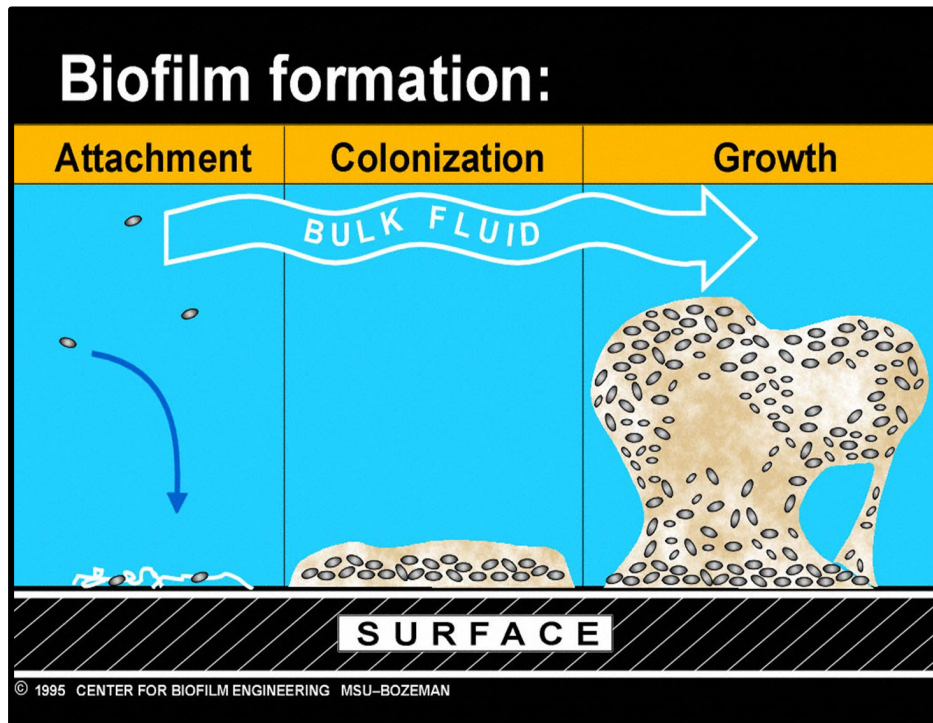


Hemodialysis



BIOFILM FORMATION PROTECTS COLONIES

- Pathogens attach to the surface of the lumen in a central venous catheter and form colonies.
- Colonies grow and exude a fibrous glycocalyx that protects the organisms from antibiotics, even when shown to be sensitive *in vitro*



