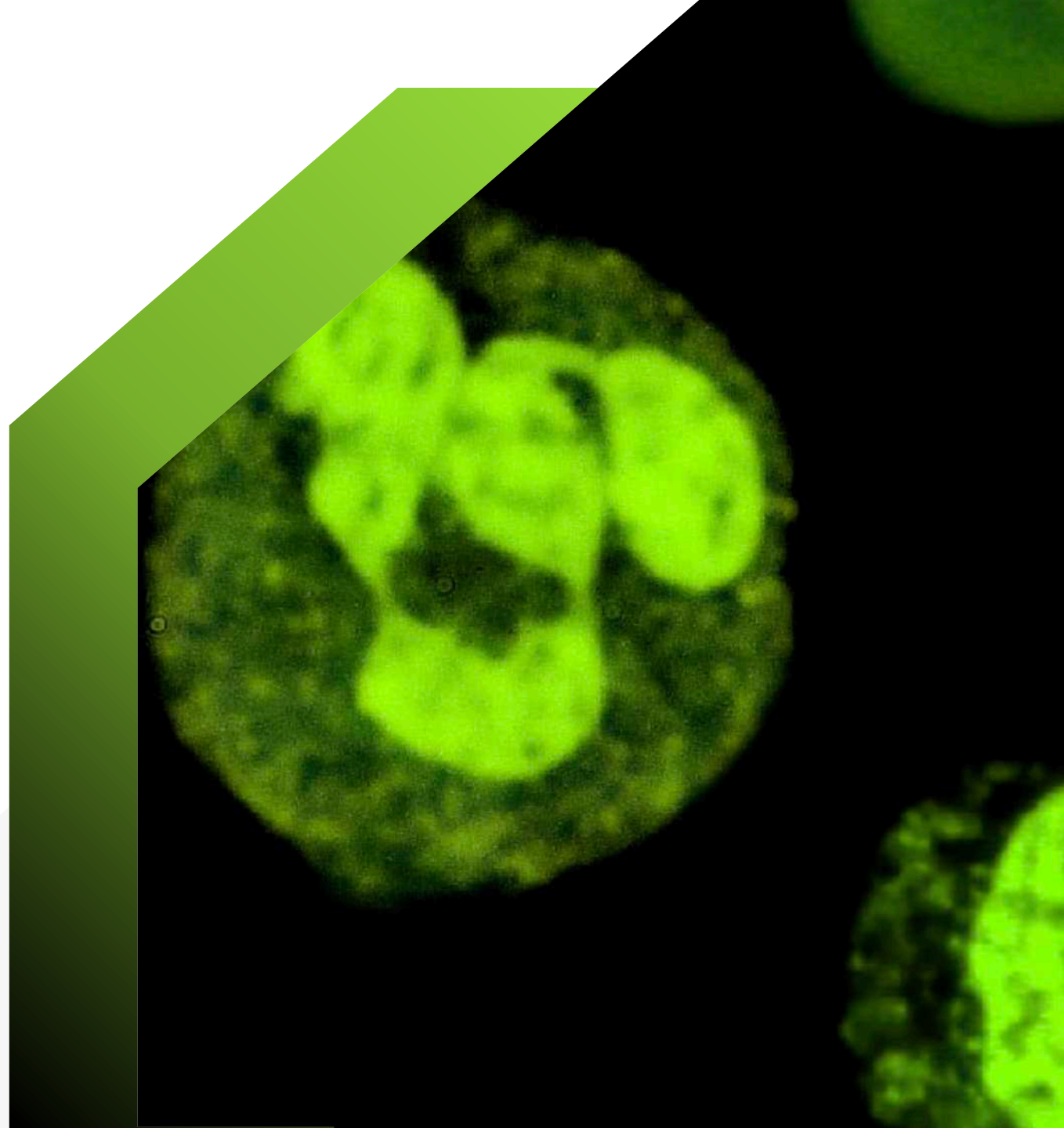




ENLIVEX

**Off-the-shelf, universal,  
macrophage reprogramming  
cell therapies for life-  
threatening and debilitating  
diseases**

