

Citius Pharmaceuticals, Inc.

(NASDAQ: CTXR)

Corporate Overview

WINTER 2022/2023

FORWARD-LOOKING STATEMENTS

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INVESTMENT HIGHLIGHTS

1 Diversified Pipeline: Building a Biotech Platform

- **BLA Filed:** I/ONTAK - purified reformulation of IL-2 diphtheria toxin fusion protein for CTCL
- **Phase 3:** Mino-Lok® - potential to be **first and only** FDA-approved product to salvage infected CVCs causing CLABSI
- **Phase 2b:** Halo-Lido Rx - potential to be **first and only** FDA-approved Rx therapy for hemorrhoids
- NC *i*-MSC™: novel stem cell therapy for acute respiratory distress syndrome (ARDS)
- Mino-Wrap: potential to be **first and only** FDA-approved product to prevent infections associated with post mastectomy breast implants

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
- ARDS market large with no approved therapies
- Tissue expander infection prevention est. $400M worldwide

3 Multiple Anticipated Catalysts in 2023

- I/ONTAK PDUFA target action date is July 28, 2023
- Mino-Lok Phase 3 trial completion
- Halo-Lido Phase 2b trial completion

4 Healthy Financial Platform

- $42 M cash as of 09/30/22
- Cash runway through December 2023
- $26.5 million invested by insiders

2022 MILESTONES & 2023 ANTICIPATED CATALYSTS

2022
MILESTONES

- Reported results of I/ONTAK Phase 3 trial
- Submitted I/ONTAK BLA
- Engaged global CRO to expand Mino-Lok trial sites internationally
- Initiated Halo-Lido Phase 2b trial
- Expanded clinical, regulatory and commercial infrastructure

2023
ANTICIPATED CATALYSTS

- I/ONTAK PDUFA: July 28, 2023
- Complete Mino-Lok Phase 3 trial
  - As of 12/15/22:
    - 72 of 92 failure events to date[1]
    - 17 patients in active treatment or pending study completion data review, which may contribute additional failure events
- Complete Halo-Lido Phase 2b trial
- Execute financial/strategic transaction(s) to support pipeline development

1. Pending finalization by Blinded Adjudication Committee.

I/ONTAK (E7777)

BLA Filed

I/ONTAK OVERVIEW

Reformulated oncology asset with an attractive near-term revenue opportunity

- Improved formulation of previously-approved drug (ONTAK) for treatment of cutaneous T-cell lymphoma (CTCL)
- Orphan indication with market est. $300-$400+M | market dynamics support new entrant
- Upside potential in PTCL and immuno-oncology (I/O)
- Phase 3 trial completed December 2021; clinical trial data consistent with prior formulation
- BLA accepted for filing November 2022; targeted launch strategy supported by concentrated prescriber base
- Multi-layered market protections include potential marketing exclusivity and complex manufacturing process

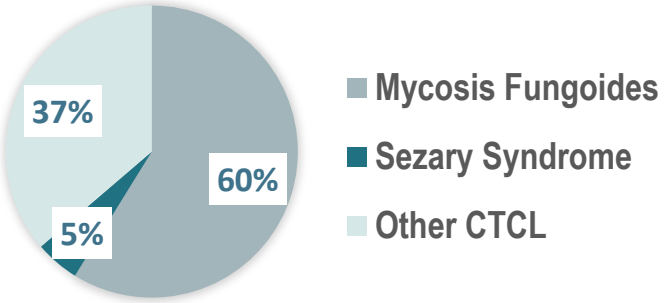
PDUFA target action date is July 28, 2023

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

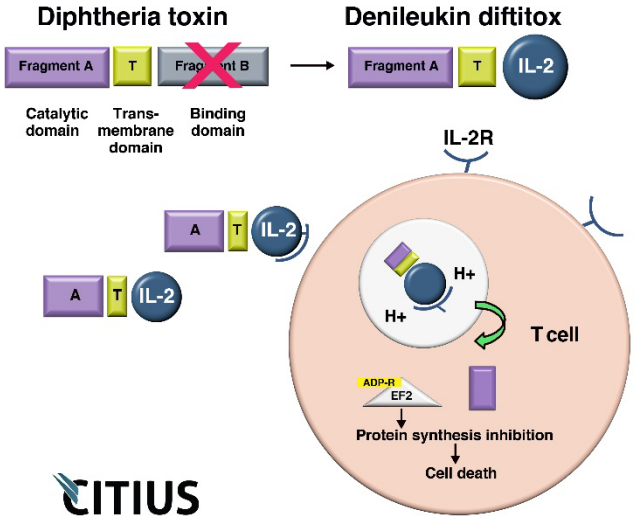
Source: Company estimates.

