

ENLIVEX – COMPANY PRESENTATION

October 2025

Nasdaq: **ENLV**



FORWARD-LOOKING STATEMENTS

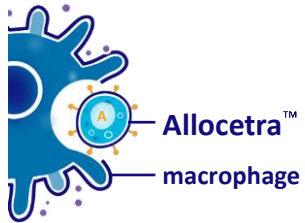
These slides and the accompanying oral presentation contain forward-looking statements and information. Forward-looking statements are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels or activity, performance or achievements 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,

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MACROPHAGE MODULATION FOR THE TREATMENT OF INFLAMMATORY DISEASES

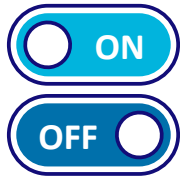
Enlivex is a clinical stage pharmaceutical company developing Allocetra™, a universal, off-the-shelf cell therapy designed to reprogram macrophages into their homeostatic state, for treatment of inflammatory diseases.

About:



Novel therapeutic modality:

macrophage modulation.



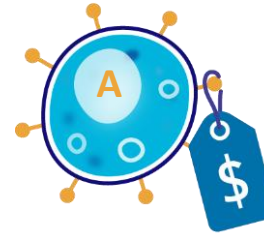
Novel approach:

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.

DRIVING INNOVATION WITH BALANCED SCIENTIFIC AND BUSINESS EXPERTISE



Shai Novik
Executive Chairman



**PROLOR
BIOTECH**

26 years of
experience

\$590M company
exit



Oren Hershkovitz
CEO



OPKO

17 years of
experience



Dror Mevorach
Scientific Founder



20 years of
experience

140+ publications



Shachar Shlosberger
CFO



**PROLOR
BIOTECH**

15 years of
experience



Einat Galamidi
CMO



gamida **Cell**

20 years of
experience



Veronique Amor-Baroukh
VP Operations



10 years of
experience



Iris Tavor
VP RA/QA



Pluristem
Therapeutics Inc.

20 years of
experience



Chen Ankri
Sr. Director of pre-clinical & clinical pharma



10 years of
experience



Sigal Arad
Sr. Director of Human Resources



15 years of
experience

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.

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:

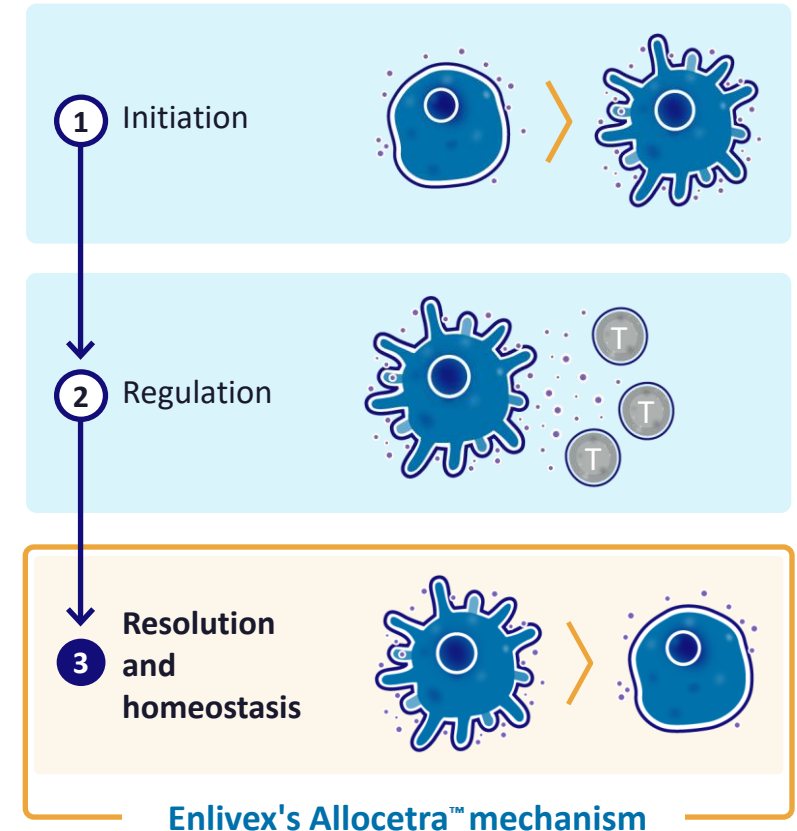
-  Recruit other immune cells
-  Defend against pathogens
-  Cleanup senescent or dead cells
-  Control tissue homeostasis and repair

Role in inflammation:

-  Antigen presentation
-  Cytokine secretion
-  Phagocytosis
-  Immunomodulation

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

Macrophages orchestrate inflammation and its resolution.