NASDAQ Ticker: ENLV



# 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: next-generation, differentiated cell therapies

## PAST

- Autologous
- Not scalable
- High COGS
  
- Engineered T-cells

## FUTURE

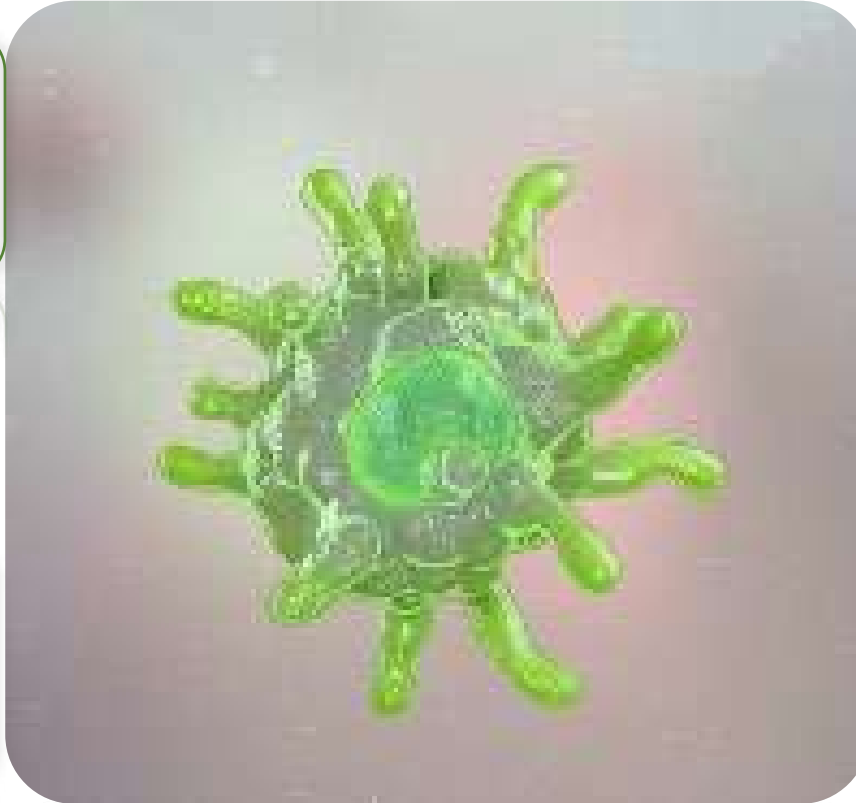
- Off-the-shelf
- Scalable
- Low COGS
  
- &
- New cell modalities

- NKs 
- Gamma-delta 
- Macrophages 

# Immune system balance: macrophages are key player

Primary immune cells that regulate immune activity

First-responders to pathogenic challenge and orchestrate the immune response



In some diseases, macrophages are negatively-reprogrammed and become non-homeostatic

Non-homeostatic macrophages cause excess damage and become part of the disease pathophysiology

# Macrophage homeostasis implies proper function for its specific tissue, environment, and challenge.

Reprogramming imbalanced macrophage populations can lead to disease resolution





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## Allocetra™

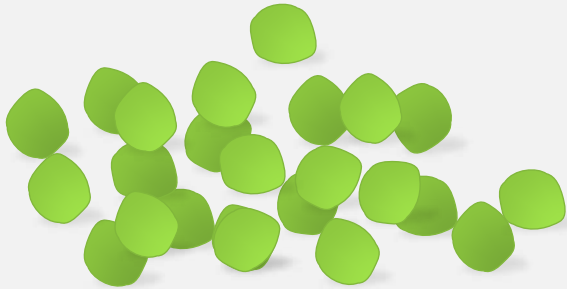
- **First-ever cell therapy designed to restore macrophage homeostasis, overall immune rebalancing.**
- **Provide a highly-differentiated new modality that may offer effective treatment to sepsis and osteoarthritis patients.**



# Allocetra™ for macrophage reprogramming: the manufacturing process

Proprietary, universal, off-the-shelf, frozen-formulation, macrophage-reprogramming cells

## Allocetra™ characteristics



- Mononuclear cells collected from healthy donors.
- Modified through a proprietary process to:
  - Express PtdSer (“eat me” signal) on their surface.  
Enabling engulfment into macrophages via specific interaction with various receptors.
  - Yet maintain their membrane intact.
- Universal, allogeneic, irradiated, off-the-shelf, frozen, and ready-to-use.

## Allocetra™ delivery into macrophages via engulfment

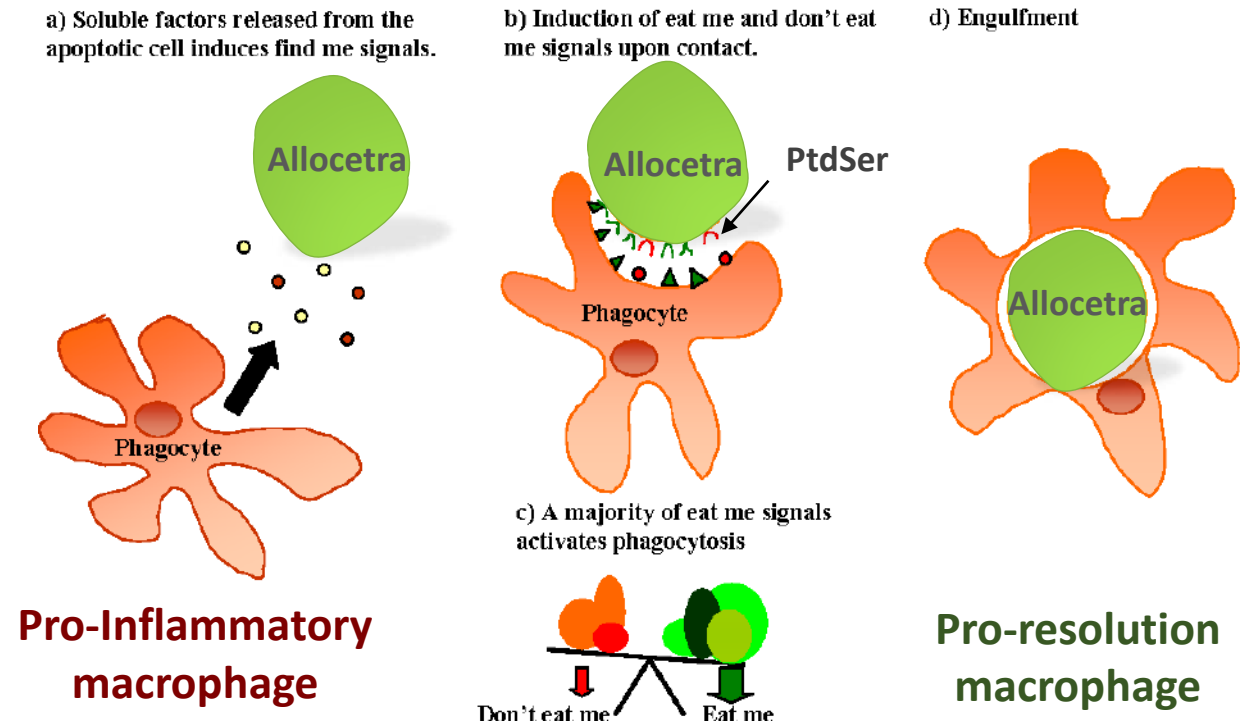


Figure adapted from Nilsson, A. (2009). Mechanisms involved in macrophage phagocytosis of apoptotic cells.

