COMPANY PRESENTATION

January 2025

Nasdaq: **ENLV**

ENLIVEX

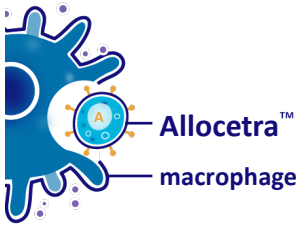
FORWARD-LOOKING STATEMENTS

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.

MACROPHAGE MODULATION FOR THE TREATMENT OF INFLAMMATORY DISEASES

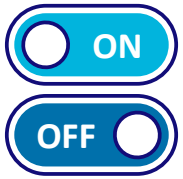
Enlivex is a clinical stage pharmaceutical company developing Allocetra™, a universal, off-the-shelf cell therapy designed to reprogram macrophages into their homeostatic state, for treatment of inflammatory diseases.

About:



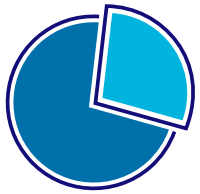
Novel therapeutic modality:

macrophage modulation.



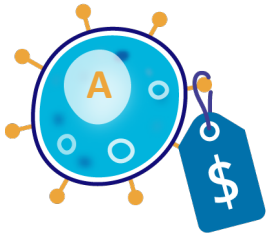
Novel approach:

allogeneic cells to trigger macrophage reprogramming.



Substantial market:

unmet need in inflammatory and autoimmune diseases.



Cost-effective cell therapy:

simple manufacturing process yielding a ready-to-use off-the-shelf cell therapy.

What's new:

1. Announced positive interim data from a Phase I/II moderate knee OA trial and initiation of Phase II stage of the study
2. Dosed first patient in a Phase I Psoriatic Arthritis
3. Announced adaptation of Bitcoin treasury strategy (up to $1MM)

ENLIVEX

DRIVING INNOVATION WITH BALANCED SCIENTIFIC AND BUSINESS EXPERTISE

Shai Novik
Executive Chairman
ngenla · PROLOR BIOTECH
26 years of experience
$590M company sale

Oren Hershkovitz
CEO
ngenla · OPKO
16 years of experience

Dror Mevorach
Scientific Founder
20 years of experience
140+ publications

Shachar Shlosberger
CFO
PROLOR BIOTECH
15 years of experience

Einat Galamidi
VP Medical
gamida cell
20 years of experience

Veronique Amor-Baroukh
Senior Director of Operations
WEIZMANN INSTITUTE OF SCIENCE
10 years of experience

Iris Tavor
Senior Director of RA/QA
Pluristem Therapeutics Inc.
20 years of experience

Chen Ankri
Director of pre-clinical & clinical pharma
10 years of experience

Sigal Arad
Director of Human Resources
15 years of experience

ENLIVEX

BOARD OF DIRECTORS

Shai Novik
Executive Chairman

Founder and President of PROLOR Biotech, Sold in 2013 ($590mm transaction). Lead product, Ngenla, partnered to Pfizer, $295 million down payment, $275 upon FDA & other regulatory approvals. Ngenla by Pfizer has obtained marketing approvals in 43 countries, including Japan, EU and U.S.

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 SpliSense, a clinical stage company focused on transformative RNA-based treatments for pulmonary diseases. SpliSense pioneering platform harnesses Antisense Oligonucleotides (ASOs) for the treatment of pulmonary diseases.

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.

Abraham Havron, Ph.D.
Director

Former CEO of PROLOR Biotech. Founding team and Director of R&D of Interpharm (Merck Serono), where he led the development of REBIF, a multi-billion multiple sclerosis drug. Formerly, 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 $13B.

CELLULAR FIRST RESPONDERS: MACROPHAGES AND THEIR CRITICAL ROLE IN INFLAMMATION

Macrophages, which are found in abundance throughout the body, are immune cells that reside in or infiltrate human tissue.

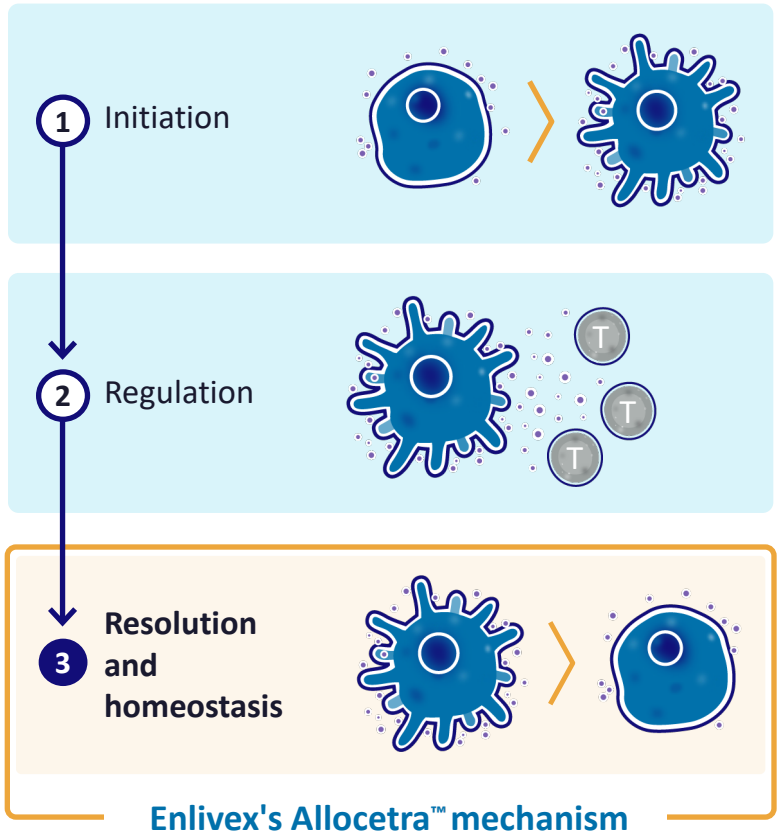
Main functions:

- Recruit other immune cells
- Defend against pathogens
- Cleanup senescent or dead cells
- Control tissue homeostasis and repair

Role in inflammation:

- Antigen presentation
- Cytokine secretion
- Phagocytosis
- Immunomodulation

Macrophages orchestrate inflammation and its resolution.



The current understanding among researchers is that disrupted inflammatory processes form the basis of many diseases, beyond “classical” inflammatory diseases.

ENLIVEX

PROMOTING BALANCE: APOPTOTIC CELLS FACILITATE MACROPHAGE HOMEOSTASIS

Prof. Dror Mevorach
Scientific Founder

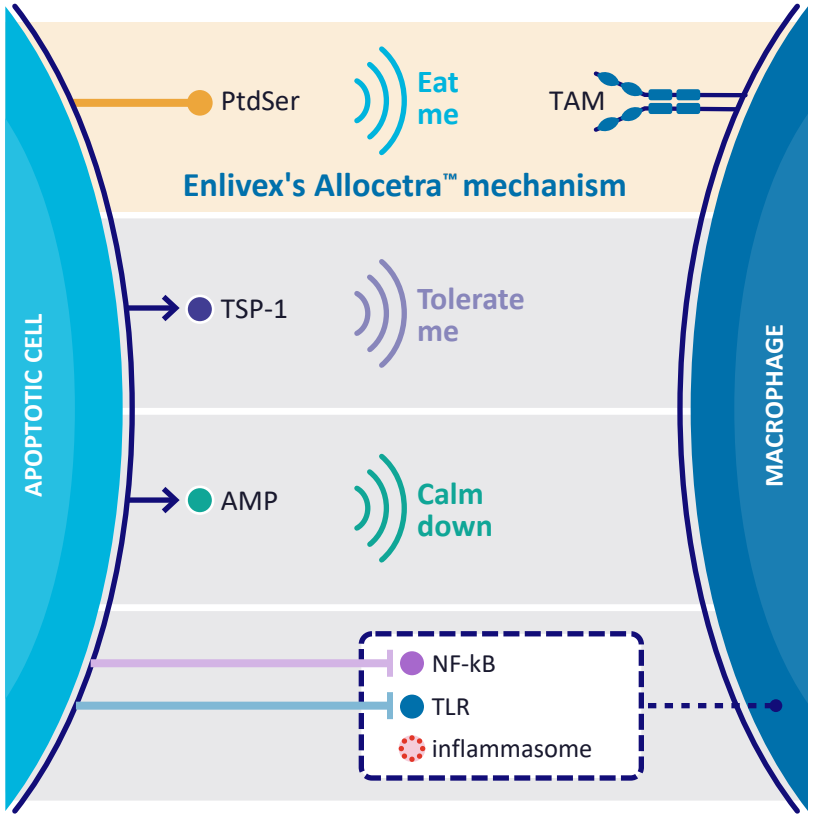
Apoptotic Cells Induce NF-kB and Inflammasome Negative Signaling
Amir Grau, Adi Tabib, Inna Grau, Inna Reiner, Dror Mevorach

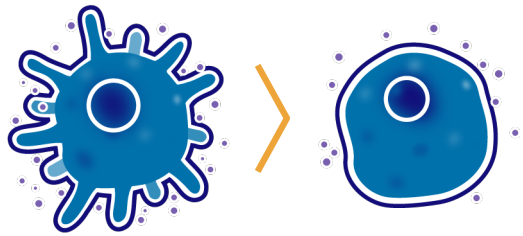
PLOS One, 2015

Apoptotic Cells induced Signaling for immune Homeostasis in Macrophages and Dendritic Cells
Uriel Trahtemberg and Dror Mevorach

Frontiers in immunology, 2017

How apoptotic cells influence macrophages

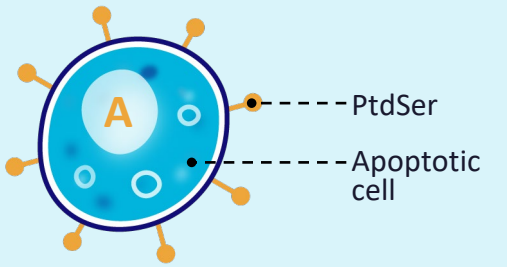




The interaction between apoptotic cells and macrophages contributes to the pro-resolution and immune-modulating effects of Allocetra™, promoting macrophage and immune homeostasis.