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



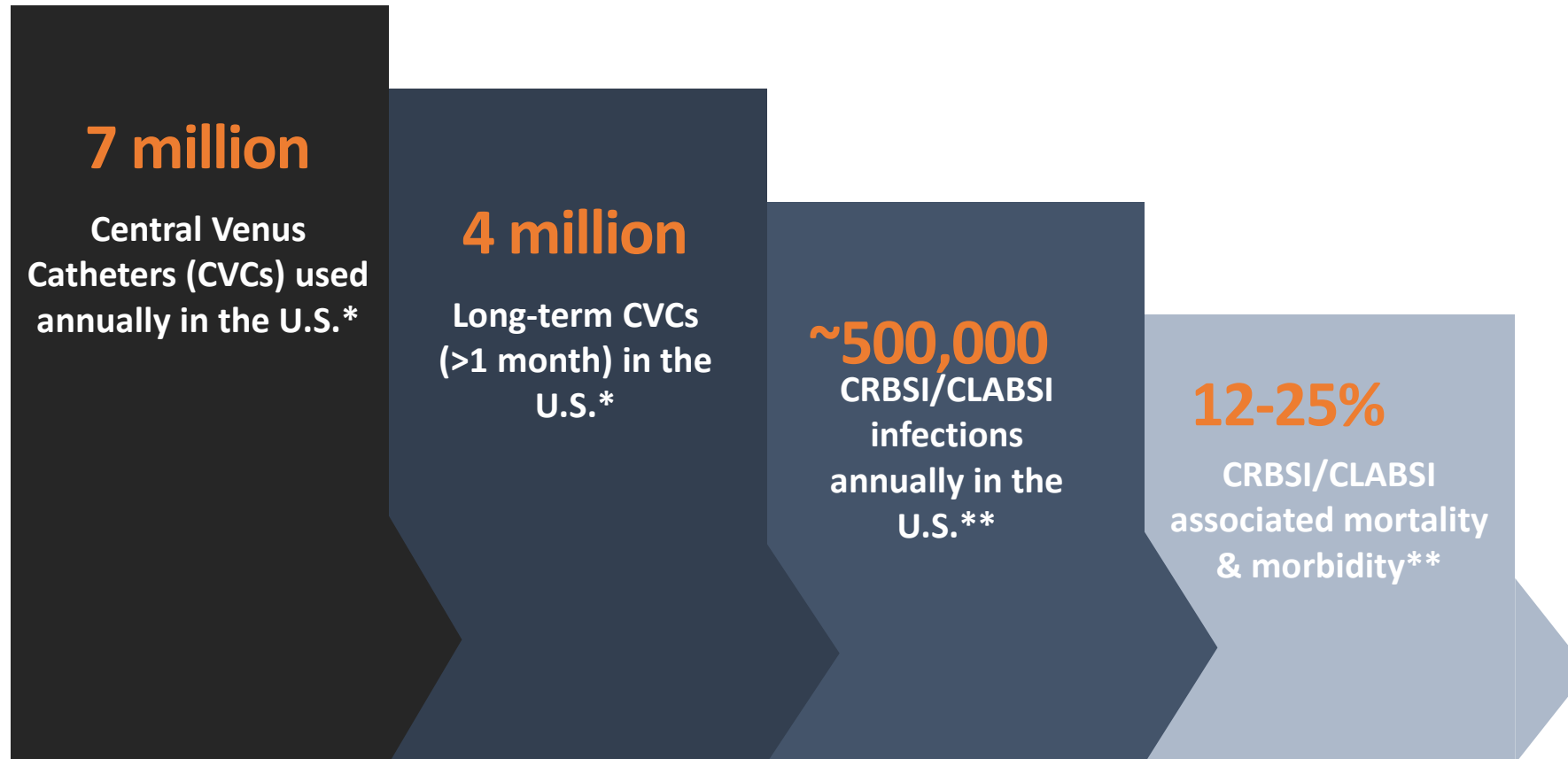
High cost

~\$10K cost of R&R procedure
\$46K-\$65K cost of CRBSI/CLABSI episode

* Chافتari, 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



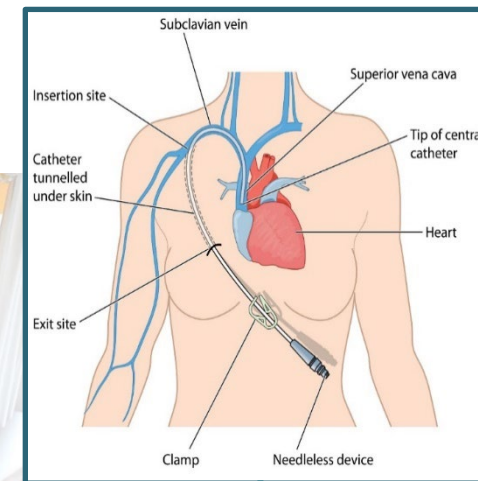
Non-invasive and adjunct to systemic therapy



Lowers risks to patient

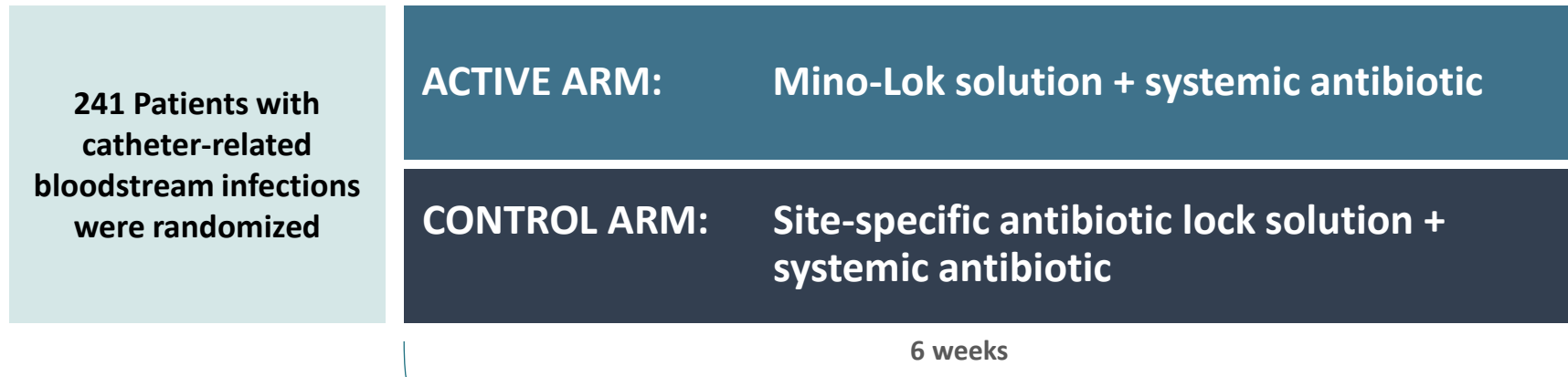


Lower cost alternative: significantly less than removal and replacement



MINO-LOK PHASE 3 PIVOTAL TRIAL COMPLETED

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



- 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

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



HALO-LIDO

Halobetasol/Lidocaine



Potentially the first FDA-approved prescription product to treat hemorrhoids

- 10+ Million patients report symptoms of hemorrhoidal disease; 1/3 seek physician treatment¹
- A cream formulation containing halobetasol propionate (highly potent steroid) and Lidocaine HCl
- Phase 2b enrollment completed
 - 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



SUMMARY



WHY INVEST? WHY NOW?

Diversified late-stage biopharmaceutical company with commercialization anticipated in 1H 2025

- LYMPHIR poised to launch 1H 2025
- Pipeline of additional late-stage assets
- Attractive investor entry points
 - CTXR market cap as of 1/9/2025: ~\$30 million
 - CTOR market cap as of 1/9/2025: ~\$80 million
- Management and shareholder alignment - \$26.5 M invested by founders with successful pharma/biotech track record