Nasdaq

Ticker: ENLV

ENLIVEX

immune rebalancing

Life-saving immunomodulating cell therapies

May 2020

Forward-Looking Statements

These slides and the accompanying oral presentation contain forward-looking statements and information. Forward-looking statements are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels or activity, performance or achievements to be materially different from those anticipated by such statements. The use of words such as "may", "might", "will", "should", "could", "expect", "plan", "anticipate", "believe", "estimate", "project", "intend", "future", "potential" or "continue", and other similar expressions are intended to identify forward looking statements. For example, all statements we make regarding (i) the initiation, timing, cost, progress and results of our preclinical and clinical studies and our research and development programs, (ii) our ability to advance product candidates into, and successfully complete, clinical studies, (iii) the timing or likelihood of regulatory filings and approvals, (iv) our ability to develop, manufacture and commercialize our product candidates and to improve the manufacturing process, (v) the rate and degree of market acceptance of our product candidates, (vi) the size and growth potential of the markets for our product candidates and our ability to serve those markets, and (vii) our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates, are forward looking. All forward-looking statements are based on current estimates, assumptions and expectations by our management that, although we believe to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that we expected. Any forward-looking statement speaks only as of the date on which it was made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law. This presentation is not, and nothing in it should be construed as, an offer, invitation or recommendation in respect of our securities, or an offer, invitation or recommendation to sell, or a solicitation of an offer to buy, any of our securities in any jurisdiction. Neither this presentation nor anything in it shall form the basis of any contract or commitment. This presentation is not intended to be relied upon as advice to investors or potential investors and does not take into account the investment objectives, financial situation or needs of any investor.

Enlivex Company Overview

We develop intelligent immunomodulating cell therapies to rebalance life-threatening hyperimmune responses, in complex indications with unmet medical need.

NASDAQ GS	ENLV
Cash & equivalents	$12MM (Dec. 31, 2019) $24.75MM financing closed March 5, 2020
Shares Outstanding	13.4MM
HQ	Nes Ziona, Israel

Investment Highlights

Paradigm shifting immunotherapy

For complex, life-threatening indications without therapies

Advanced clinical-stage pipeline

Promising results of PhIb (sepsis) and PhIIa (GvHD) studies, initiating Sepsis Phase IIb study

Short regulatory approval pathway

Specialized regulation in Europe potentially enabling post-Phase II marketing approval

Multi-billion dollar underserved markets

Sepsis | Solid Tumors
Bone-Marrow Transplantations

Strong leadership

Previously founded and managed PROLOR Biotech, a $560M exit event; Signed partnership with Pfizer, $295 Million down payment

Cash balance

~$60 Million invested; Cash balance supporting multiple clinical milestone within 18-24 months

Management

Shai Novik Executive Chairman	Founder of Prolor Biotech, Sold in 2013 ($560mm transaction). Lead product partnered to Pfizer, $295 million down payment, $275 upon FDA approval. Phase III endpoint met Oct 2019.	PROLOR BIOTECH Protein.Longevity.Redefined
Oren Hershkovitz CEO	Former Director of CMC, VP R&D and CEO of OPKO Biologics (PROLOR Biotech). Led multiple clinical programs in Phase I, II and III. Ph.D. in Immunology.	OPKO Biologics
Dror Mevorach Chief Medical & Scientific Officer	Director, Rheumatology Research Centre and Molecular Immunology; and Director, Centre for Rare diseases, Hadassah Medical Center, Jerusalem.	Weill Cornell Medical College
Odelia Ben-Shitrit Head of Clinical Operations	Over 20 years of experience in clinical trials and operational management in various therapeutic areas. Former Teva and PAREXEL clinical leader.	teva
Dan Fishelovitch Head Of CMC	Former CMC Director, NeuroDerm Ltd, and Formulation Scientist at Teva Pharmaceutical Industries Ltd. Ph.D. from the faculty of Medicine, Tel-Aviv University in structural Bioinformatics.	parexel
Shachar Shlosberger CFO	~Former Prolor Biotech Ltd Finance Director where she was responsible for the overall financial operations in Israel and US. A C.P.A., and holds a M.B.A. in Accounting and Business Administration.	NeuroDerm A Mitsubishi Tanabe Pharma Group Company