# Allocetra™ for macrophage reprogramming

## Pipeline of reprogrammable macrophage-modulated indications

Indication	Global Market Size	Pre-Clinical	Phase Ib	Phase IIb	Potential support for EU Conditional Marketing Approval Submission	Post EU Marketing US Phase 3
Organ failure associated with Sepsis	\$33B		Completed	Randomized, controlled Phase II ongoing	Top-line data for Phase II April 24'	
Moderate knee osteoarthritis	\$7B			Randomized, controlled Phase I/II	Top-line data for Phase I/II Q3-25'	
End-stage knee osteoarthritis	\$2B		Phase I/II Ongoing		Top-line data for Phase I/II EOQ3-24'	





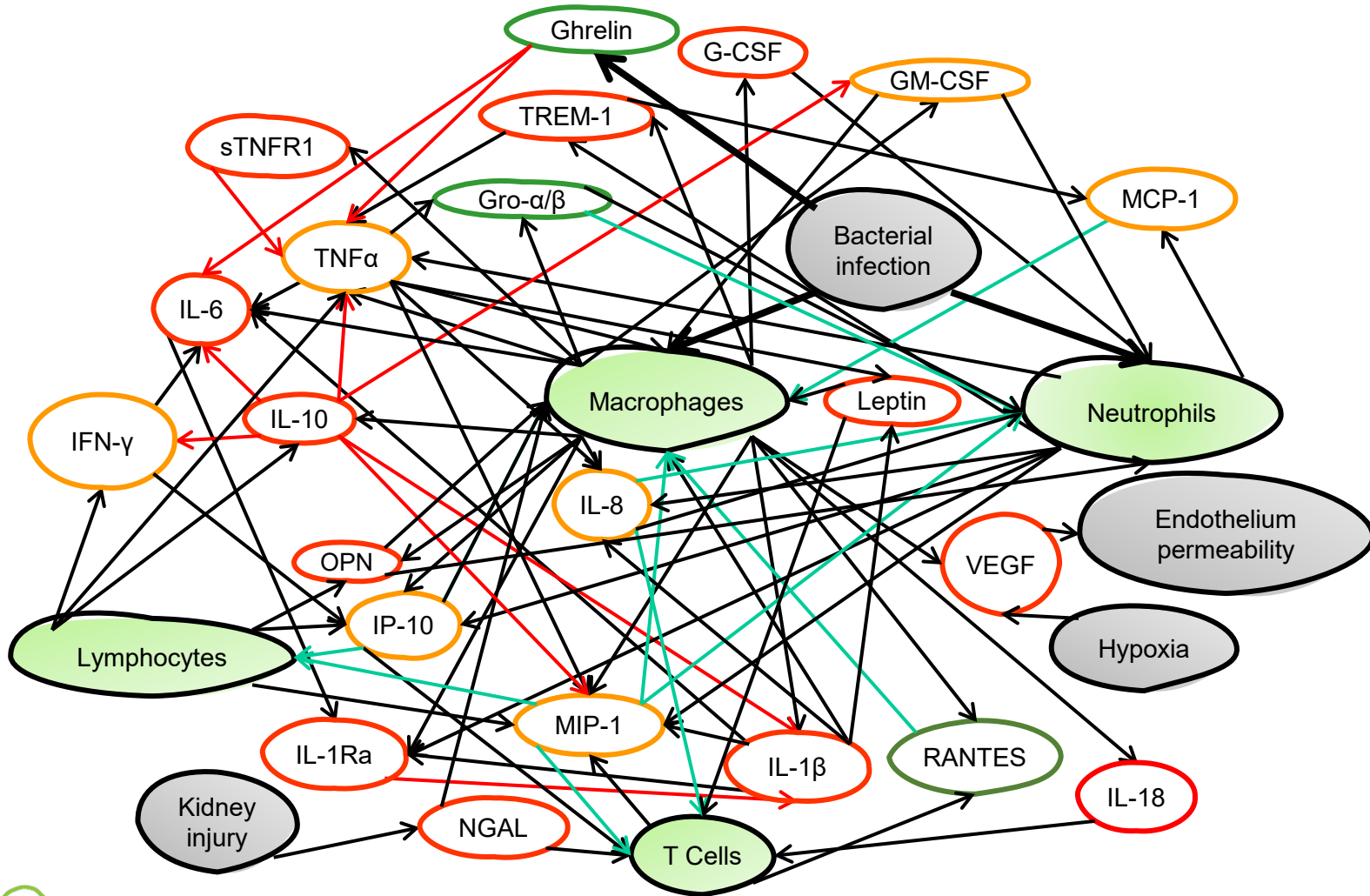
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**Allocetra™**

Reprogramming macrophages responsible  
for organ failure in Sepsis



# Cytokine/Chemokine network in sepsis: the impossible task of resolving sepsis with inhibition of a certain cytokine or signaling pathway