ENLIVEX

ALLOCETRA™: AN OFF THE SHELF CELL THERAPY DESIGNED TO RESTORE MACROPHAGE HOMEOSTASIS

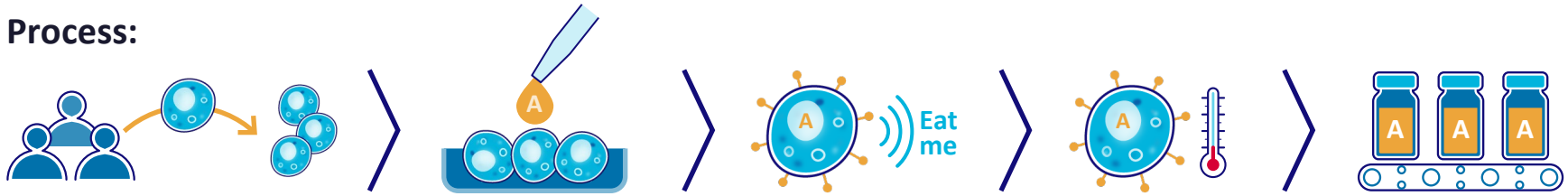


Allocetra™

Allogeneic mononuclear cells collected from healthy donors induced to a stable apoptotic state.

- harnesses the same biological activity seen in naturally occurring apoptotic cells;
- presents a highly-differentiated, off-the-shelf, cellular therapy modality.

Process:



collect cells from healthy donors

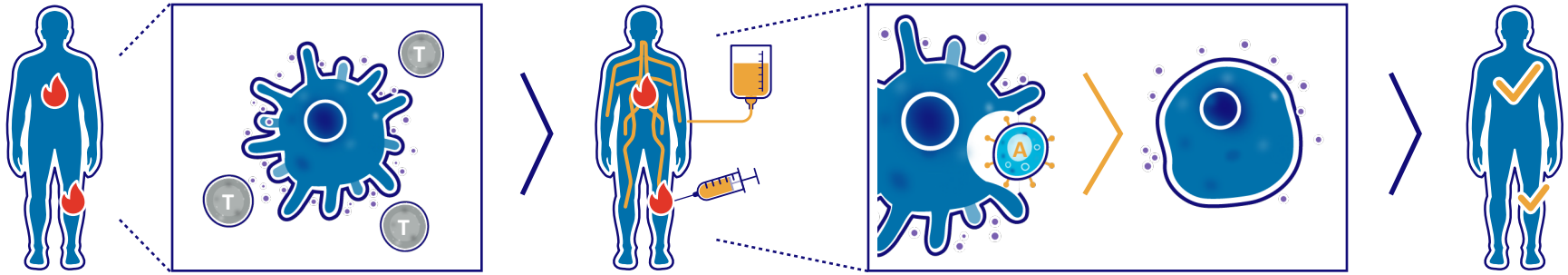
proprietary apoptotic cell modification process

cells express "eat me" signal

cells are frozen

off the shelf, cost effective cell therapy

Mechanism:



1. Patient with systemic or joint inflammation

2. Allocetra™ cells are injected into the patient

3. Allocetra™ cells are engulfed by macrophages

4. Macrophage homeostasis is restored

ENLIVEX

ALLOCETRA™ PIPELINE: BUILDING MOMENTUM

Indication	Study #	Administration	Pre-clinical	Phase I/II	Phase II	Phase III
Organ failure associated with sepsis	**ENX-CL-02-002** NCT04612413	Systemic administration	**Randomized, controlled, Phase II, 120 patients, ongoing. Efficacy stage completed; safety follow-up continues**			
Moderate knee osteoarthritis	**ENX-CL-05-001** NCT06233474	Local knee injection		**Randomized/controlled, 160 patients, enrolling**		
End-stage knee osteoarthritis	**0189-22-KMC** NCT06208241	Local knee injection		**Investigator-initiated, 18 patients, enrolling**		
Basal thumb osteoarthritis	**0006-24-KMC** NCT06459063	Local thumb injection		**Investigator-initiated, 56 patients, enrolling**		
Psoriatic arthritis	**ENX-CL-06-001** NCT06522035	Local injection to different joints		**Open-label in 6 patients, enrolling**		
Temporomandibular joint osteoarthritis	**1400-24-SMC** NCT06748651	Local TMJ injection		**Open-label in 6 patients, enrolling**		

ENLIVEX

A COMPREHENSIVE PICTURE: INFLAMMATORY DISEASE TREATMENT LED BY EXTENSIVE RESEARCH

	Sepsis* ✓ complete	COVID-19* ✓ complete	Vanishing bone disease ✓ complete
Patient population	N=10 — at least 2 organ dysfunctions, maximum of 5	N=21 — severe and critical patients	N=1 — 4-year inflammatory and erosive process of the shoulder
Phase / trials	1 completed trial: Phase I/II	2 completed trials: Phase I/II, Phase II	Compassionate case
Administration method	Systemic administration	Systemic administration	Local injection
Safety	Favorable safety profile, no drug related SAEs	No drug related SAEs or drug related AE	No drug related SAEs or drug related AE
Efficacy	10 / 10 **10/10** Complete recovery with no residual organ failure.	21 / 0 **0/21** mortality on day-28.	Inflammation (CRP) down **93%** to within normal range Fluid down **50%**
		21 / 19 **19/21** recovered and were discharged from the hospital by day-28.	**Patient discharged following 9 months in hospital. Hasn't been re-hospitalized for 3 years in subsequent follow-up.**

* Frontiers in Immunology 2021: Apoptotic Cells for Therapeutic Use in Cytokine Storm Associate with Sepsis-A Phase Ib Clinical Trial

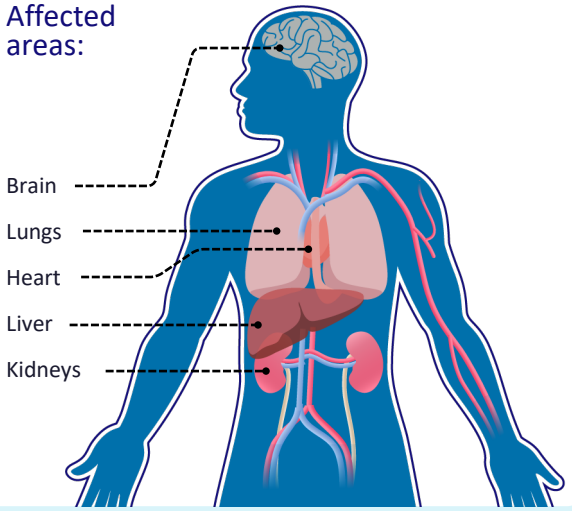
* Frontiers in Immunology 2023: Apoptotic Cells for treatment of acute respiratory distress syndrome associated with CCOVID-19

ALLOCETRA™
FOR THE TREATMENT
OF SEPSIS

ENLIVEX

SEPSIS: A GLOBAL HEALTH CHALLENGE WITH SUBSTANTIAL MARKET OPPORTUNITY

Disease



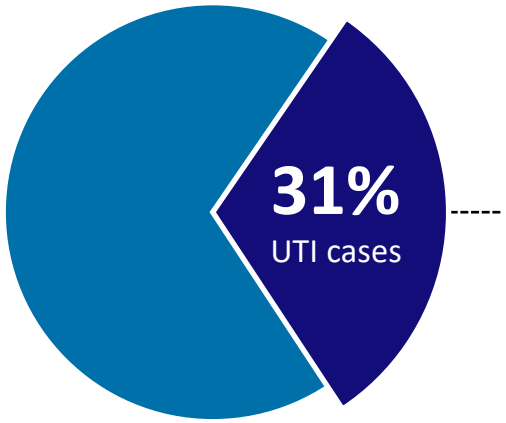
A life-threatening overactive immune response to infection that attacks the body and leads to:

- tissue damage,
- organ failure,
- death.

Market

$33B Global market (severe Sepsis only[2])

Up to 31% of sepsis cases start as urinary infections (UTI)[1]



~9.8M annual cases worldwide

1.6M deaths

Standard of care

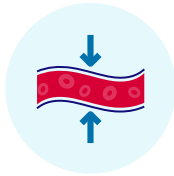
Currently there are no FDA/EMA approved drugs to treat sepsis.

SOC only treats complications of sepsis and does not address core dysregulated immune response.