ALLOCETRA™

Pipeline of life-saving therapies for complex immune-modulated indications

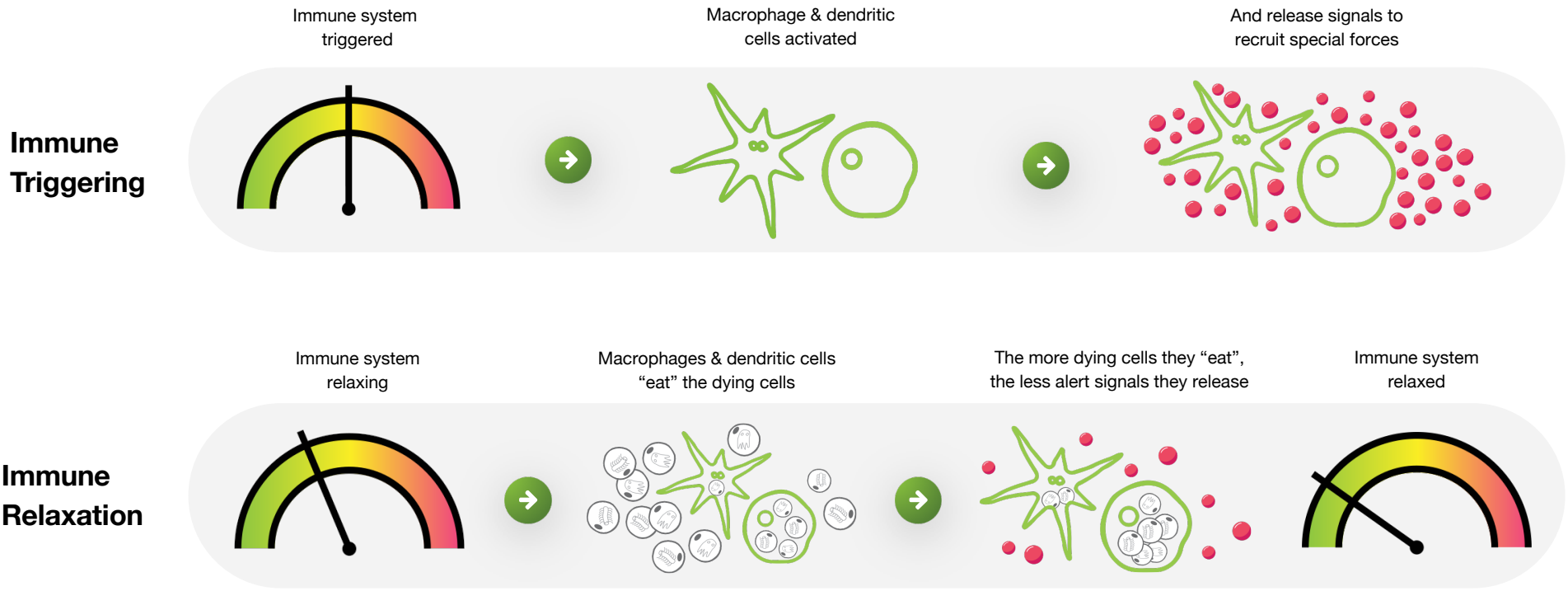
Indication	Global Market Size	Pre-Clinical	Phase Ib	Phase IIb	EU Conditional Marketing Approval	Post EU Marketing US Phase 3
Treatment of organ failure associated with Sepsis	$33B		Completed	Phase IIb Initiation Q3-4 2020		
Treatment of organ failure associated with COVID-19	$1B			Phase II Initiation Q2 2020		
Prevention of post-Bone Marrow Transplantations (BMT) complications	$3B			Phase IIa Completed, Phase II Initiation Q1 2022		
Solid tumor "immune checkpoint" microenvironment modulation	$4B	Completed				