MΦ: Macrophages

→ Activation

→ Inhibition

→ Chemotaxis

○ Downregulated in most of the patients

○ Downregulated in 50% of the patients

○ Upregulated in most patients

**Macrophage reprogramming to “manufacturer settings” is required to obtain sepsis resolution**



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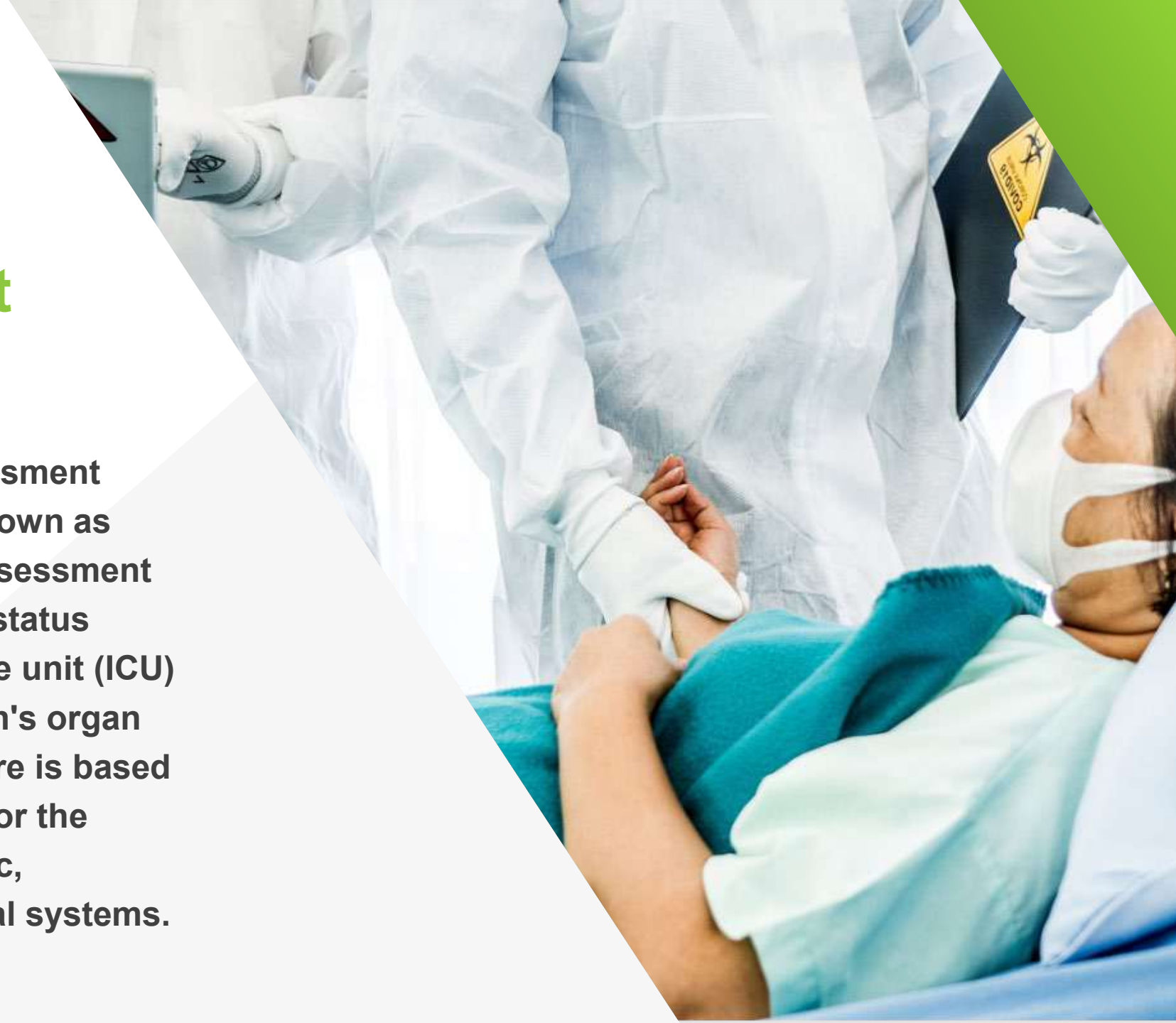
**Allocetra™**

Phase Ib clinical trial of macrophage  
reprogramming in Sepsis patients



# 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

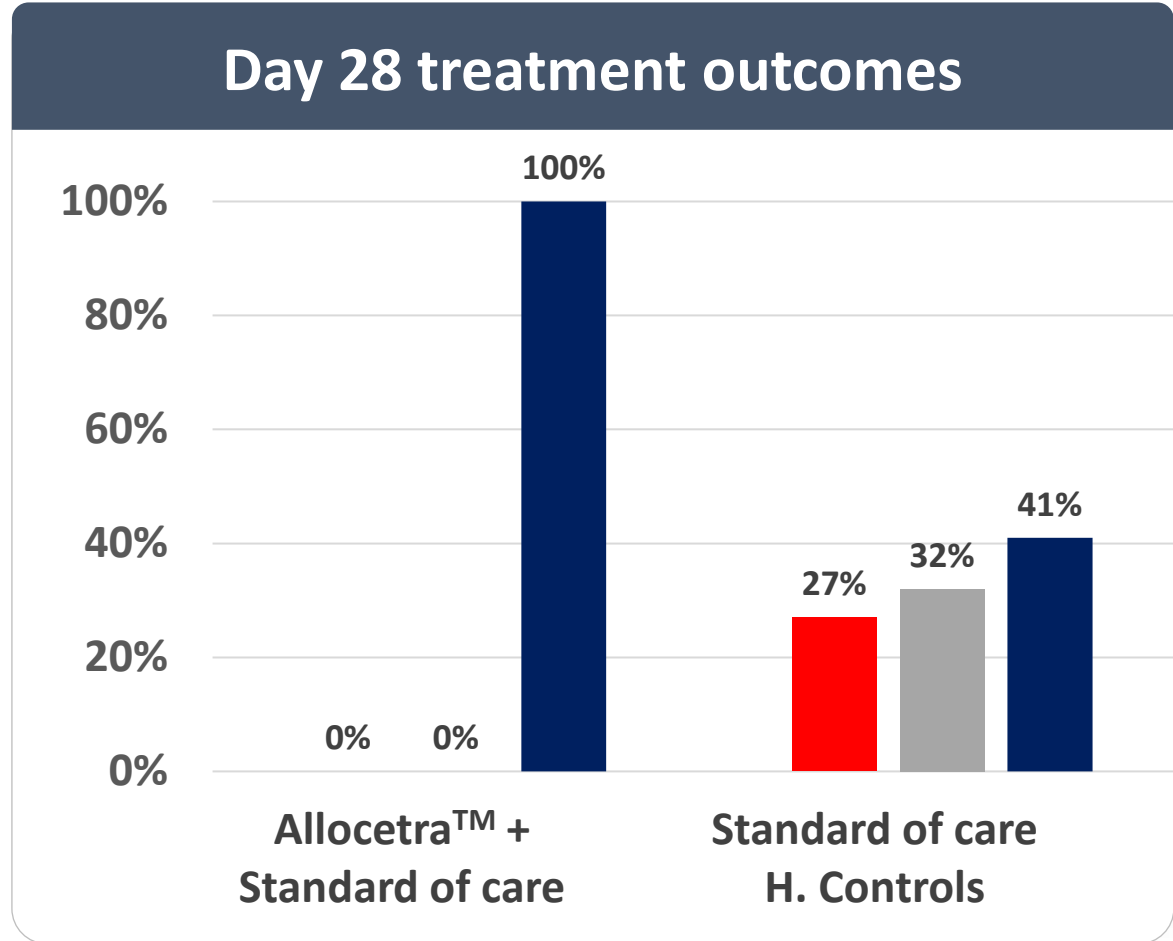
	Treated (n=10)	Matched Controls (n=37)
Average age	71.5 (51-83)	71.25 (50-83)
Male/female	80/20	80/20
Average diagnosis SOFA	3.4 (2-6)	3.47 (2-7)
Average diagnosis Apache II score	12.3 (8-21)	14.25 (5-24)