Patients receive:


Antibiotics


IV fluids

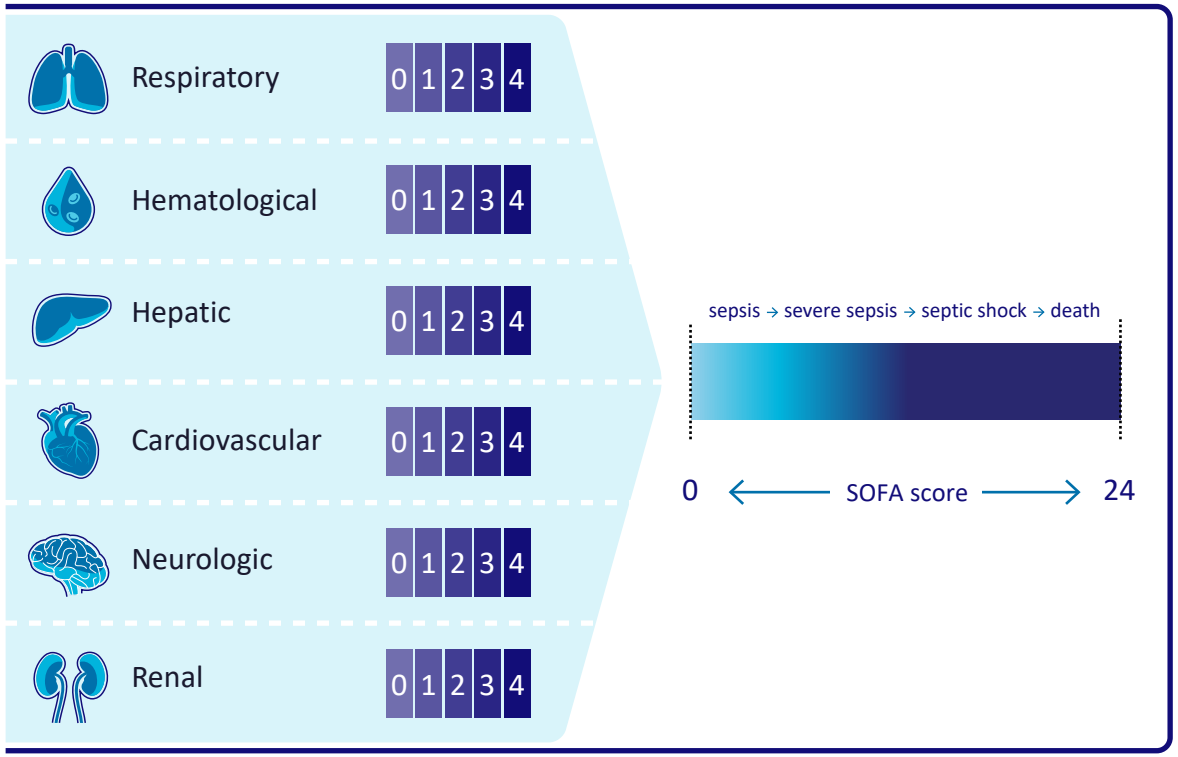

Vasopressors

1 - Management of Urosepsis in 2018, Bonkat et. Al. , European Urology Focus Volume 5, Issue 1, (2019)
2 - Number of severe cases (www.cdc.gov/sepsis/what-is-sepsis) of 675,000 for US & EU (estimated 25% of the sepsis cases) multiplied by the expected product pricing of $50k = 33B

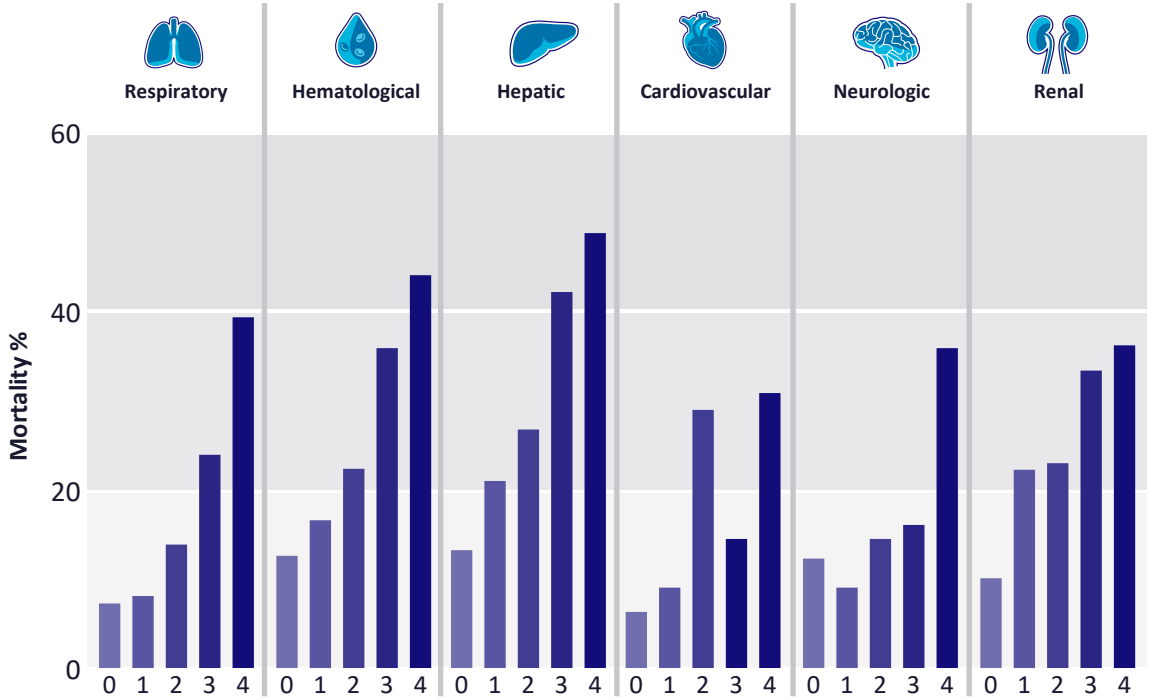
ENLIVEX

A TREATMENT FOR SEPSIS IS AN UNMET MEDICAL NEED

SOFA[1] is a scoring system that assesses the severity of failure of the key organ systems involved in sepsis, scoring 0-4 for each body system, and a maximum of 24 points.



Specific organ system SOFA score predicts the estimated mortality risk[1]



1 - Polkki et al. Association of Sequential Organ Failure Assessment (SOFA) components with mortality. Acta Anaesthesiol Scand. 2022;66:731–741.

ENLIVEX

SEPSIS PHASE I/II:
INDICATION OF EFFECT OF ALLOCETRA™

Indication: organ failure associated with sepsis

Patient criteria:

N=10

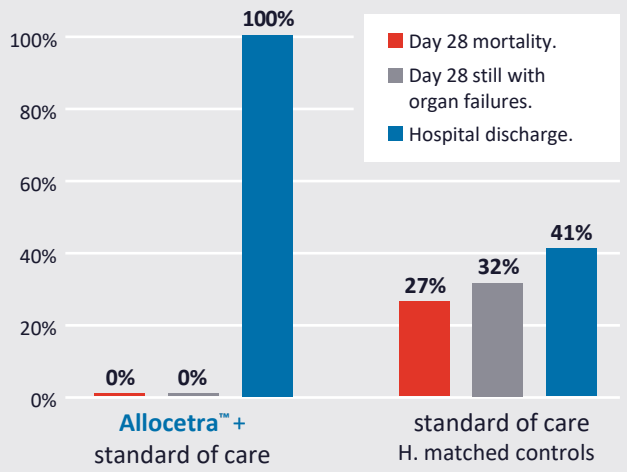
at least 2 organ dysfunctions (kidney, lungs, cardiovascular, hematological, liver).

Treatment:

Allocetra™ + SOC

Systemic administration

Day 28 treatment outcomes:



Result:

All 10 patients treated had complete organ recovery and were discharged from the hospital by day 28.

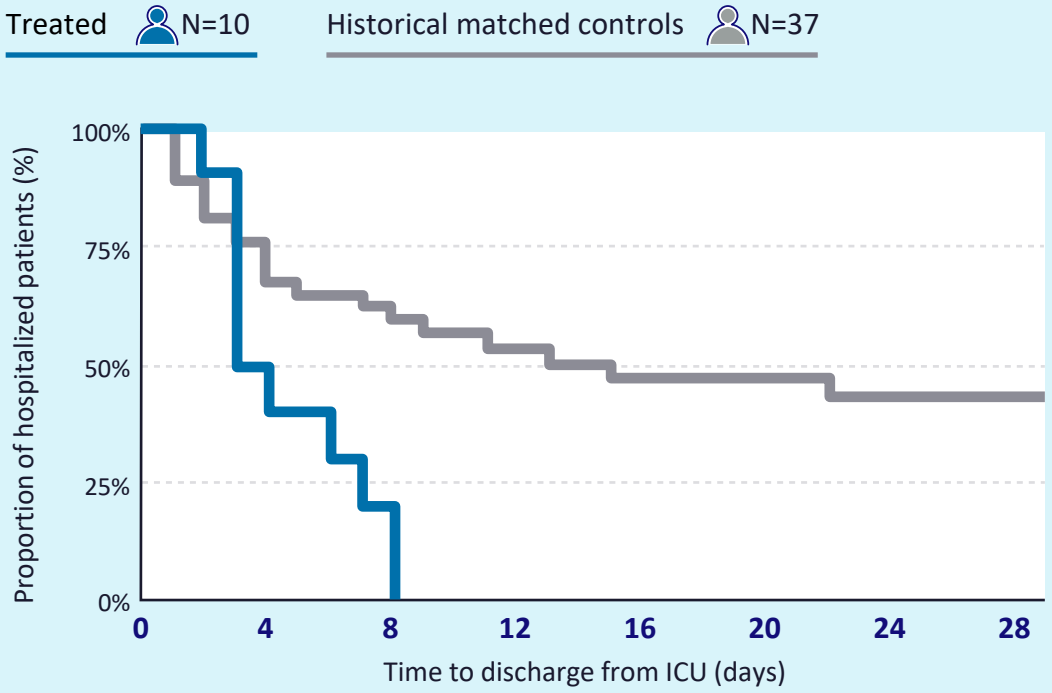
Allocetra™ macrophage reprogramming led to dramatic improvement, when compared with historical matched controls that received standard of care only.