Allocetra™

Mechanism of Action

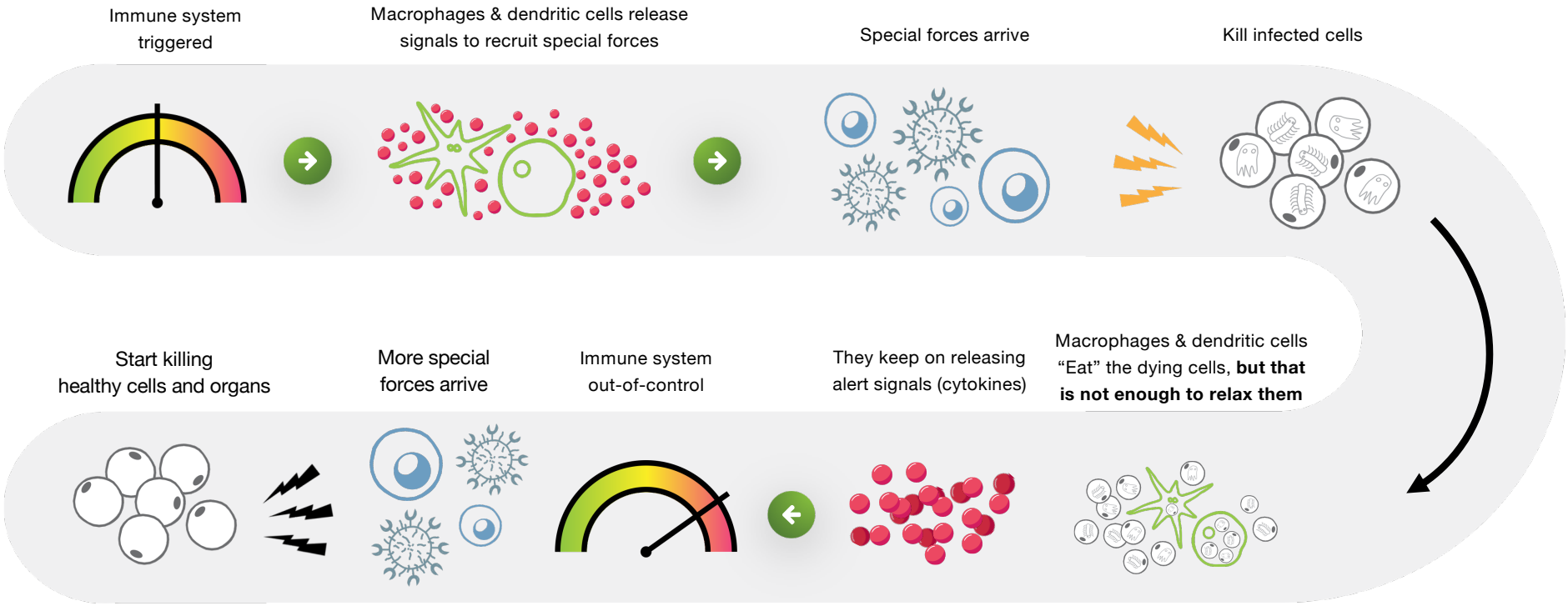
ENLIVEX
immune rebalancing

The role of macrophages and dendritic cells



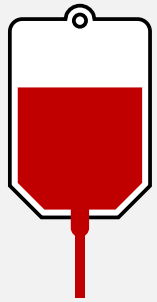
Abnormal immune response: cytokine storms

Trigger attacks of immune cells on healthy organs, and may result in organ damage, failure and mortality

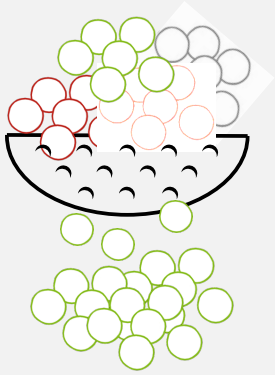


Allocetra™

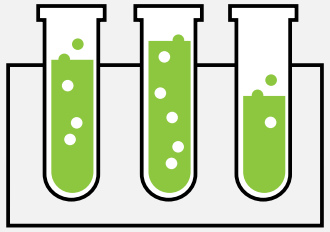
Proprietary, early-apoptotic, stable formulation of mononuclear cells



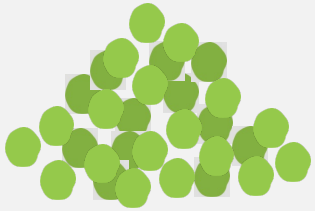
Matched or unmatched (off-the-shelf) donor blood



Selection of mononuclear cells ONLY Lymphocytes, Monocytes



Chemically inducing programmed cell death of the selected cells



Billions of semi-apoptotic (dying) ALLOCETRA cells ready to be infused

Macrophages/DCs/Monocytes

Designed By Evolution To Be Pivotal Immune Regulators, Controlling Triggering & Relaxation Of Multiple Immune Subsystems