I/ONTAK MECHANISM OF ACTION (MOA)

Directly targets both malignant T-cells and immunosuppressive Tregs via binding to the IL-2 receptor on these cells

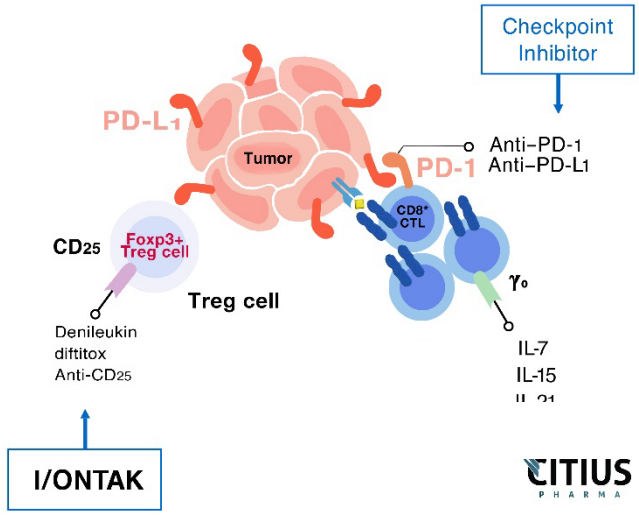
Targets Malignant Cells

- Binds to IL-2 receptor to kill tumor cells directly
- Potential additional indication in peripheral T-cell lymphoma (PTCL)