ENLIVEX

SEPSIS PHASE I/II: ALLOCETRA™ TREATMENT LEADS TO IMPROVED PATIENT OUTCOMES

Statistically significant improvement in duration of hospitalization and SOFA score vs. matched controls

Time to ICU discharge:



Average SOFA score during 28 days:

Drastic difference in organ failure resolution

	day 14	day 28
Historical matched controls N=37	4.4	3.4
Treated N=10	0.0	0.1
Difference	4.4	3.3

ENLIVEX

SEPSIS 28-DAY MORTALITY RATE REMAINS HIGH AS DEMONSTRATED IN RECENT CLINICAL TRIALS IN SEPSIS WORLDWIDE

REVIVAL[1] **Phase III (AM-PHARMA)** Pickkers et al, 2024	**ASTONISH**[2] **Phase IIb (INOTREM)** Francois et al, 2023	**Analysis of 2 randomized controlled trials**[3] **(VARIOUS ACADEMIA)** Karakike et al, 2019
Patient population:	Patient population:	Patient population:
N=649	N=355	N=448
SOFA: ~9	SOFA: ~10	SOFA: 6-8
Acute kidney injury **100%**	Septic shock **100%**	Septic shock: **20% - 43%**
28-day mortality **28%**	28-day mortality **25-32%**	28-day mortality **23-30%**

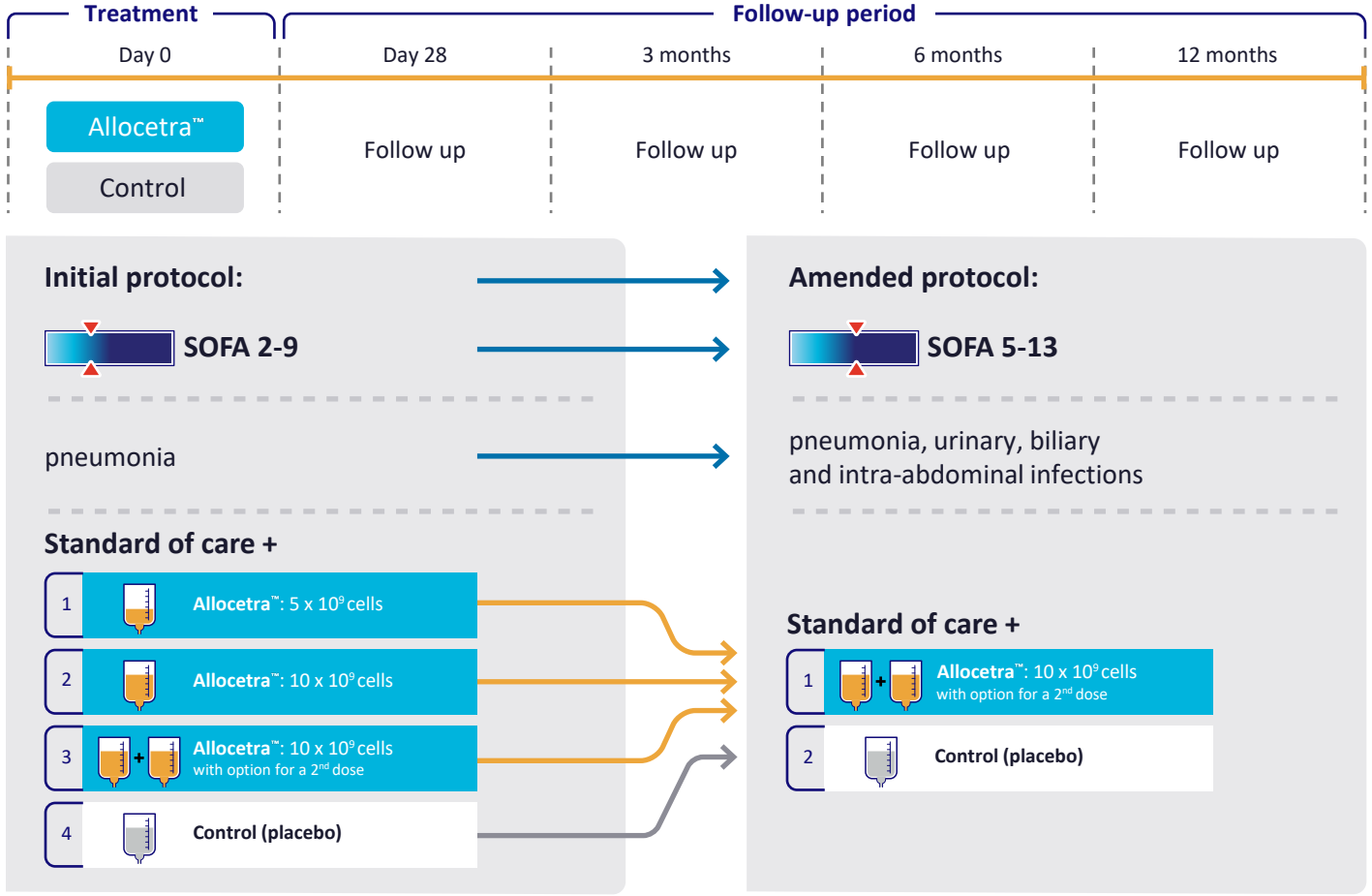
28-days mortality range 23-30%

1 - Pickkers, P., Angus, D.C., Bass, K. et al. Intensive Care Med 50, 68–78 (2024). https://pubmed.ncbi.nlm.nih.gov/38172296/
2 - François B. et al. ASTONISH investigators. Lancet Respir Med. 2023 Oct;11(10):894-904. https://pubmed.ncbi.nlm.nih.gov/37269870/
3 - Karakike et al. The early change of SOFA score as a prognostic marker of 28-day sepsis mortality: analysis through a derivation and a validation cohort. Critical Care (2019) 23:387.

ENLIVEX

ENX-CL-02-002 SEPSIS PHASE II RANDOMIZED CONTROLLED STUDY

Phase II study design:



Patient distribution:

	Treated	mITT
Control	45	37
All Allocetra™ treated	75	50
Total	120 (safety population)	87 (efficacy population)

Endpoints:

- **Primary:** Safety/change in SOFA score.
- **Secondary:** Mortality.

ENLIVEX

ENX-CL-02-002 SEPSIS PHASE II RANDOMIZED CONTROLLED STUDY ALLOCETRA™ GROUP PRESENTED A HIGHER MORTALITY RISK

Demographics and baseline characteristics:

mITT population[1]	Control N=37	Allocetra™ N=40	
Age	64.2 (30-89)	65.1 (30-89)	
BMI	27.2 (17-38)	26.3 (17-39)	
Screening SOFA	8.1 (5-12)	8 (5-13)	
APACHE II[2]	21.1 (6-44)	20.5 (6-47)	
Septic shock	24 (65%)	31 (78%)	↑+20%
Invasive ventilation	16 (43%)	23 (58%)	↑+35%
Pneumonia	14 (38%)	16 (40%)	
Urinary (UTI)	9 (24%)	9 (22.5%)	
Intra-abdominal	5 (14%)	10 (25%)	
Skin and soft tissue infections Acute	4 (11%)	3 (7.5%)	
cholangitis	5 (13%)	2 (5%)	

Allocetra™-treated cohorts presented **20%** higher frequency of septic shock and **35%** higher frequency of invasive ventilation compared with the control cohort.

These attributes are associated with higher mortality rates.

1 - Analysis of modified intent-to-treat (mITT) population for all patients who were randomized, received the high dose of Allocetra™ or placebo, had a screening total SOFA score >= 5 points above pre-admission total SOFA score and had at least one post-baseline total SOFA score.
2 - Acute Physiology and Chronic Health Evaluation (APACHE) II is an ICU score system, used to determine the severity of disease at baseline.