- ALLOCETRA is a next-generation immunomodulating therapy for diseases associated with complex immune modulation
- Allows control of macrophages/DCs/monocytes, to induce:
  - Homeostasis **OF EACH** critical immune modulation subsystems that are off-balanced during a disease associated with complex immune modulation (level III)

Allocetra's MOA

Restoring immune homeostasis through modulation of macrophage/DC activity

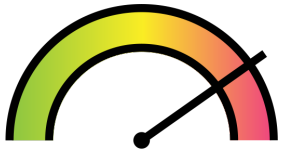
01 Cytokine Storm →

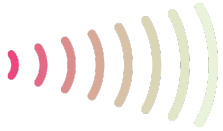
02 Allocetra™ infusion →

03 Macrophage feeding →

04 Alert signals decrease →

05 Normal immune state





Allocetra™

Treatment of organ failure associated with sepsis

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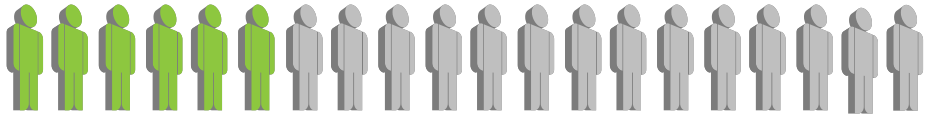
immune rebalancing

Sepsis is the 3rd leading cause of death in the U.S.

SEPSIS is a body's overwhelming, life-threatening response to infection, involving hyperactivation of multiple immune pathways and a resulting cytokine storm. It can lead to tissue damage, organ failure, and death.



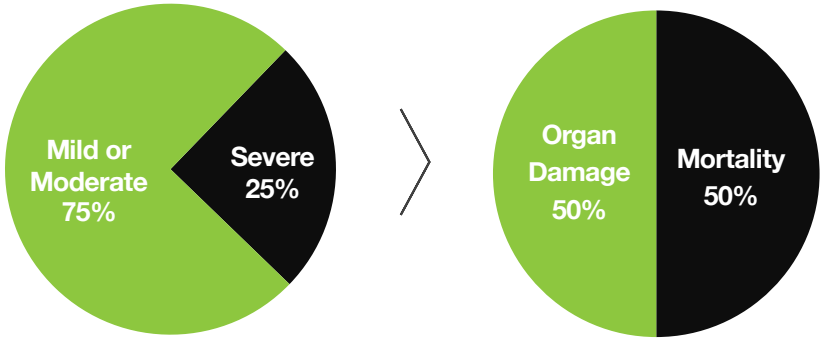
Each year, at least **1.7 million** adults in America develop sepsis.

Nearly **270,000** Americans die as a result of sepsis each year.

1 in **3**

One in three patients who die in a hospital have sepsis.

SEPSIS CATEGORIES



OUTCOME

Allocetra™ is well positioned to treat the complex pathophysiology of sepsis

- Well-characterized MOA
- Activates natural immune rebalancing pathways
- Modulation at the core (macrophages, DCs, monocytes) results in homeostasis **OF EACH** critical immune modulation subsystem that is off-balanced during sepsis, unlike previously unsuccessful drugs designed to treat sepsis

ALLOCETRA's Homeostatic Effect on:

Macrophages I Monocytes I DCs

Homeostatic effect on each, and among all, subsystems involved in sepsis and similar conditions

Allocetra™

Phase Ib Clinical Trial in Severe Sepsis Patients with an Off-The-Shelf Universal Product

ENLIVEX
immune rebalancing

Sequential Organ Failure Assessment (SOFA) Score

The sequential organ failure assessment score (SOFA score), previously known as the sepsis-related organ failure assessment score, is used to track a person's status during the stay in an intensive care unit (ICU) to determine the extent of a person's organ function or rate of failure. The score is based on six different scores, one each for the respiratory, cardiovascular, hepatic, coagulation, renal and neurological systems.