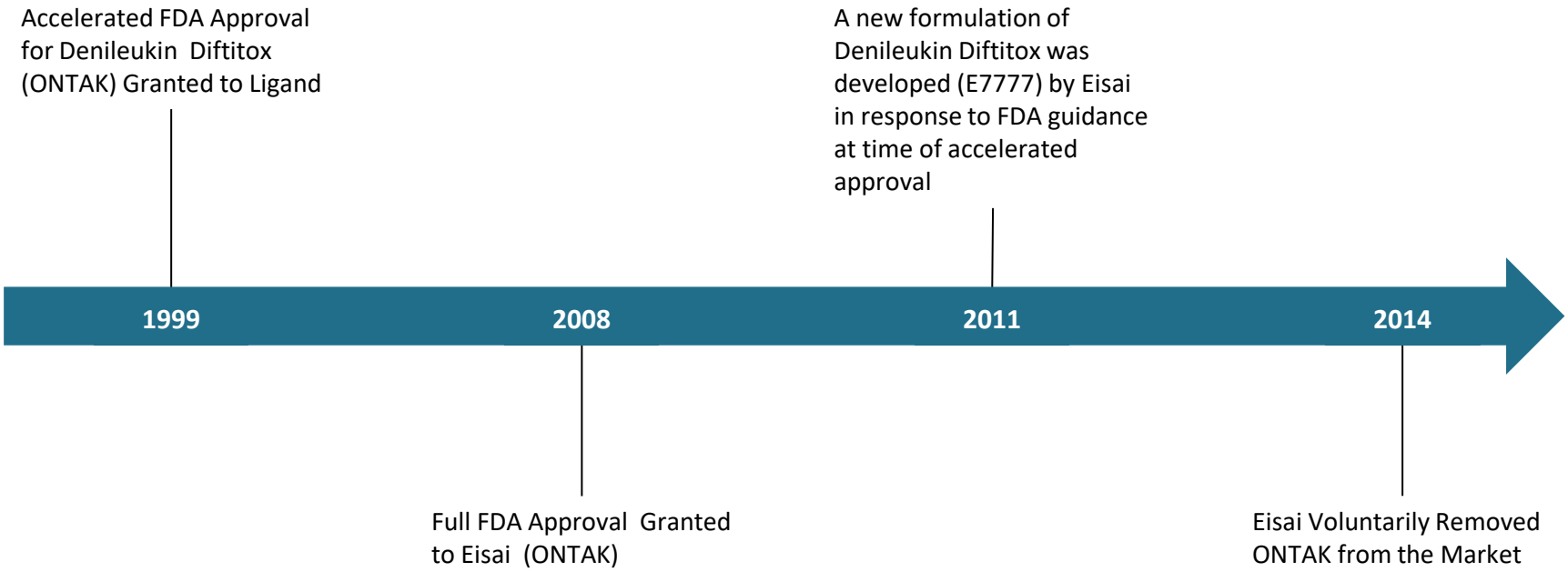
Eliminates Immunosuppressive Tregs

- Creates immune response against tumors by eliminating Treg cells
- Potential as I/O combination therapy



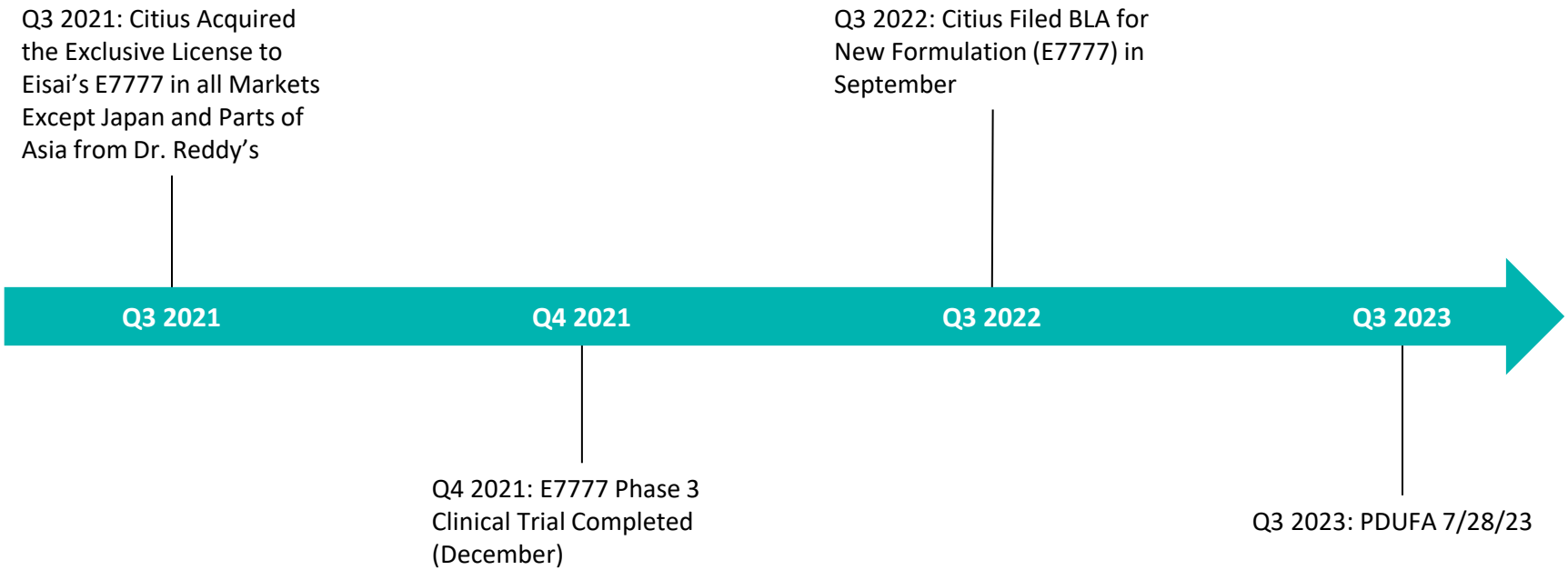
ORIGINS OF ONTAK

- ONTAK was FDA-approved and commercially available in the U.S. between 1999 – 2014
- E7777 (I/ONTAK) was developed by Eisai in 2011 as a purified and more bioactive formulation in response to FDA guidance
- Eisai voluntary removed ONTAK from the market in 2014



I/ONTAK LICENSING AND FDA PATHWAY

- Citius acquired the exclusive license to Eisai's E7777 (I/ONTAK) in September 2021
- Phase 3 clinical trial completed December 2021; data was consistent with the prior formulation and no new safety signals were identified
- Citius submitted a BLA for E7777 (I/ONTAK) in September 2022
- PDUFA target action date set for end of July 2023