PROMOTING BALANCE: APOPTOTIC CELLS FACILITATE MACROPHAGE HOMEOSTASIS



Prof. Dror Mevorach
Scientific Founder



Apoptotic Cells Induce NF- κ B and Inflammasome Negative Signaling

Amir Grau, Adi Tabib, Inna Grau, Inna Reiner, [Dror Mevorach](#)

PLOS One, 2015

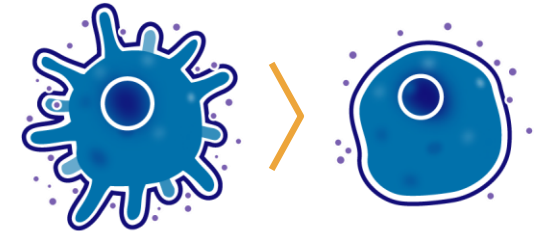
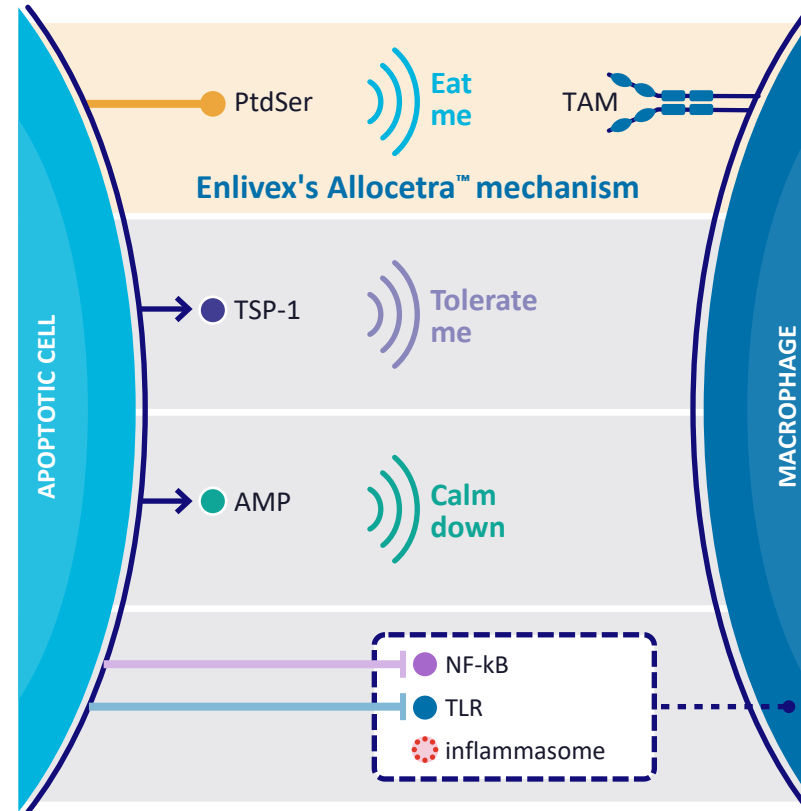


Apoptotic Cells induced Signaling for immune Homeostasis in Macrophages and Dendritic Cells

Uriel Trahtenberg
and [Dror Mevorach](#)

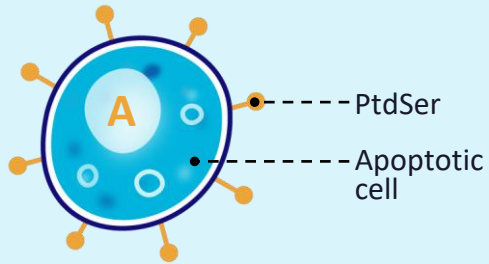
Frontiers in immunology, 2017

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.