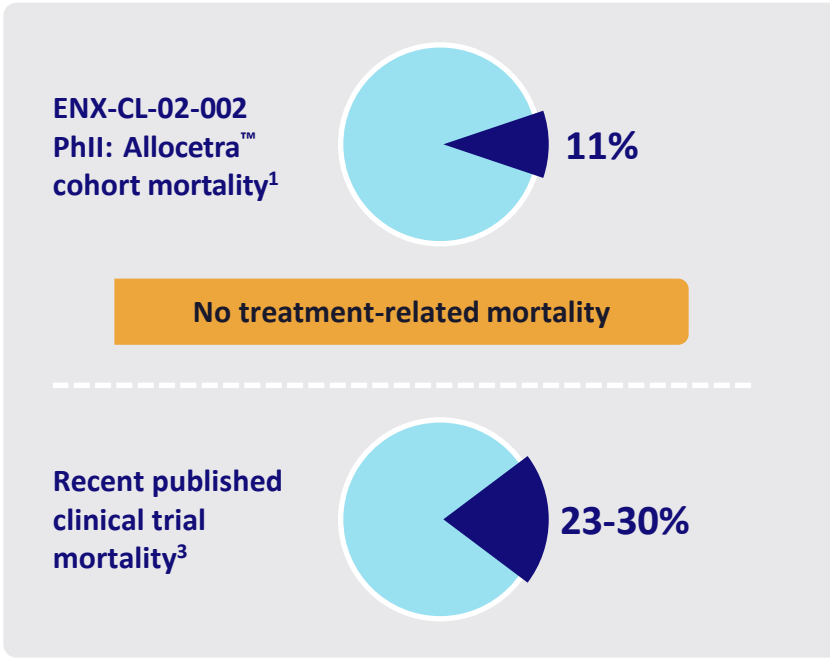
ENLIVEX

ENX-CL-02-002 PHASE II: ALLOCETRA™ COHORT STAND-ALONE ANALYSIS DEMONSTRATES SUBSTANTIAL REDUCTION IN ORGAN FAILURE SCORES

28-day analysis:
SOFA by infectious origin of sepsis[1]

Patient population by origin of sepsis[2]	UTI	Respiratory	Internal abdominal
SOFA score before treatment	7.75 (avg)	6.47 (avg)	7.70 (avg)
SOFA score after treatment	0.75 (avg)	2.07 (avg)	4.90 (avg)
Reduction in organ failure score (SOFA)	90% ↓ -7 (avg)	68% ↓ -4.40 (avg)	36% ↓ -2.80 (avg)

28-day mortality rate:



1 - Analysis of modified intent-to-treat (mITT) placebo population for all patients who were randomized, had a screening total SOFA score ≥ 5 points above pre-admission total SOFA score, had at least one post-baseline total SOFA score, and determined as eligible by an Adjudication Committee.
2 - Number of patients in cholangitis and skin/soft tissue groups were too small for analysis.
3 - Compared with recently-completed sizable clinical trials – Revival Phase III (2024), Astonish Phase IIb (2023), Karakike (2019) – in which mortality rates were in the range of 23% - 30%.

ENLIVEX

ENX-CL-02-002 PHASE II: UTI HIGH-RISK PATIENTS, POTENTIAL INDICATION OF EFFECT, SUBSTANTIAL MARKET

Potential indication of effect in high-risk UTI patients

UTI	Population: screening SOFA ≥7		D1-14	D1-28
N=9	Control	Average reduction in SOFA score:	-7.22	-6.75
		Stdev:	2.28	2.12
N=6	Allocetra™	Average reduction in SOFA score:	-9.00	-8.40
		Stdev:	2.28	2.61
		% over control:	25%	24%
		p-value:	0.0814	0.1181

→ Despite higher risk of the Allocetra™-treated group

	Septic shock	Respiratory SOFA	Coagulation SOFA	Cardiovascular SOFA	Renal SOFA
		≥3	≥3	=4	≥3
Control N=9	78%	22%	33%	33%	11%
Allocetra™ N=6	100%	33%	17%	83%	50%

1 - Management of Urosepsis in 2018, Bonkat et. Al. , European Urology Focus Volume 5, Issue 1, (2019).

ENLIVEX

ENX-CL-02-002 PHASE II: CONTROL COHORT RESULTS ARE NOT ALIGNED WITH EXPECTED MORTALITY

Control cohort

The control cohort, which was relatively small, exhibited uncharacteristically high organ recovery rates and low mortality, that are not aligned with recent clinical trials data[1].

This unusual result, taken together with higher risk patient population in the Allocetra™ cohort, makes it challenging to interpret the results in the non-high risk UTI population.

Control cohort stand-alone analysis, day 28: organ failure score (SOFA) by infectious origin of sepsis

Patient population[2]	UTI	Respiratory	Internal abdominal	Cholangitis	Skin/Soft tissue
SOFA score before treatment	8	6.86	8.20	9.20	9.00
SOFA score after treatment	0.63	1.71	4.20	1.00	1.25
Reduction in organ failure score (SOFA)	84%	75%	49%	98%	86%

1 - Compared with recently-completed sizable clinical trials – Revival Phase III (2024), Astonish Phase IIb (2023), Karakike (2019) – in which mortality rates were in the range of 23%–30%.
2 - Analysis of modified intent-to-treat (mITT) placebo population for all patients who were randomized, had a screening total SOFA score >= 5 points above pre-admission total SOFA score, had at least one post-baseline total SOFA score and determined as eligible by an Adjudication Committee.

ENLIVEX

ENX-CL-02-002 PHII: 28 DAYS, ALLOCETRA™ FAVORABLE SAFETY PROFILE[1]

TEAE = Treatment Emergent Adverse Event	Control (N=45)	Allocetra™ (N=75)
Patients with at least one TEAE	80.0% (n=36)	82.7% (n=62)
TEAEs CTCAE Grade ≥ 3	55.6% (n=25)	50.7% (n=38)
TEAEs Related/ Probably Related	15.6% (n=7)	9.3% (n=7)
TEAEs leading to IP Interruption/ Discontinuation	0	2.7% (n=2)
TEAEs leading to Death	2.2% (n=1)	13.3% (n=10)
Related/ Probably Related	0	0
Not Related[2]	2.2% (n=1)	13.3% (n=10)
Patients with at least one Serious TEAE	37.8% (n=17)	36.0% (n=27)
Related/ Probably Related Serious TEAEs	2.2% (n=1)	0

Patients distribution	Treated	mITT
Control	45	37
All Allocetra™ treated	75	50
Total	120 (safety population)	87 (efficacy population)

vs 23-30%
recent published clinical trials

1 - Safety was evaluated in 120 patients (all treated groups).
2 - Fatal adverse events were independently reviewed by the Data Safety Monitoring Board, who confirmed the determination of not related.
3 - Compared with recently-completed sizable clinical trials – Revival Phase III (2024), Astonish Phase IIb (2023), Karakike (2019) – in which mortality rates were in the range of 23% - 30%.

ENLIVEX

ENX-CL-02-002 PHII: SUMMARY AND CONCLUSIONS

- The efficacy (mITT) population presented a 20% higher frequency of septic shock in Allocetra™-treated patients compared to placebo, and a 35% higher frequency of invasive ventilation – both key determinants of disease severity, potentially indicating risk imbalance between the groups.

- Stand-alone analysis of the Allocetra™-treated patients demonstrated a substantial reduction in organ failure scores (SOFA) and low mortality rate as compared with expected mortality[1]. The analysis showed reductions, by day 28, in organ failure scores (SOFA) of 90% for sepsis patients whose infection source was urinary tract (UTI), 68% for patients whose infection source was community-acquired pneumonia, and 36% for patients whose infection source was internal abdominal.

- A potential indication of relative efficacy is demonstrated in a population of high risk UTI patients.

- Up to 31 percent of sepsis cases start as UTIs, representing up to 9.8 million cases annually in the U.S. and Europe, leading to as many as 1.6 million deaths[2]. This a substantial target market for a potential commercialization of Allocetra™ in sepsis, and the Company intends to consider, upon reviewing the totality of the data, a potential follow-on, randomized, controlled study of solely high risk UTI sepsis population.

- The interpretation of efficacy in other populations is challenged by the difference in risk profile of the Allocetra™ group.

- Safety: No serious adverse events were reported as related to study treatment, and overall fewer events were considered related to Allocetra™ compared to placebo (9.3% vs 15.6%). All deaths were determined to be unrelated to treatment, as further confirmed by the independent DSMB. No safety signals were detected.

- Patient follow-up is ongoing to complete 12-month evaluation.

1 - Compared with recently-completed sizable clinical trials – Revival Phase III (2024), Astonish Phase IIb (2023),Karakike (2019) – in which mortality rates were in the range of 23%–30%.
2 - Management of Urosepsis in 2018, Bonkat et. Al. , European Urology Focus Volume 5, Issue 1, (2019).