OVERVIEW OF PHASE 3 CLINICAL TRIAL (STUDY 302)

- Pivotal, multicenter, open-label, single-arm study of I/ONTAK 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
- The study was conducted in two parts with an initial Lead-In Study to determine the optimal dose of I/ONTAK, followed by the Main Study
  - The Lead-In study was completed with 21 subjects treated at doses of 6 to 15 µg/kg/day, with final data collection completed in August 2015
  - A dose of 9 µg/kg/day was selected for the Main Study
- A total of 91 subjects with Stage I-IV CTCL were enrolled in the Main Study, with participants administered 9 µg/kg/day of I/ONTAK (E7777) by intravenous infusion over 60 minutes (+/-10 minutes) on 5 consecutive days per cycle every 21 days
- A total of 71 subjects with Stage I-III persistent or recurrent CTCL from the Lead-In and Main Studies were assessed for efficacy, with 69 subjects included in the Primary Efficacy Analysis Set
- The FDA provided written comments in December 2021 indicating that their efficacy evaluation will be based on study results showing the lower limit of a 95% confidence interval to exceed a clinically relevant response rate (determined during BLA review)
  - I/ONTAK efficacy may be supported with data from the prior ONTAK study that led to its initial approval
  - The FDA will consider the adequate magnitude of duration of response and an acceptable risk/benefit ratio

STUDY 302: PHASE 3 CLINICAL TRIAL RESULTS

- Primary Endpoint: Objective Response Rate = complete response + partial response
- I/ONTAK (E7777) demonstrated meaningful benefits for trial patients who had previously been treated
  - 9µg I/ONTAK (E7777) efficacy results are consistent with results of ONTAK at 18µg/9µg
  - Overall rates of adverse events (AEs) are consistent with previous ONTAK studies

Independent Primary Efficacy Analysis Set[1]

49%

Nearly half of patients on the trial experienced a complete response, partial response or durable stable disease

36.2%

ORR[2]

95% CI (25%, 48.7%)

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).

STUDY 302: 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, with ≥ 80% maximum reduction in skin tumor in ~1/3 of patients[1]



RAPID RESPONSE TIME

1.4 months

Median number of months to response among patients who experienced clinical benefit



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 almost one-third of these subjects (32.8%, 21/64) having a ≥80% maximum decrease in skin tumor burden from baseline. 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).

STUDY 302: NO NEW SAFETY SIGNALS

Overall, I/ONTAK 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

5.8%

Low rate of Grade ≥3 capillary leak syndrome at 9µg



VISUAL IMPAIRMENT

0.0%

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



INFUSION REACTION

4.3%

Limited infusion site reaction



CUMULATIVE TOXICITY

0.0%

Mitigates discontinuation of drug use*

* 11.6% patients discontinued drug use in Study 302

PROMISING OPPORTUNITIES FOR ADDITIONAL INDICATIONS

- Potential expanded indication to include PTCL
  - 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 the potential safety and efficacy of I/ONTAK for potential as an immuno-oncology combination therapy
  - I/ONTAK in combination with anti-PD 1 pembrolizumab (KEYTRUDA®) in patients with recurrent or metastatic solid tumors
    - "The efficacy of T-regulatory cell depletion with E7777 combined with immune checkpoint inhibitor, pembrolizumab, in recurrent or metastatic solid tumors: Phase I/II Study" (IND #157242)
    - Collaboration with the University of Pittsburgh
  - I/ONTAK given prior to lymphodepletion (LD) chemotherapy and KYMRIAH® (tisagenlecleucel) CAR T-cell therapy for the treatment of relapsed/refractory diffuse large B-cell lymphoma (DLBCL) considered at a high risk for failure from KYMRIAH® alone
    - "Phase I/II Trial Using E7777 to Enhance Regulatory T-Cell Depletion Prior to Tisagenlecleucel (Kymriah) Therapy for Relapsed/Refractory Diffuse Large B-Cell Lymphoma (DLBCL)" (IND #153242)
    - 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

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
- I/ONTAK's (E7777) differentiated mechanism of action reinforces rationale for inclusion among the current core therapeutic options in the U.S. market