High degree of matching: treated vs controls

	Treated (n=10)	Matched Controls (n=37)
Average age	71.5 (51-83)	71.25 (50-83)
Male/female	80/20	80/20
Average diagnosis SOFA	3.4 (2-6)	3.47 (2-7)
Average diagnosis Apache II score	12.3 (8-21)	14.25 (5-24)

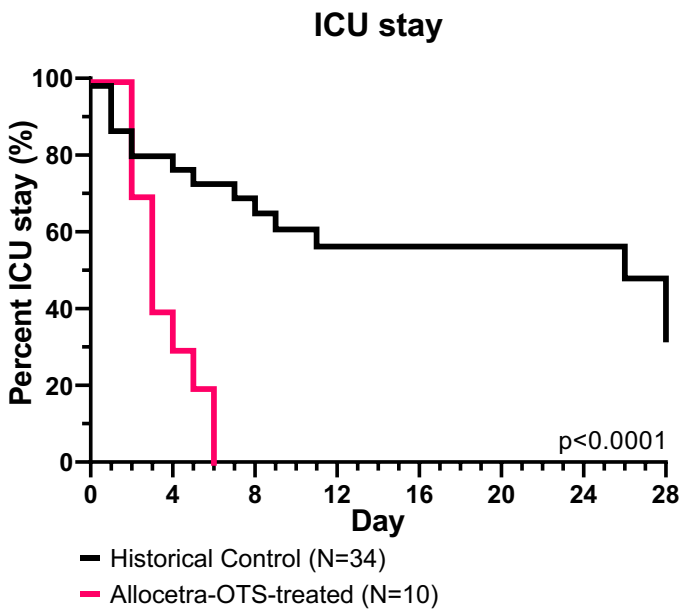
Sepsis source		
Pneumonia	50%	53%
Biliary infections	30%	25%
Endovascular	10%	8.3%
UTI	10%	14%

Allocetra™ treatment leads to improved patient outcomes

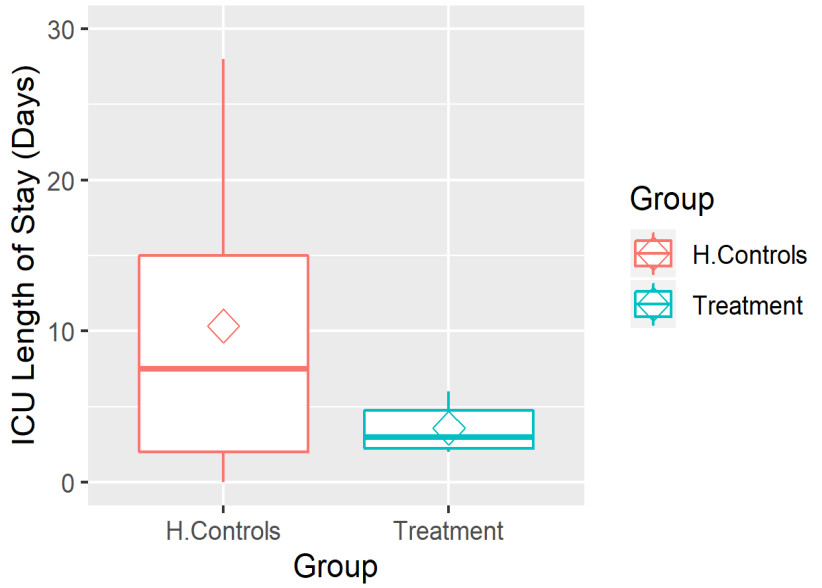
Maximal SOFA Score	Treated (n=10)	Matched Controls (n=37)
Diagnosis SOFA (Avg.)	3.4 (2-6)	3.47 (2-7)
MAX SOFA (Avg.)	3.4 (2-6)	7.04 (2-18)
MAX SOFA Delta from diagnosis (%)	0%	102%
28-day mortality	0%	28%
Avg ICU stay (days)	4	11

Statistically significant improvement in hospitalization vs. matched controls

Time to ICU discharge



Average duration of hospitalization



Phase Ib results show Allocetra™ treatment was well tolerated

All patients recovered from the septic condition and were discharged alive

No SAEs, 44 AEs, no related AEs, six possibly related AEs

No dose limiting toxicity was observed

No evidence of autoimmunity or autoantibodies

Clinical summary: complete recovery from any organ failure for all 10 patients and 100% 28-day survival