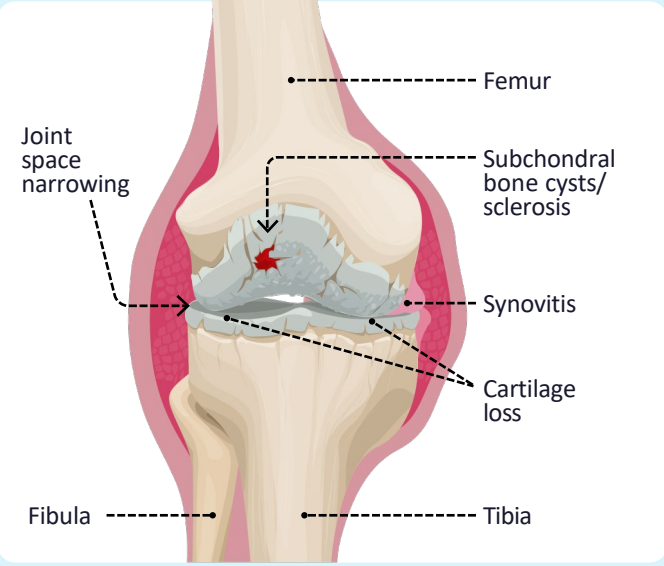
ENLIVEX

ALLOCETRA™
FOR THE TREATMENT
OF OSTEOARTHRITIS

ENLIVEX

OSTEOARTHRITIS: A GROWING MARKET WITH SIGNIFICANT POTENTIAL

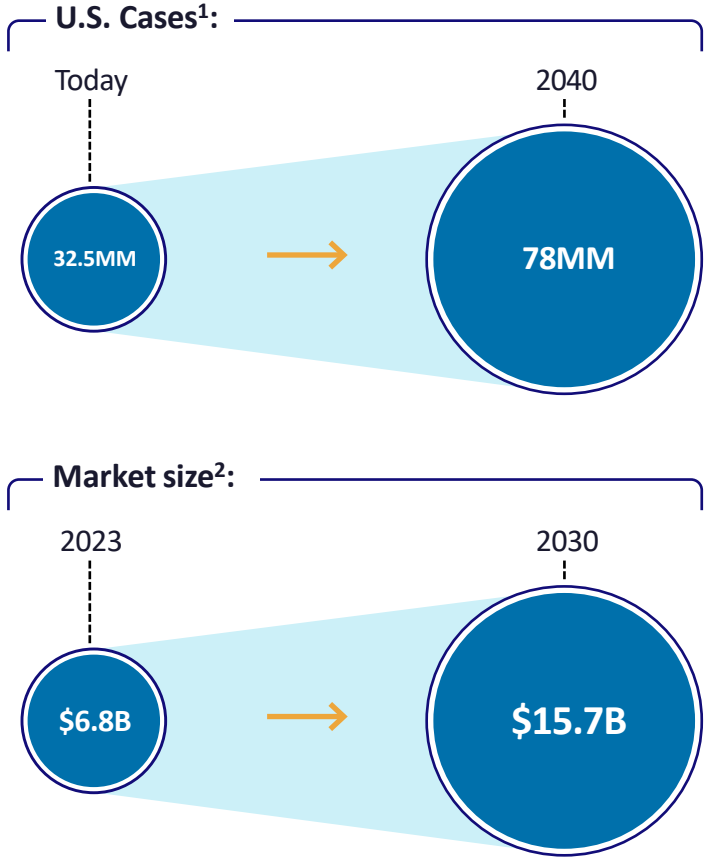
Disease overview



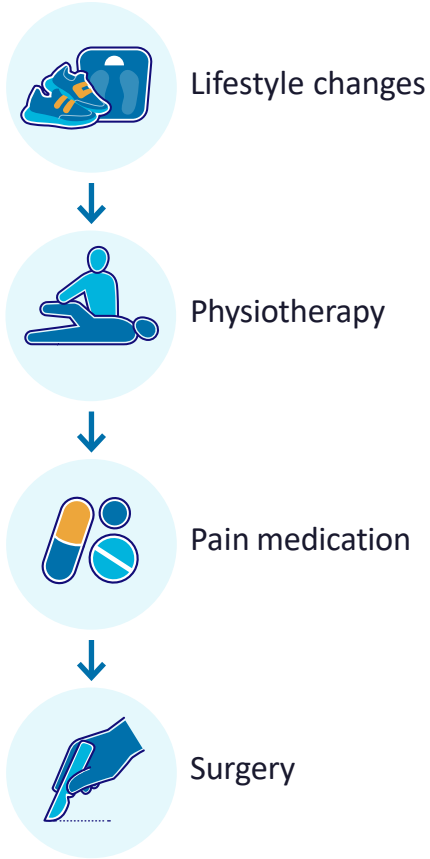
Disease manifestation:

cartilage damage, abnormal bone remodeling, and inflammation of the synovium.

Market



Standard of care



1 - Arthritis Foundation (https://www.arthritis.org/)
2 - Verified Market Research reports

ENLIVEX

MACROPHAGES ARE AN EMERGING NEW TARGET FOR OSTEOARTHRITIS TREATMENT

The role of innate **immunity in osteoarthritis**: when our first line of defense goes on the offensive.

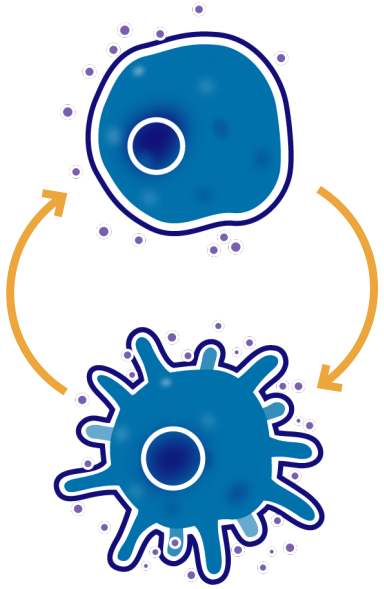
Eric W. Orlowsky and Virginia Byers Kraus

The Journal of Rheumatology 2015

Characterizing heterogeneity in the response of synovial mesenchymal progenitor cells to **synovial macrophages** in normal individuals and **patients with osteoarthritis.**

Akash Fichadiya, Karri L Bertram, Guomin Ren, Robin M Yates and Roman J Krawetz

Journal of Inflammation 2016



Imbalance of M1/M2 **macrophages** is linked to severity level of knee **osteoarthritis.**

Baolong Liu, Maoquan Zhang, Jingming Zhao, Mei Zheng and Hao Yang

Experimental and therapeutic medicine 2018

An emerging target in the battle against **osteoarthritis: macrophage** polarization.

Yulong Sun, Zhuo Zuo and Yuanyuan Kuang

International Journal of Molecular Sciences 2020

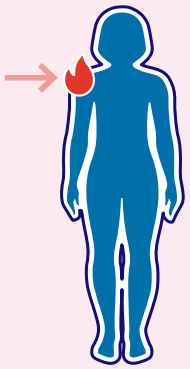
Synovial macrophages in osteoarthritis: the key to understanding pathogenesis?

Amanda Thomson and Catharien M. U. Hilkens

Frontiers in Immunology 2021

ALLOCETRA™ COMPASSIONATE CASE RESULTS

Patient with vanishing bone disease



Female,
70 years old
with vanishing
bone disease

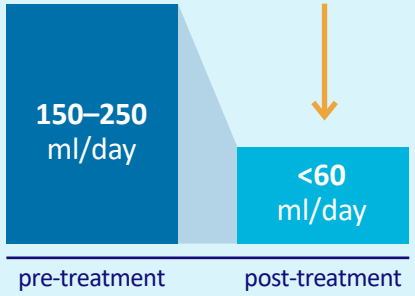
- Complete destruction of the humeral head on X-ray;
- Significant inflammatory reaction on MRI;
- Significantly elevated ESR & CRP;
- Extended hospitalization: 4 years of hospital visits, including 9 months continuous hospitalization with permanent shoulder port.

Treatment:

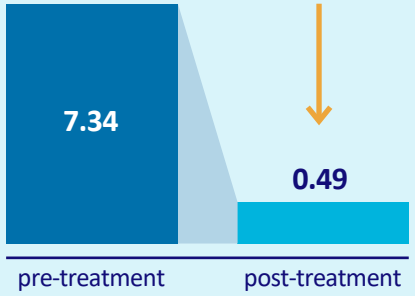
5 intra-joint infusions

Result:

Fluid drainage declined



CRP declined
(normal range ≤0.5)



✓ No longer required hospitalization:
Patient discharged following 9 months in hospital.
Has not been re-hospitalized for 3 years in subsequent follow-up.

ENLIVEX

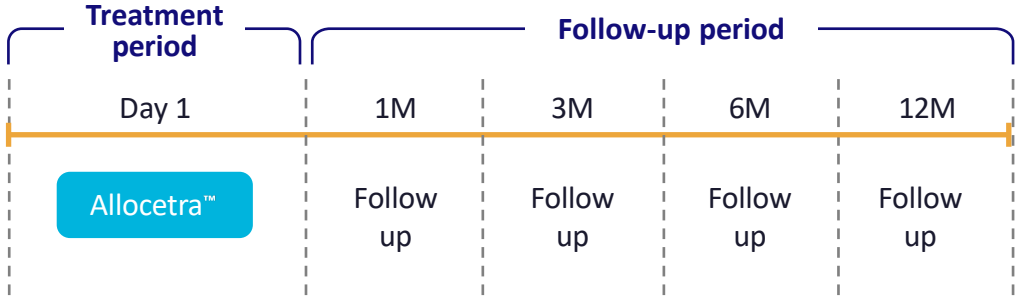
0189-22-KMC - END-STAGE KNEE OSTEOARTHRITIS TRIAL DESIGN

Investigator-initiated Phase I/II study

N=18

End stage osteoarthritis indicated for knee replacement surgery.

local knee injection



Endpoints:

Primary:
Safety and tolerability.

Secondary:
Change from baseline in pain.