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

# Allocetra™ macrophage reprogramming leads to improved outcomes for sepsis patients

Alive and organs recovered on day 28: 100% vs 41%

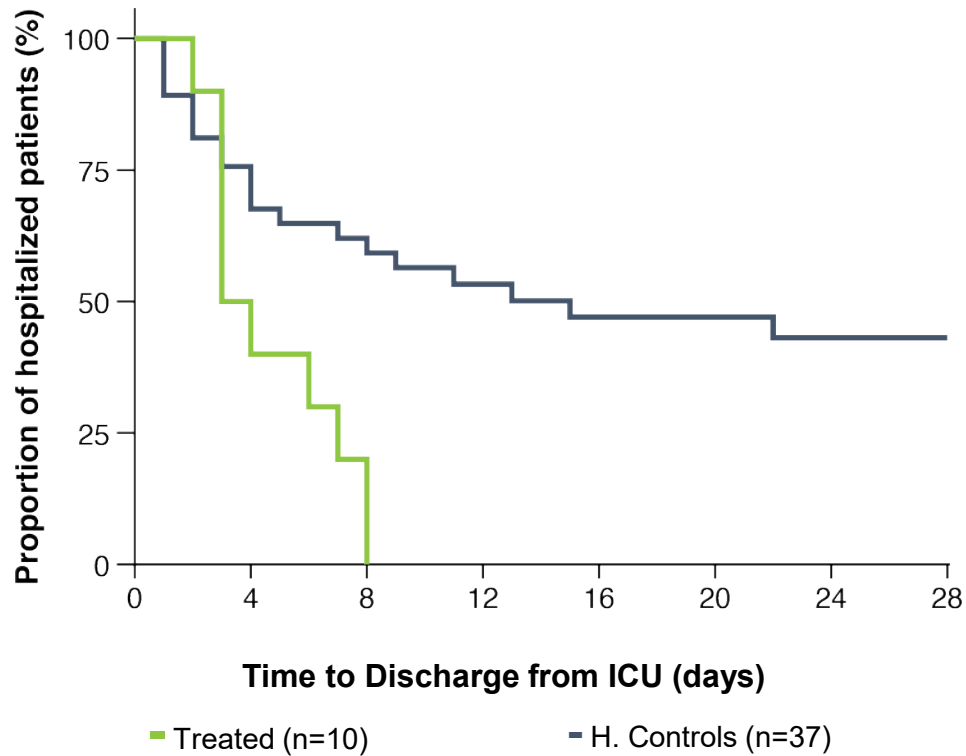
- Day 28 mortality
- Day 28 still with organ failures
- Hospital discharge



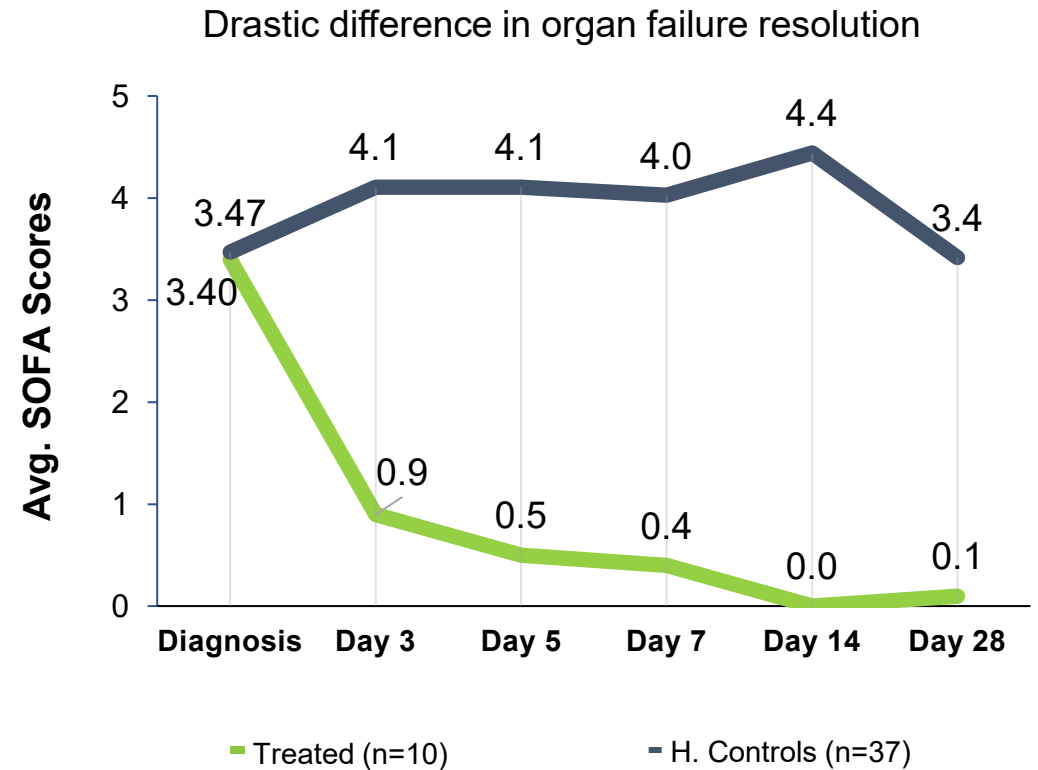
# Allocetra™ macrophage reprogramming leads to improved outcomes for Sepsis patients