Sepsis characteristics and organ recovery

Organ Dysfunction	Each patient had at least 2 organ dysfunctions, maximum of 5
Kidney	3/9 patients (33%) had new-onset acute kidney injury, all have completely recovered to baseline kidney function
Lungs	5/10 (50%) of patients had lung involvement, no patient required mechanical ventilation, all patients recovered to normal saturation and no oxygen supplement upon discharge
Cardiovascular	3/10 (30%) of patients had mean arterial pressure <70 but none needed vasopressors
Hematological	8/10 patients (80%) had significant thrombocytopenia, with complete recovery in all.
Liver	4/10 patients (40%, of which 3 had biliary tract infection) had hyperbilirubinemia, with complete recovery in all. 5/10 patients had elevated liver enzymes (AST ALT) >3 above normal range, with complete recovery in all.

Sepsis - Phase IIb clinical plan

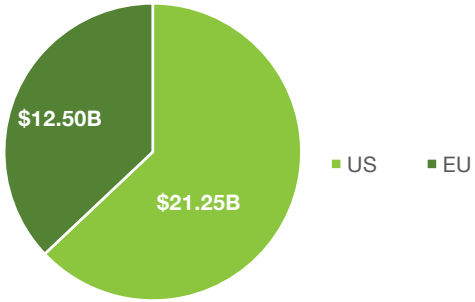
	Sepsis Phase IIb
Addressable global market	$33 Billion market (severe Sepsis only)
Type	Controlled, randomized, multi-center (5 centers)
Patients	120 (75 treated, 40 control) , SOFA < 10, Pneumonia-sourced
Duration	28 days / patient
Recruitment	12 Months
End-points	Safety, Change in SOFA score
Secondary	Mortality
First patient dosed	By Q4/2020

Sepsis treatment is a $33 billion market with no approved drug

Significant demand, no approved drug

	Regulatory Approvals	Number of Annual Patients
US	None	**1.7M**
EU	None	**1.0M**

Severe sepsis segmentation & market size ($US)



Status	Company	Addressable issue	Mechanism of action
Terminated 2018	FERRING	Prevent Vascular Leakage	Increase Arterial Pressure
Unclear, no reports	TiGENIX	Severe Pneumonia	Immune modulator
Phase II/III Q2 2020	ENLIVEX	ALL	Overall Immune Rebalancing

Estimated Pricing & TAM

$50,000 x 675,000 Patients PA (global)

= $33 Billion TAM

ENLIVEX immune rebalancing

SOURCE: US Centers for Disease Control and Prevention (CDC) 2018

Sepsis go-to-market strategy

Sepsis Phase IIb, 120 patients, expected initiation by Q4 2020

Q3/2021 interim data,
Q4/2021 top-line data

Pending study results, apply for conditional marketing authorization in Europe (EMA), and start selling the product in Europe.

Initiate a post-marketing global Phase III, targeting regulatory approval in the U.S. and conversion of conditional marketing authorization in Europe to permanent.