CITIUS PHARMA

I/ONTAK (E7777)
(denileukin diftitox)

Differentiated MOA targets IL-2 receptor

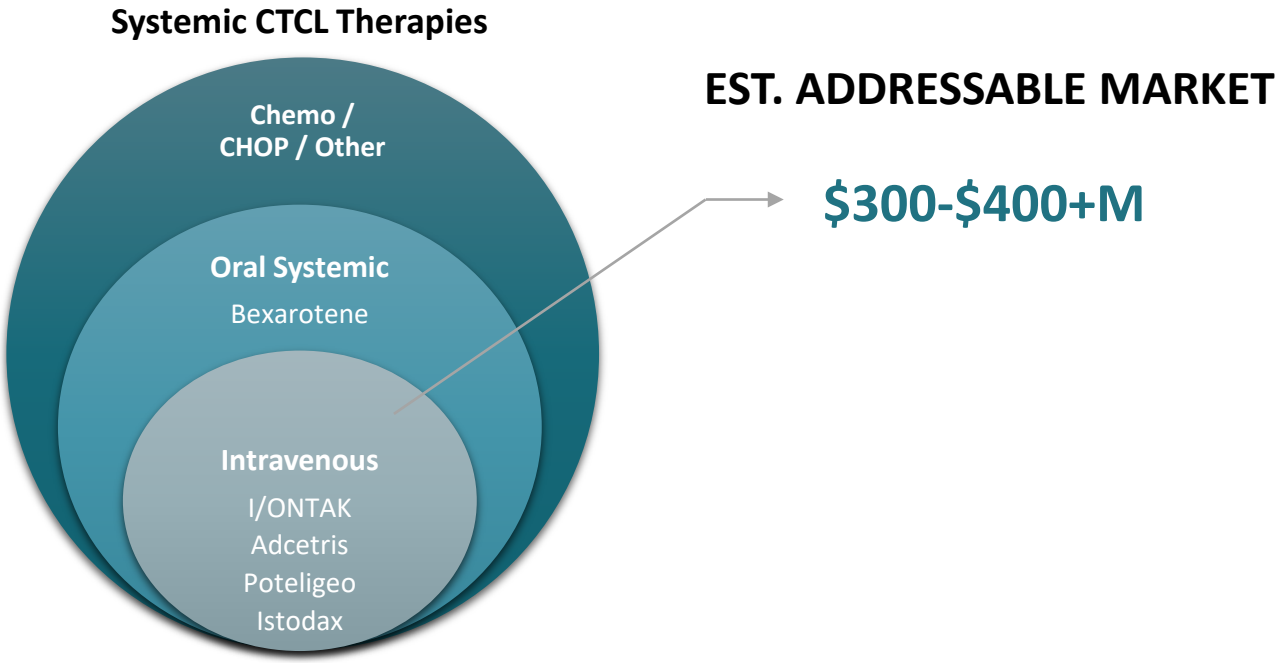
Potential to be additive to market

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

E7777 expected to be included among core targeted systemic therapy options

MARKET OPPORTUNITY

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



MINO-LOK®

Phase 3

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**

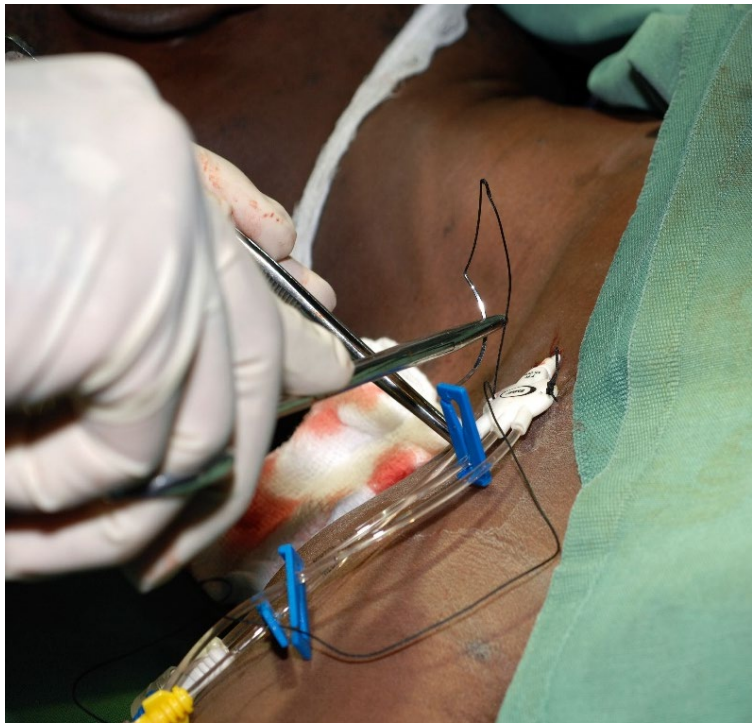
* Shah H., Bosch W., Hellinger W. C., Thompson K. M. (2013). Intravascular catheter-related bloodstream infection. Neurohospitalist 3, 144–151. doi: 10.1177/1941874413476043.