ClinicalTrials.gov Registration: NCT06208241

ENLIVEX

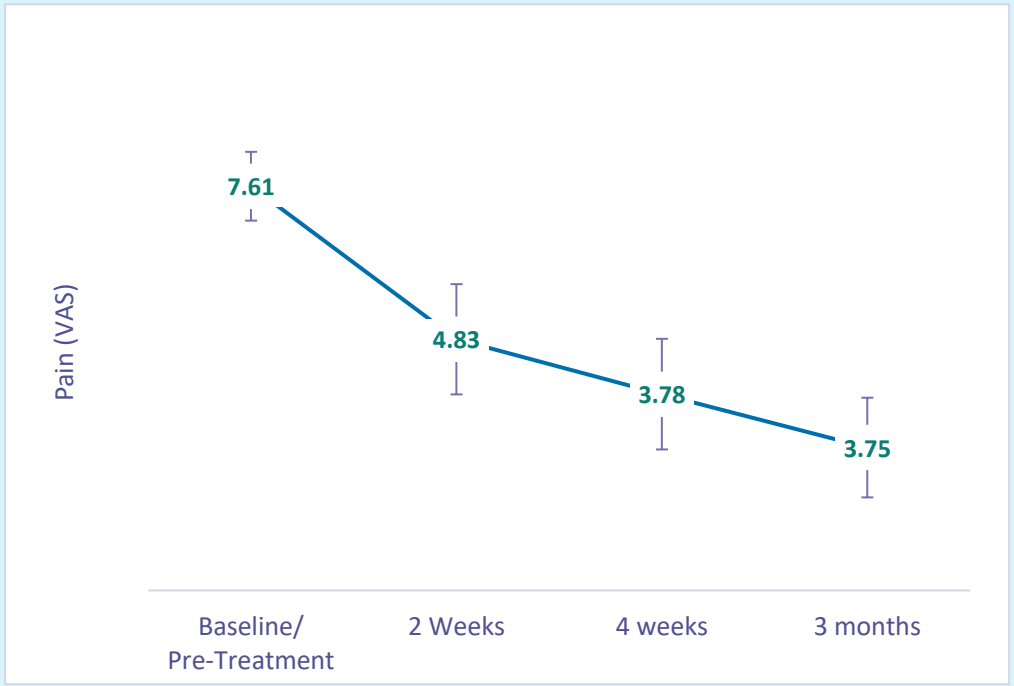
END-STAGE KNEE OSTEOARTHRITIS
POSITIVE INTERIM DATA, 50% REDUCTION IN PAIN

Investigator-initiated Phase I/II study: End-stage osteoarthritis indicated for knee replacement surgery

Target enrollment = 18

Three-month interim data from 9 patients showed a significant reduction in pain and a favorable safety profile.

- **Pain reduction:** patients reported an average pain reduction of **51%** from baseline.
- **Complete Pain Resolution:** **2/9** of patients reported complete pain relief, from an average pain level of 8.5 to a pain level of 0; pain scale used in the study ranged from 0 (no pain) to 10 (maximum pain).
- **Avoidance of Surgery:** **89%** of patients did not proceed with knee replacement surgery at three months post-injection.
- **Safety:** No severe adverse events related to Allocetra™ were reported.



ENLIVEX

ENX-CL-05-001 - MODERATE KNEE OA CLINICAL TRIAL DESIGN

Phase I/II randomized, double-blind, placebo-controlled, multi-country study

Patient criteria:

patients with symptomatic knee OA who have failed to respond to conventional OA therapy;

Age 45-80 years;

Kellgren-Lawrence (K-L) Grade 2 or 3.

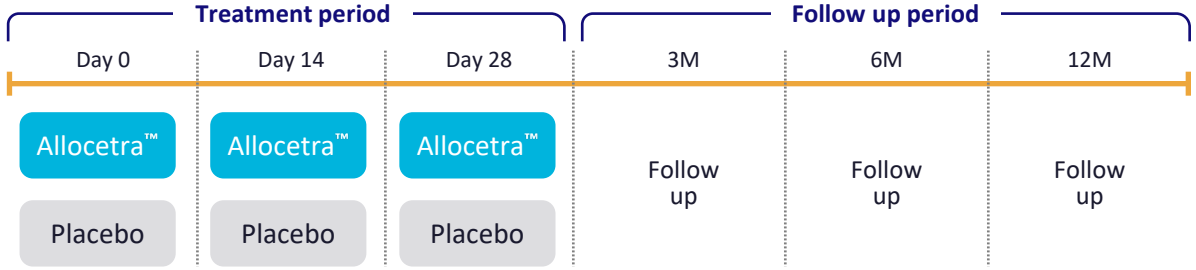
Local knee Injection

Multi-country, multi-center

Part 1: Safety (run-in) — 15 patients

- 0 — Escalating doses
  - 1 — Dose 1: repeated dosing
  - 2 — Dose 2: repeated dosing
  - 3 — Dose 3: repeated dosing
  - 3b — Dose 3: repeated dosing

Part 2: Randomization — >130 patients



Endpoints:

Primary:
Safety and tolerability.

Secondary:
Change in weekly NRS pain and WOMAC assessments.

ClinicalTrials.gov Registration: NCT06233474

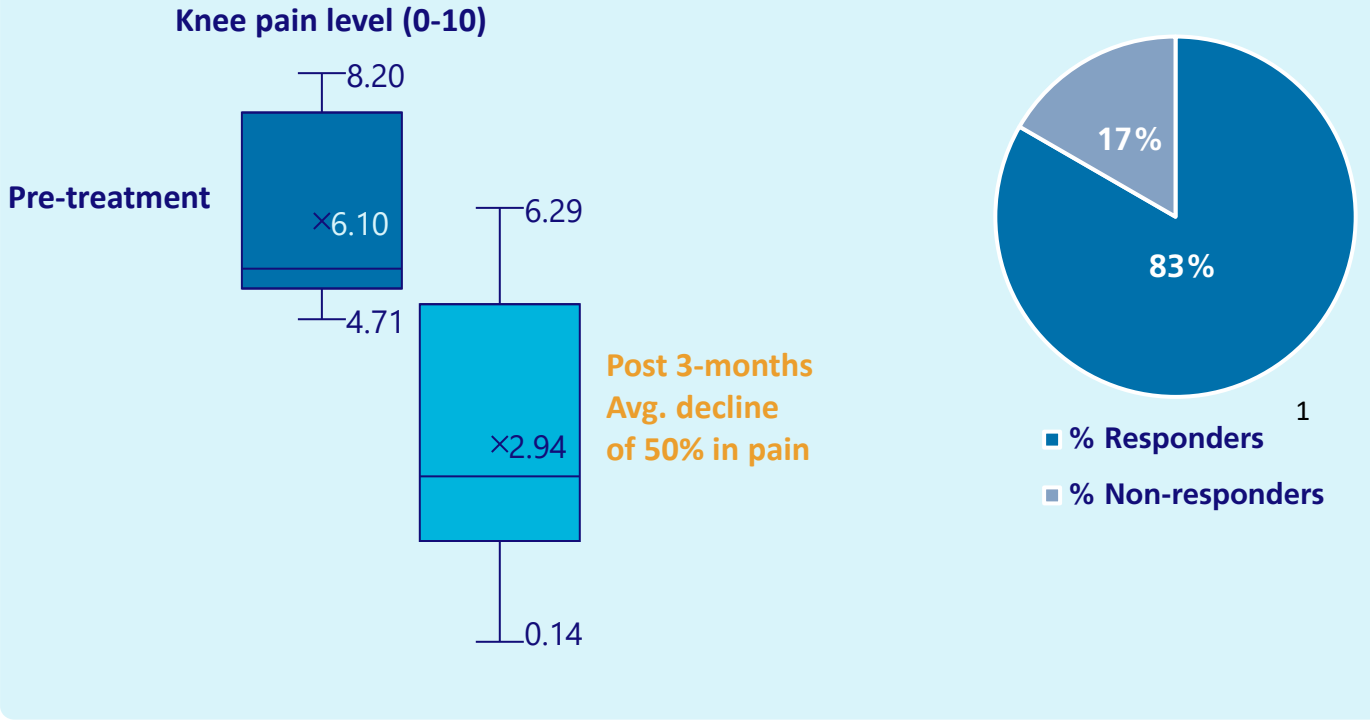
ENLIVEX

ENX-CL-05-001 - MODERATE KNEE OA CLINICAL TRIAL DESIGN: POSITIVE INTERIM DATA , 50% REDUCTION IN PAIN

Three-months interim data from 12 patients showed a significant reduction in pain and function and a favorable safety profile.

- **Pain reduction:** patients reported a statistically significant average pain reduction of **50%** from baseline at 3 months post injections ($p<0.0007$).
- **Functionality:** **42%** statistically significant improvement in functionality
- **Responders to treatment:** **83%** of patients presented a substantial response to Allocetra™ treatment .
- **Safety:** No severe adverse events related to Allocetra™ were reported. Independent safety committee approved to move to Phase II with the highest dose evaluated

Substantial pain reduction post Allocetra™ treatment



1 –Responders were defined as patients that either met the OMERACT-OARSI criteria (Outcome Measures in Arthritis Clinical Trials-Osteoarthritis Research Society International), or had at least 40% pain reduction

ENLIVEX

0006-24-KMC BASAL THUMB OA CLINICAL TRIAL DESIGN

Investigator initiated Phase I/II randomized, double-blind, placebo-controlled study

Patient criteria:

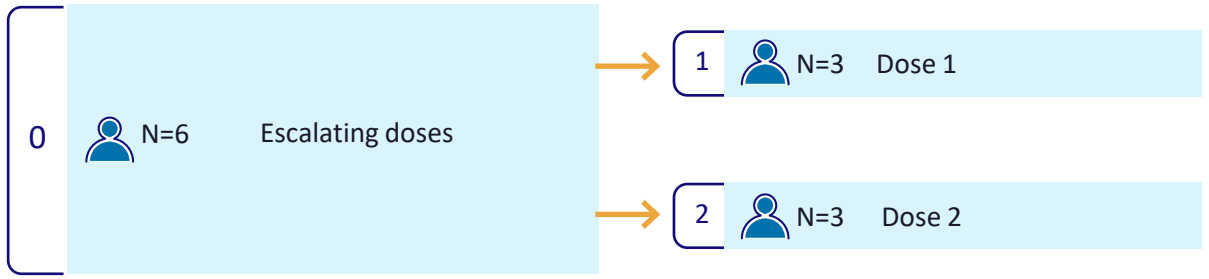
patients with basal thumb joint (first carpometacarpal (CMC) joint) osteoarthritis;

Age >40 years;

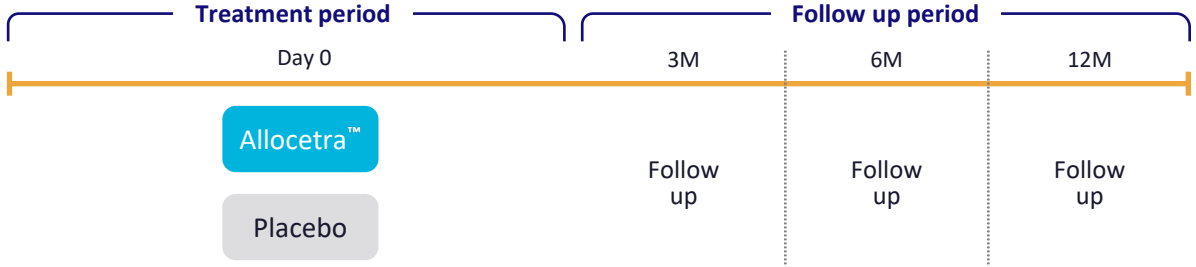
Eaton classification Grade 2 or 3.