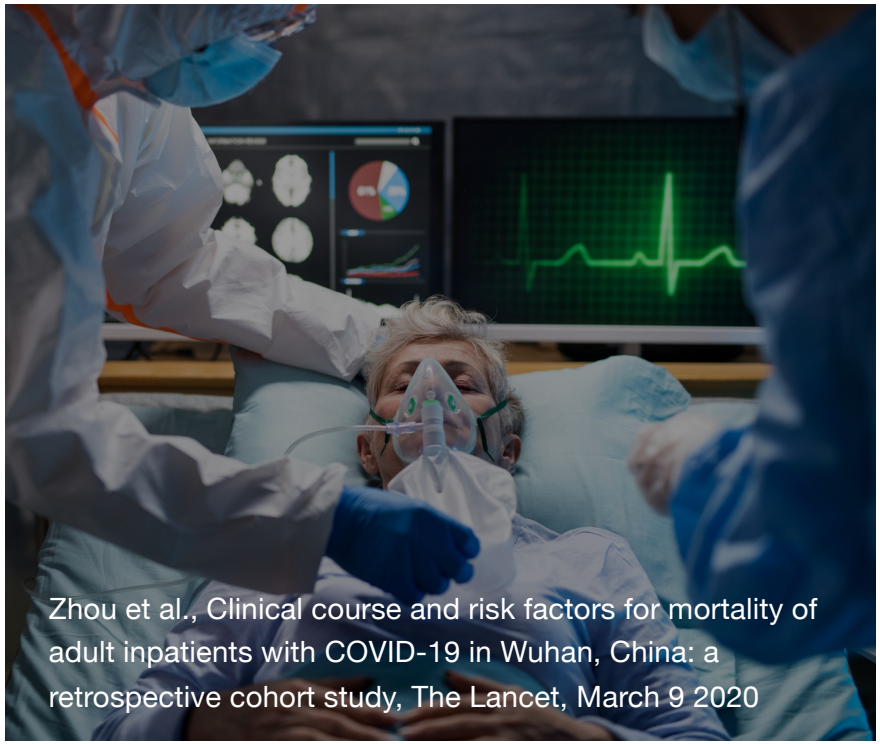
Preventing & treating

COVID-19 organ failure & mortality

COVID-19 patients cause of death: sepsis, typically associated lung failure

191 severe COVID-19 patients in the Wuhan area

- 54 mortalities
- All 54 mortalities (100%) had sepsis
- Majority of sepsis was lung-associated – 92% of the 54 patients had ARDS.
- Cardiac & kidney injury in ~50-59% of mortalities



Zhou et al., Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study, The Lancet, March 9 2020

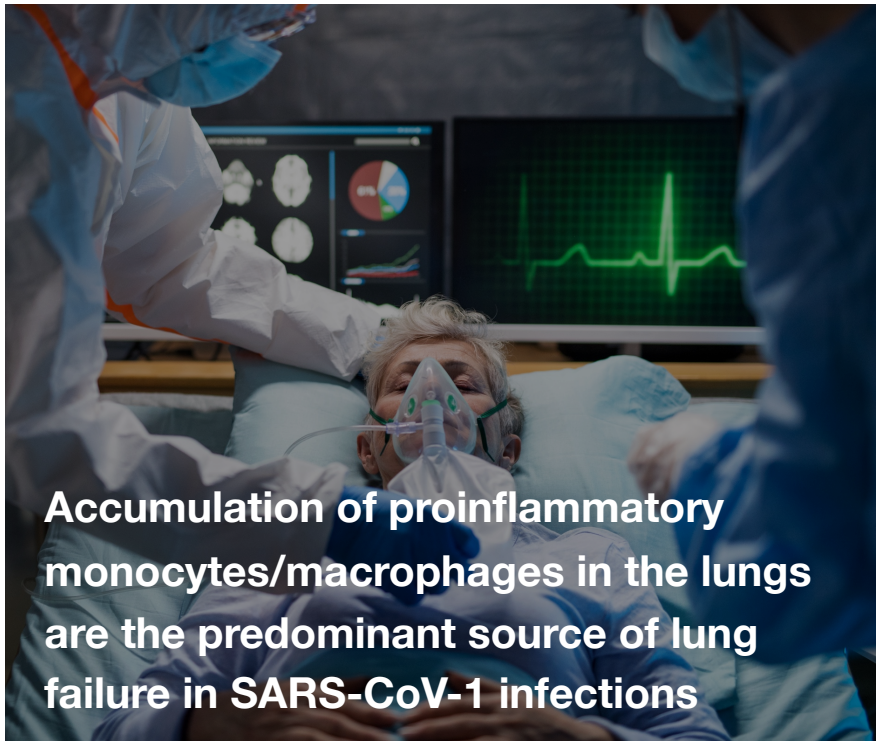
Controlling macrophages in the lungs may prevent lung failure in SARS-CoV-1/2 infections (I)

SARS-CoV-1

Channappannavar et al. Pathogenic human coronavirus infections: causes and consequences of cytokine storms and immunopathology .

Semin Immunol 2017

"Accumulation of inflammatory monocytes/macrophages and neutrophils in the infected lung. Proinflammatory monocytes/macrophages and neutrophils are the predominant source of cytokines/chemokines associated with lethal state of the disease."



Controlling macrophages in the lungs may prevent lung failure in SARS-CoV-1/2 infections (II)

SARS-CoV-2

Liao et al. The landscape of lung bronchoalveolar immune cells in COVID-19 revealed by single-cell RNA sequencing.