Statistically significant improvement in hospitalization and SOFA vs. matched controls

## Time to ICU discharge



## Average SOFA score during 28 days



# Clinical summary of macrophage reprogramming in Sepsis Phase Ib: complete recovery from any organ failure for all 10 patients and 100% 28-day survival

## Sepsis clinical characteristics and organ recovery

<b>Organ Dysfunction</b>	Each patient had at least 2 organ dysfunctions, maximum of 5
<b>Kidney</b>	3/9 patients (33%) had new-onset acute kidney injury, all have completely recovered to baseline kidney function
<b>Lungs</b>	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
<b>Cardiovascular</b>	3/10 (30%) of patients had mean arterial pressure <70 but none needed vasopressors
<b>Hematological</b>	8/10 patients (80%) had significant thrombocytopenia, with complete recovery in all.
<b>Liver</b>	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

## Allocetra™ macrophage reprogramming Phase II clinical plan

	Sepsis Phase II
Addressable global market	\$33 Billion market (severe Sepsis only)
Type	Controlled, randomized, multi-country, multi-center
Patients	80-160, SOFA < 10, Source: pneumonia, biliary, urinal tract, and peritoneal infections
Duration	28 days / patient
Recruitment	12 Months
End-points	Safety, Change in SOFA score
Secondary	Mortality
First patient dosed	Q2/2021



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**Allocetra™**

**Phase Ib & II Clinical Trials in COVID-19  
Patients in Severe or Critical Condition**



## Despite strong clinical results, COVID-19 business opportunity is de-prioritized

- Primary reasons:
  - Availability of therapeutics for mild/moderate patients
  - Dominance of Omicron variants, who seem to cause less severe disease in most patients
  - Regulators “step-back” and reluctance to provide emergency use authorizations, requirements for large Phase IIIs

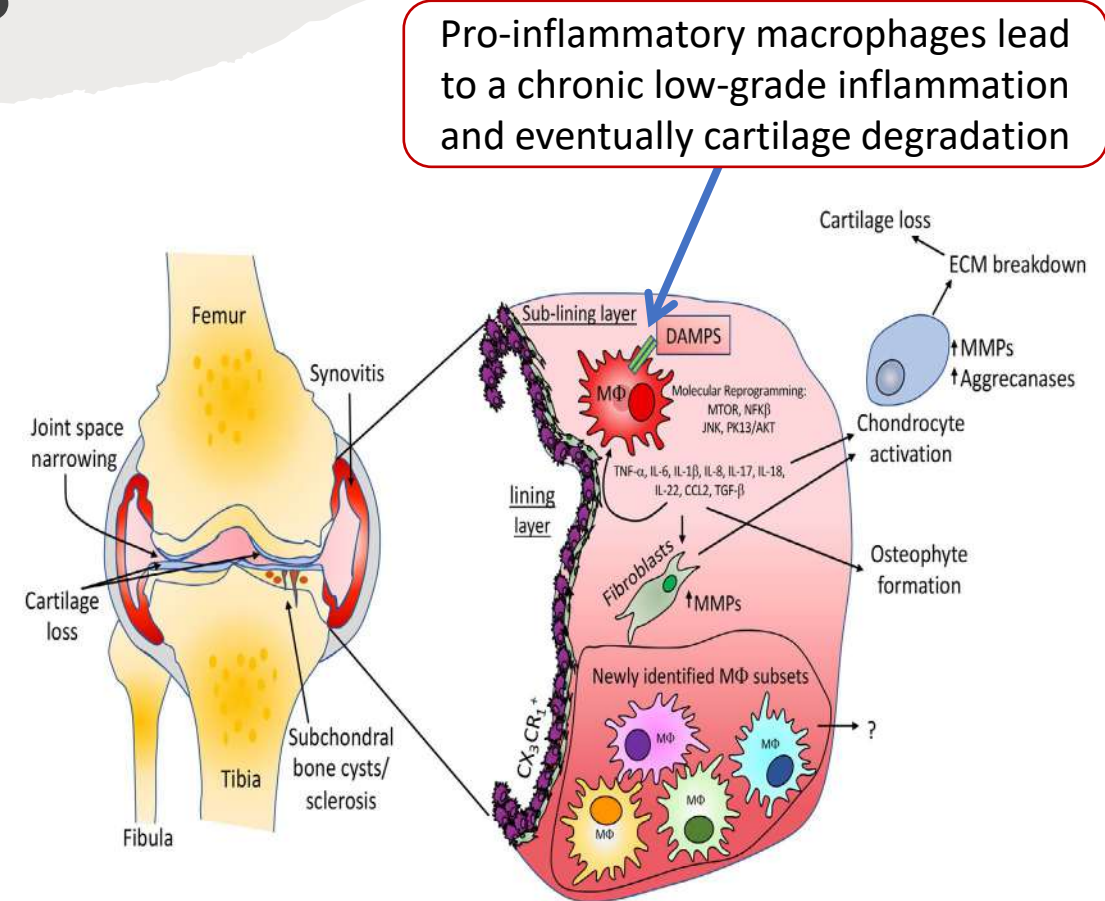
# Allocetra™: Positive Phase Ib and top line Phase II results in COVID-19