Local thumb Injection

Part 1: Safety (run-in) — 6 patients



Part 2: Randomization — >40 patients



Endpoints:

Primary:
Safety and tolerability.

Secondary:
Change from baseline in pain and function.

ClinicalTrials.gov Registration: NCT06459063

ENLIVEX

ENX-CL-06-001 TRIAL FOR PSORIATIC ARTHRITIS (PsA)

ENX Phase I study

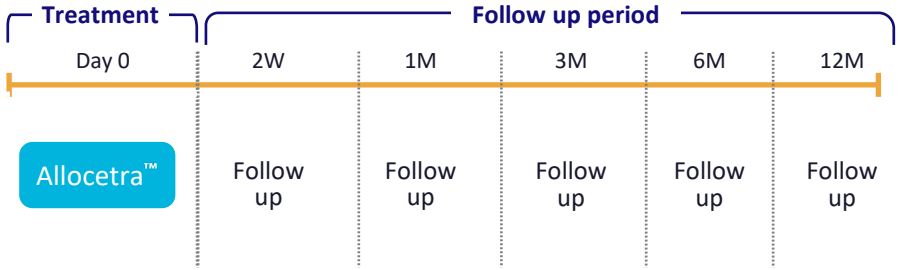
Patients with PsA with at least one joint unresponsive to conventional treatment;

Age 18 or above

Local Injection to knee, elbow or ankle

1 N=3 On systemic therapy with an unresponsive joint

2 N=3 Unresponsive to steroid injection



Endpoints:

Primary:
Safety.

Secondary:
Change in pain and PsA meds assessments.

ClinicalTrials.gov Registration: NCT06522035

ENLIVEX

1400-24-SMC TEMPOROMANDIBULAR OSTEOARTHRITIS (TMJ-OA)

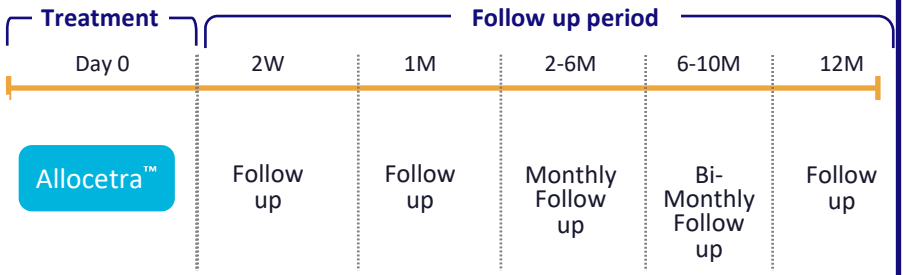
Investigator-initiated Phase I study

Local Injection to TMJ

Patients with TMJ-OA unresponsive to conventional treatment;

Age 18 or above

1	N=3	Failed IA TMJ steroid injection
2	N=3	Failed oral therapies



Endpoints:

Primary:
Safety.

Secondary:
Change in TMJ pain (NRS) and TMJ function.

ClinicalTrials.gov Registration: NCT06748651

ENLIVEX

MILESTONES MET & PLANNED

Q4 2024

Moderate knee osteoarthritis Phase I/II - Phase I stage 3m readout (randomized, controlled, powered).

2025 EOQ2 (planned)

Basal thumb osteoarthritis Phase I/II Topline 3m Readout (randomized, controlled)
.

2025 Q3 (planned)

Moderate knee osteoarthritis Phase I/II 3m Readout (randomized, controlled, powered).

2025 EOQ3 (planned)

Basal thumb osteoarthritis Phase I/II 6m Topline (randomized, controlled).

2025 Q4 (planned)

Moderate knee osteoarthritis Phase I/II 6m data (randomized, controlled, powered).

ENLIVEX

EXTENSIVE IP PROTECTION

11 Patents — USA

22 Patents

- Australia
- Canada
- China
- France
- Germany
- Israel
- Japan
- United Kingdom

Expected protection up to

2043

ENLIVEX

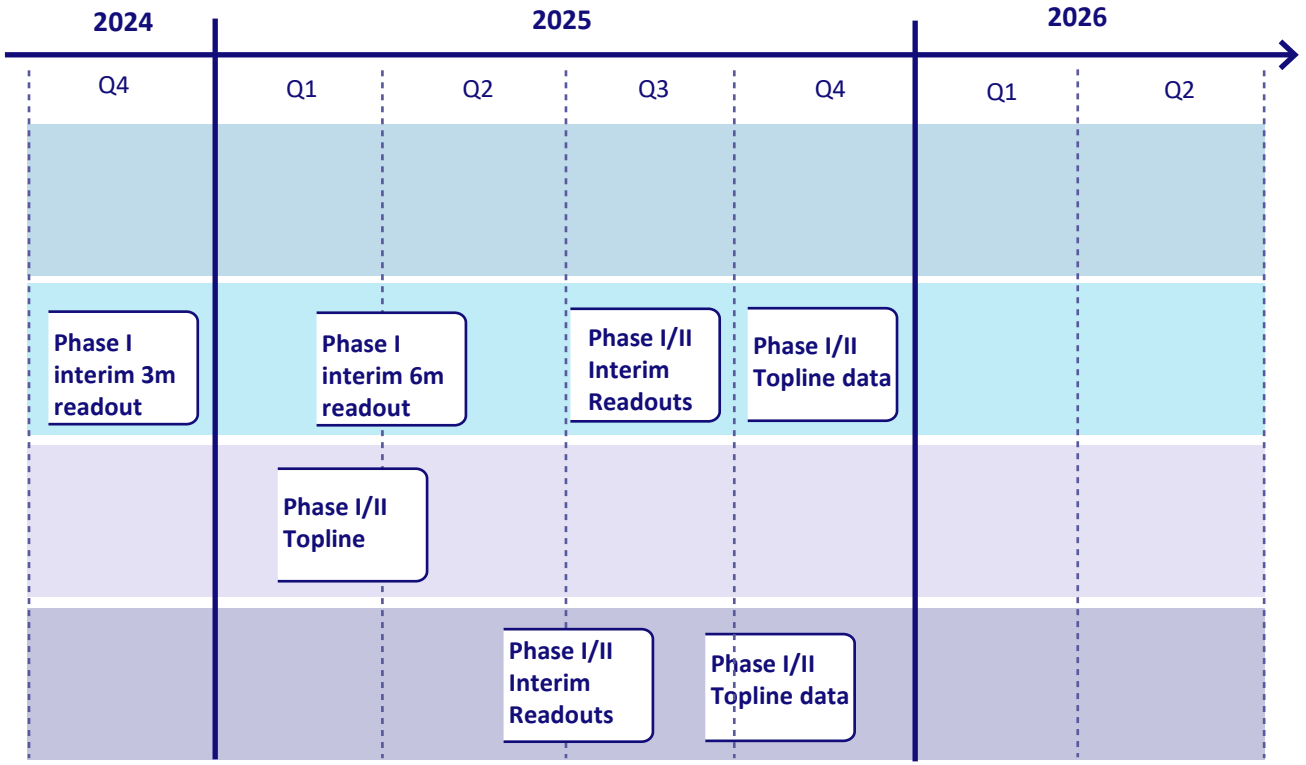
FINANCIAL SUMMARY

ENX-CL-02-002
Organ failure associated with Sepsis

ENX-CL-05-001
Moderate knee osteoarthritis

0189-22-KMC
End-stage knee osteoarthritis

0006-22-KMC
Basal thumb osteoarthritis



NASDAQ GS
ENLV

Cash & equivalents
$24.5 MM (Sep. 30, 2024)

Debt
none

Shares outstanding
21.9 MM (Sep. 2024)

Estimated cash runway through
Dec. 31, 2026

ENLIVEX

INVESTMENT SUMMARY

- Management team with a track record of creating shareholder value and getting drug products through marketing approvals globally in multi-billion dollar market segments
- Cost-effective, novel therapeutic modality with strong IP protection
- Targeted at high and low grade inflammation in multi-billion dollar segments with poor treatment alternatives
- Platform for multiple indications. Allocetra™ can be infused systemically or locally to treat various diseases
- Simple, scalable, and cost-effective manufacturing process resulting in an off-the-shelf cell therapy
- Favorable safety profile demonstrated across 140+ patients
- Clinical data supportive of proposed MOA

ENLIVEX

THANK YOU