** 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

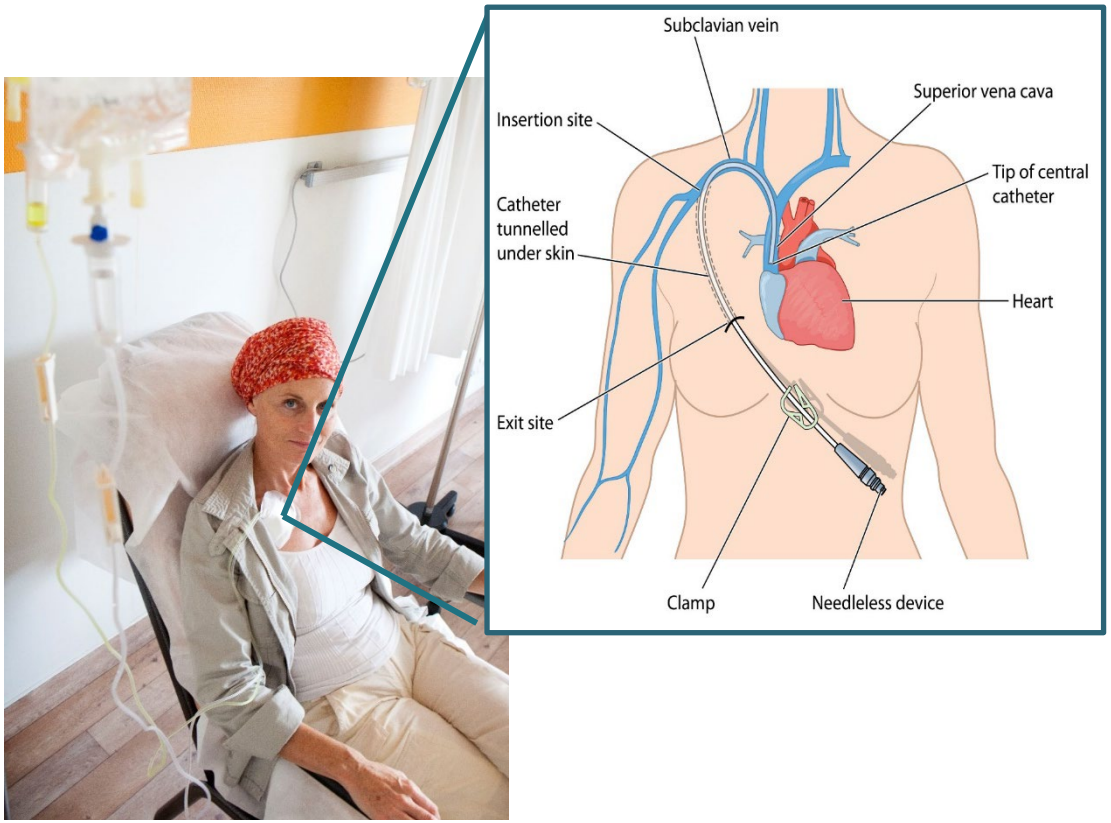
- Limited availability of other vascular sites
- Does not address need to maintain infusion therapy
- Potential for complications: infectious, thrombotic and mechanical
- 57%-67% of patients experience adverse physical and psychological symptoms from catheter R&R*
- High cost
  - ~$10K cost of R&R procedure
  - $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 SOP
  - Procedure can be performed by any healthcare provider
- ✓ **Not flushed into the venous system**
- ✓ **Lower cost alternative**
  - Significantly < R&R