Clinical Trial	# Patients enrolled	Disease Severity *	Clinical Outcome		Hospitalization Post Administration of Allocetra™	
			Recovered Day 28	Mortality Day 28	Discharged Day 28	Duration (days, avg.)
Phase Ib	5	2 Severe, 3 Critical	5/5 (100%)	0/5 (0%)	5/5 (100%)	6.6
Phase II	16	9 Severe, 7 Critical	14/16 (87.5%)	0/16 (0%)	14/16 (87.5%)	5.3
<b>Total</b>	21	11 Severe, 10 Critical	19/21 (90.5%)	0/21 (0%)	19/21 (90.5%)	5.6

- 0/21 (0%) mortality on day-28
- 19/21 (90.5%) patients recovered and were discharged from the hospital by day-28
- Average duration of hospitalization post administration of Allocetra™ for discharged patients was 5.6 days
- 2/21 (9.5%) patients, both of whom had critical illness at the time of Allocetra™ treatment, were hospitalized in the ICU on a respirator on day-28

# Allocetra and Osteoarthritis

- Osteoarthritis (OA) is a worldwide highly prevalent chronic joint disease that causes pain, disability, and loss of function.
- Globally, prevalent cases of OA increased from 247.51 million in 1990 to 527.81 million in 2019.
- Market size is valued at \$7.0 Billion and is projected to reach \$13.1 Billion by 2031.
- Poor treatment alternatives.
- Macrophages are considered an emerging target in OA.
- Allocetra's unique MoA may lead to disease amelioration and resolution using a novel treatment approach with a competitive market price.



# Osteoarthritis vertical - severe compassionate case as basis for Allocetra potential

- 70-year old patient who suffered for many years from vanishing bone disease (Gorham-Stout syndrome)
- A rare disease characterized by destruction of osseous matrix and proliferation of vascular structures, resulting in complete destruction and absorption of the patient's shoulder joint.
- Despite exhaustive therapeutic attempts, the patient's disease remained refractory to treatment and continued to deteriorate, with continuous production of synovial fluid, necessitating permanent drainage of the shoulder and, as a consequence, requiring extended hospitalization for a duration of nine months prior to compassionate treatment with Allocetra™ to the shoulder joint.
- Following five **intra-articular Allocetra™ injections**, substantial improvement was documented
  - 70% reduction in fluid drainage
  - 93% reduction in CRP, back to normal range
  - Downregulation of IL-22 (dysregulation of wound healing of synovial tissue), IL-8 (neutrophilic chemotactic factor), IL-6 (innate immunity), IL-9 (apoptosis prevention) and MIP-1-β (chronic inflammation).
- Patient was successfully discharged from the hospital. At the two-year follow-up, CRP remained within normal range, shoulder remained without swelling, and the clinical improvement was maintained without any need for re-hospitalization.

# Osteoarthritis vertical, ongoing and planned clinical trials

- **End-stage knee osteoarthritis**

- Investigator-initiated Phase I/II, 12 patients
- Patients have already been indicated for knee replacement surgeries
- Offered an injection of Allocetra™ in lieu of surgery
- First patient dosed
- Data readouts EOQ3-24

- **Moderate knee osteoarthritis**

- Company sponsored Phase I/II
- Patients with KL2-KL3 knee osteoarthritis
- Randomized, controlled, statistically-powered 120-150 patients
- Scheduled initiation Q1-24
- Top-line data planned Q3-25



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**Allocetra™**

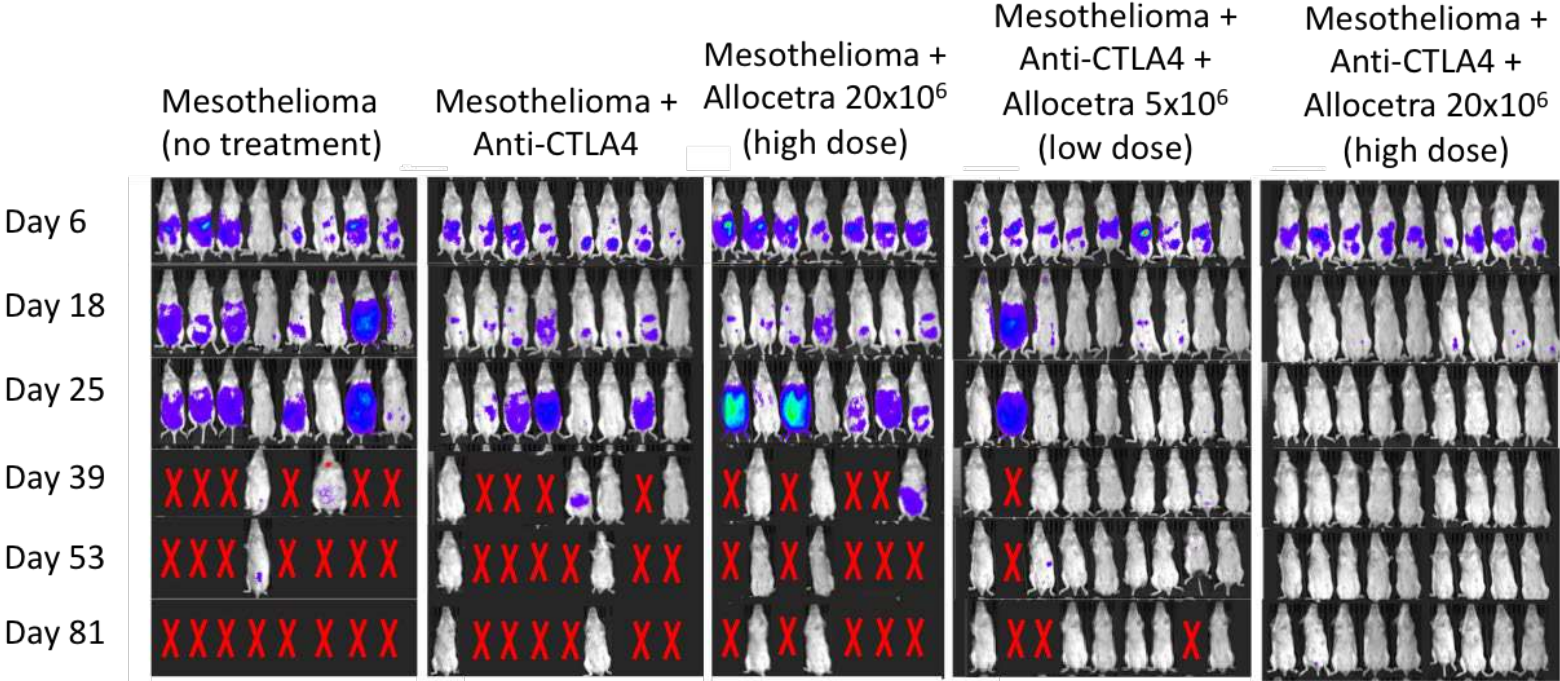
**Macrophage reprogramming in solid tumor  
microenvironment**