Preprint 2020

"monocyte-derived FCN1+ macrophages …. overwhelm in the severely damaged lungs from patients with ARDS. These cells are highly inflammatory and enormous chemokine producers implicated in cytokine storm."

Peer-reviewed, robust science

frontiers in Immunology

Apoptotic Cells induced Signaling for immune Homeostasis in Macrophages and Dendritic Cells

Uriel Trahtemberg and Dror Mevorach, 2017

nature REVIEWS IMMUNOLOGY

Apoptotic cell clearance: basic biology and therapeutic potential

Ivan K.H. Poon, Christopher D. Lucas, Adriano G. Rossi and Kodi S. Ravichandran, 2014

Biology of Blood and Marrow Transplantation

The Official Journal of the American Society for Blood and Marrow Transplantation

Single Infusion of Donor Mononuclear Early Apoptotic Cells as Prophylaxis for Graft-versus-Host Disease in Myeloablative HLA-Matched Allogeneic Bone Marrow Transplantation: A Phase I/IIa Clinical Trial

Dror Mevorach, Biology of Blood and Marrow Transplantation, 2014

European Journal of Immunology

iC3b-opsonized apoptotic cells mediate a distinct anti-inflammatory response and transcriptional NF-jB-dependent blockade

Gil Amarilyo, Dror Mevorach, et al., European Journal of Immunology 2010

Intellectual property

Target	Territory	Status	Filing	Term
Immune disease medicament comprising A modulator of the binding between A heparin binding domain of thrombospondin-1 & A beta1 integrin	US, EU ROW	Granted Granted	2009 2006	2027 2026
Disease therapy using dying or dead cells	US, EU, IL ROW	Granted Granted	2014 2006	2026 2025
Therapeutic apoptotic cell preparations, method for producing same and uses thereof	US, EU, AU, JP ROW	Granted In-Process	2014 2013	2033 2033
Combination immune therapy and cytokine control therapy for cancer treatment	US ROW	In-Process In-Process	2016 2017	2036 2037
Therapeutic pooled blood apoptotic cell preparations and uses thereof	US, ROW	In-Process	2016	2036
Therapeutic apoptotic cells for cancer therapy	US, ROW	In-Process	2017	2037
Therapeutic apoptotic cells for sepsis	US, ROW	In-Process	2018	2038
Therapeutic apoptotic cells for the treatment of osteoarthritis	US, ROW	In-Process	2019	3131

Planned milestones

Q2 2020
Initiation of
COVID-19 Phase II

Q2 2020
Interim data
COVID-19 Phase II

Q3 2020
Final data
COVID-19 Phase II

Q3-4 2020
Initiation of sepsis
Phase IIb, 120 patients

Q2-3 2021
Interim data
sepsis Phase IIb

Q4 2021
Top line data
sepsis Phase IIb

Financial Summary

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Cash	$12MM (Dec. 31, 2019) $24.75MM financing closed March 5, 2020
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Funded Through	Q1-2023

Board Of Directors

Shai Novik Executive Chairman	Founder of Prolor Biotech, Sold in 2013 ($560mm transaction). Lead product partnered to Pfizer, $295 million down payment, $275 upon FDA approval	**Abraham Havron,Ph.D.** Director	Former CEO of Prolor Biotech. Founding team and Director of R&D of Interpharm (Merck Serono) ,VP CMC of BioTechnology General Ltd., and VP of Clal Biotechnology Industries Ltd.
Hyun Gyu Lee, Ph.D., M.D Director	Executive Director, Investment Division, Korea Investment Partners Co., Ltd	**Baruch Halpert** Director	Over 20 years of experience in VC and Private Equity as an entrepreneur, corporate finance advisor, senior executive and an investor
Bernhard Kirschbaum, PhD Director	Former Executive Vice President & Member of the Board at Merck Serono, Head of Global Research & Early Development	**Sangwoo Lee** Director	Executive Director of the Investment Department & Head of U.S. Branch at Korea Investment Partners Co. Ltd
Gili Hart, Ph.D Director	Formerly with Prolor Biotech, led the pre-clinical, clinical and pharmacological activities. CEO of Mitoconix Bio, a biopharmaceutical company developing disease modifying therapies addressing unmet medical needs	**Michel Habib** Director	CEO of HBL, former Managing Partner of Agate-MaC Fund, a healthcare VC

Thank You

www.enlivex.com

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