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®

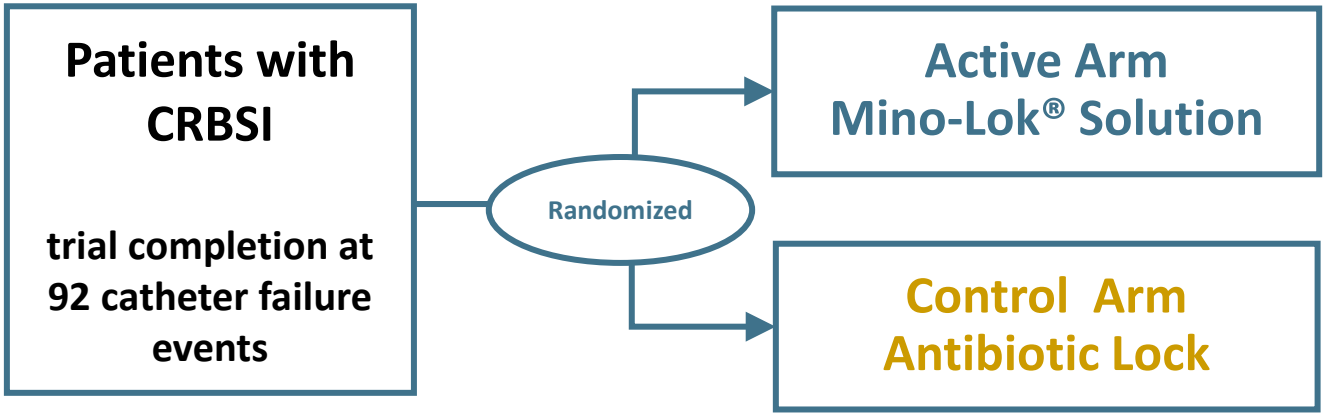
0% Complication rate for Mino-Lok® patients was 0% vs. 18% for control arm patients

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

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



Anticipated median time of 21 days vs. 38 days to achieve significance

- Primary Endpoint: Comparison of "Time to Catheter Failure" TOC = 6 weeks (42 days)
- Interim Analyses: DMC recommended proceeding with trial without modification following all 3 reviews
- Global CRO engaged to add trial sites internationally
- As of December 2022:
  - 35 planned participating clinical sites
  - 169 patients enrolled (117% of 144 anticipated patients)
  - 72 catheter failure events
  - 17 patients in treatment or pending study completion data, which may result in additional failure events

Additional trial sites expected to address lower than anticipated catheter failure event rate

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

HALO-LIDO

Phase 2b

Halobetasol/Lidocaine

HALO-LIDO AT-A-GLANCE

Potentially the first FDA-approved prescription product to treat hemorrhoids in the US

- Based on the results of Phase 2 trial in 240 patients, CTXR elected to use super potent steroid Halobetasol propionate (HBP), maintained Lidocaine HCl (LH) and developed 10 prototype formulations
- A cream formulation containing novel excipient selected for Phase 2b study
- Phase 2b study initiated April 2022
  - 5 cohorts of 60 subjects each
  - Primary endpoint: reduction in hemorrhoidal symptoms
  - Subjects to self-report using proprietary ePRO mobile app
- Data readout expected 2H 2023