**Unique & differentiated value proposition**





# Synergistic effect of Allocetra™ + anti-CTLA4 in peritoneal mesothelioma solid tumor



**Legend**

Initial cancer spread

advanced cancer spread

mouse dead **X**

mouse alive

Mortality	<b>100%</b>	<b>75%</b>	<b>71.5%</b>	<b>33%</b>	<b>0%</b>
Survival	0%	25%	28.5%	67%	100%
Complete cure	0%	25%	28.5%	67%	100%

IVIS imaging, AB12-137 study

# Enlivex - Planned Milestones (24 months)

## Q4 2022

Received FDA approval for IND  
(Phase I/II in advanced-stage  
solid tumors patients)



## April-24

Top line data macrophage  
reprogramming Sepsis  
Phase II (randomized,  
controlled)

## Q3-25

Moderate knee  
osteoarthritis Phase I/II  
top-line data  
(randomized, controlled,  
powered)

## Q3-23

Initiation of Phase I/II in  
end-stage knee  
osteoarthritis

## Q1-24

Initiation of Phase I/II in  
moderate knee  
osteoarthritis

## EOQ3-24

End-stage knee  
osteoarthritis Phase I/II  
readouts

# Financial Summary



**NASDAQ GS**

**ENLV**

**Cash**

**\$30MM (Sep 30, 2023)**

**Debt**

**None**

**Shares Outstanding**

**18.4 MM**

**Funded Through**

**Dec 31, 2025.**

# Management

**Shai Novik**  
Executive Chairman

Founder and President of PROLOR Biotech through a \$560mm sale in 2013. Lead product partnered to Pfizer, \$295 million down payment, \$275 upon FDA & other regulatory approvals. Now named Ngenla® by Pfizer, received marketing authorizations starting 2022 in Australia, Canada, Japan & Europe



**Oren Hershkovitz**  
CEO

Former Director of CMC, VP R&D and General Manager of OPKO Biologics (PROLOR Biotech). Led multiple clinical programs in Phase I, II and III. Ph.D. in Immunology including Phase 3 co-development with Pfizer which led to the approval of Ngenla®



**Dror Mevorach**  
Chief Scientific Officer

Director, Rheumatology Research Centre and Molecular Immunology; and Director, Centre for Rare diseases, Hadassah Medical Center, Jerusalem.



**Einat Galamidi**  
VP Medical

10 years at Gamida Cell Ltd., most recently served as Vice President of Clinical Development, and head of clinical development for Omisirge®, a cell therapy that received FDA approval in April 2023.



**Iris Tavor**  
Senior Director of RA/QA

13 years of experience in Quality and Regulatory Affairs in at Pluristem Ltd, where most recently Iris served as the Head of Regulatory Affairs and led submissions of several INDs and CTAs.



**Veronique Amor-Baroukh**  
Senior Director of Operations

Extensive experience as manager of Allocetra development department, CMC and operation at Enlivex, Ph.D., Molecular Neurobiology, Weizmann Institute of Science.



**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.



**Chen Ankri**  
Director of Pre-Clinical & Clinical pharmacology

Ph.D., Cancer Immunotherapy, Bar-Ilan University, Israel. Former Immunology research manager in CTG Pharma. Several years of experience in immunotherapy R&D in various biotech companies



# Board Of Directors

**Shai Novik**  
Executive Chairman

Founder and President of PROLOR Biotech, Sold in 2013 (\$560mm transaction). Lead product partnered to Pfizer, \$295 million down payment, \$275 upon FDA & other regulatory approvals. BLA filed by Pfizer late 2020.

**Roger Pomerantz**  
Vice Chairman

Former Worldwide Head of Licensing and Acquisition and Knowledge Management at Merck & Co., where he led the completion of more than 150 business development transactions. Former Global Head of Infectious Diseases for Johnson & Johnson Pharmaceuticals. Former Venture Partner at Flagship Pioneering, as well as the former President, CEO, and Chairman of the Board of Seres Therapeutics

**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

**Brian Schwartz, M.D.**  
Director

Former CMO of Arqule through its \$2.7 billion acquisition by Merck in 2020. Previously, responsible for the global clinical development of sorafenib (Nexavar®) at Bayer Healthcare.

**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.

**Andrew Singer**  
Director

Former EVP and CFO of Epizyme and Senior Biotech Investment Banker at Credit Suisse, Wells Fargo Securities and RBC Capital Markets. Led financing, partnering and M&A biopharmaceutical transactions in excess of \$13 billion.



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**Thank You**