10+ MILLION

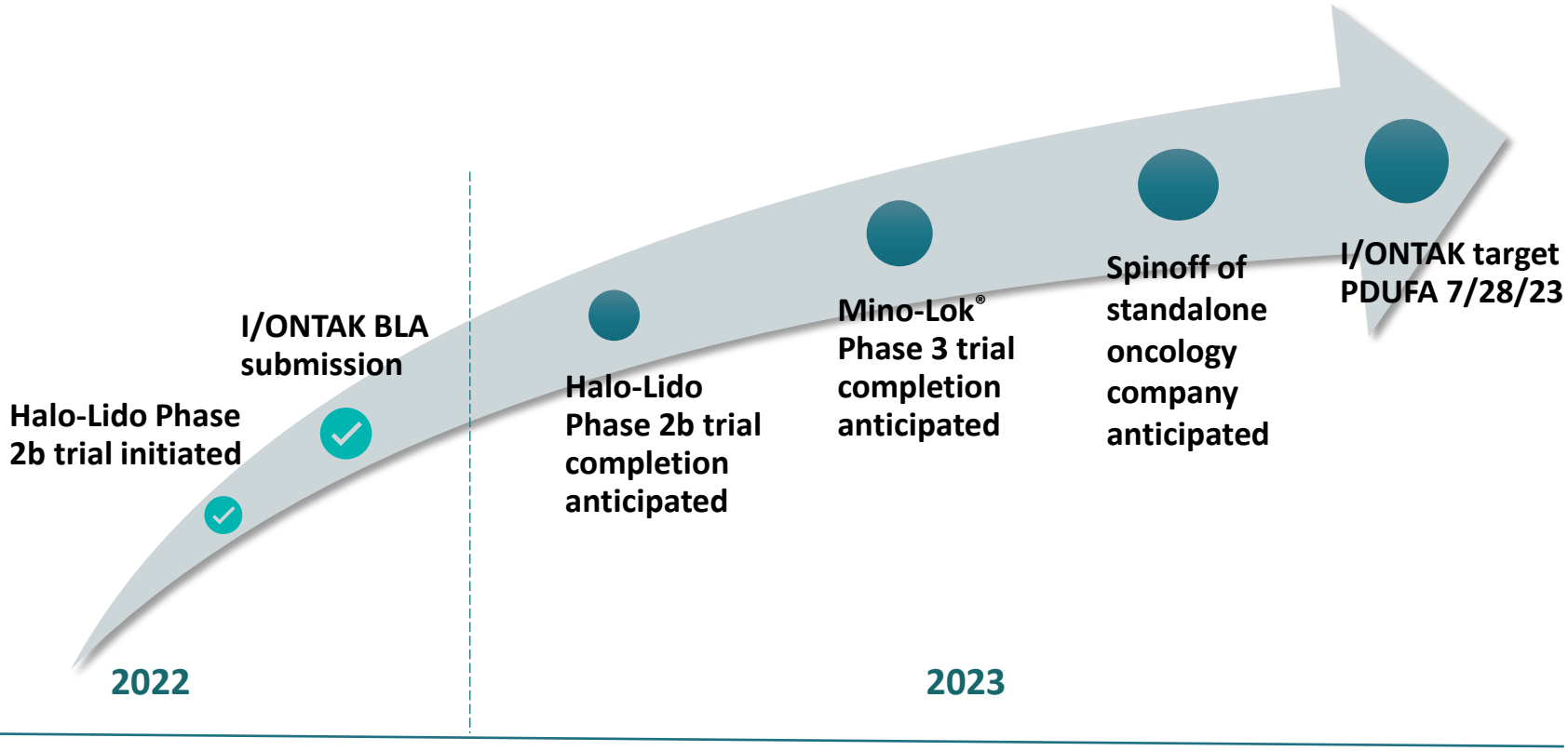
Patients report symptoms of hemorrhoidal disease and 1/3 seek physician treatment[1]

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

SUMMARY

WHY INVEST? WHY NOW?

Multiple value-creating catalysts on the horizon



HALO-LIDO
Rx therapy for hemorrhoids

MINO-LOK
Salvage CVCs

MINO-WRAP
Prevent Infections associated with breast Implants post-mastectomy

NC i-MSC
Treat ARDS with *i*-MSCs

I/ONTAK
Treat CTCL, PTCL, I/O

FINANCIAL SUMMARY

Bandwidth to Execute

- $42M cash & equivalents as of 9/30/22
- Runway through December 2023
- $26.5M invested by insiders

PRINCIPAL INSIDER SHAREHOLDERS (1)	
LEONARD MAZUR	11.8%
MYRON HOLUBIAK	2.9%

CURRENT CAPITALIZATION	SHARES	% OF FULLY DILUTED
BASIC SHARES OUTSTANDING	146,211,130	75.4%
WARRANTS	38,325,489	19.8%
OPTIONS	9,400,171	4.8%
FULLY DILUTED SHARES OUTSTANDING	**193,936,790**	**100%**

As of 9/30/22 unless otherwise noted.
(1) Beneficial stock ownership as calculated under rules of the Securities Exchange Commission as filed with the Citius Def 14 A Proxy Statement in December 2022.



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