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

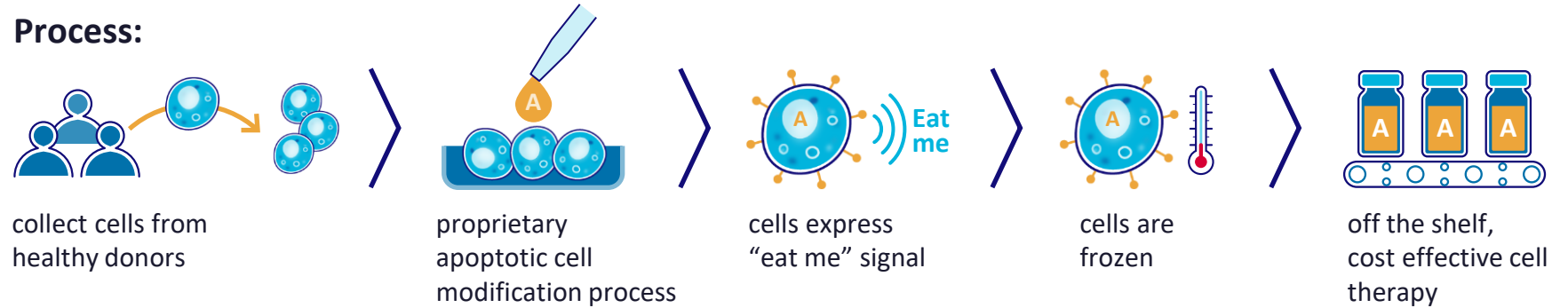


Allocetra™

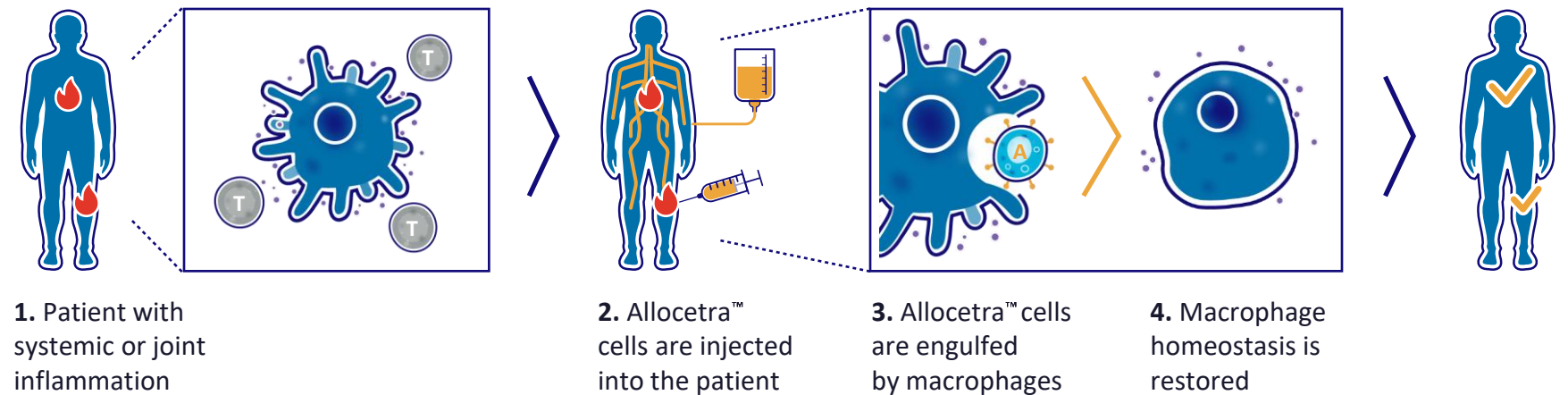
Allogeneic mononuclear cells
collected from healthy donors induced to
a stable apoptotic state.

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

Process:



Mechanism:



ALLOCETRA™ PIPELINE: BUILDING MOMENTUM

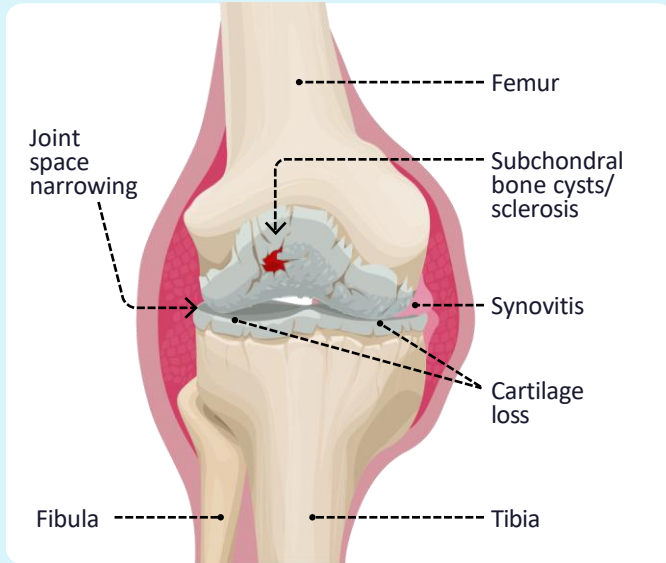
Indication	Study #	Administration	Pre-clinical	Phase I/II	Phase II	Phase III
Moderate knee osteoarthritis	ENX-CL-05-001 NCT06233474	 Local knee injection	Randomized/controlled, 149 patients, enrollment completed			
Moderate knee osteoarthritis	ENX-CL-05-002 NCT:TBD	 Local knee injection	Randomized, controlled, 150 patients,			
Basal thumb osteoarthritis	0006-24-KMC NCT06459063	 Local thumb injection	Investigator-initiated, 56 patients, enrolling			
End-stage knee osteoarthritis	0189-22-KMC NCT06208241	 Local knee injection	Investigator-initiated, 18 patients enrolled, ongoing			
Temporomandibular joint osteoarthritis	1400-24-SMC NCT06748651	 Local TMJ injection	Open-label 6 patients, enrolling			
Organ failure associated with sepsis	ENX-CL-02-002 NCT04612413	 Systemic administration	Randomized, controlled, Phase II, 120 patients Efficacy stage completed; safety follow-up completed			

Sepsis Program - seeking for potential external collaboration or out-licensing, instead of pursuing internal development

ALLOCETRA™ FOR THE TREATMENT OF OSTEOARTHRITIS

OSTEOARTHRITIS: A GROWING MARKET WITH SIGNIFICANT POTENTIAL

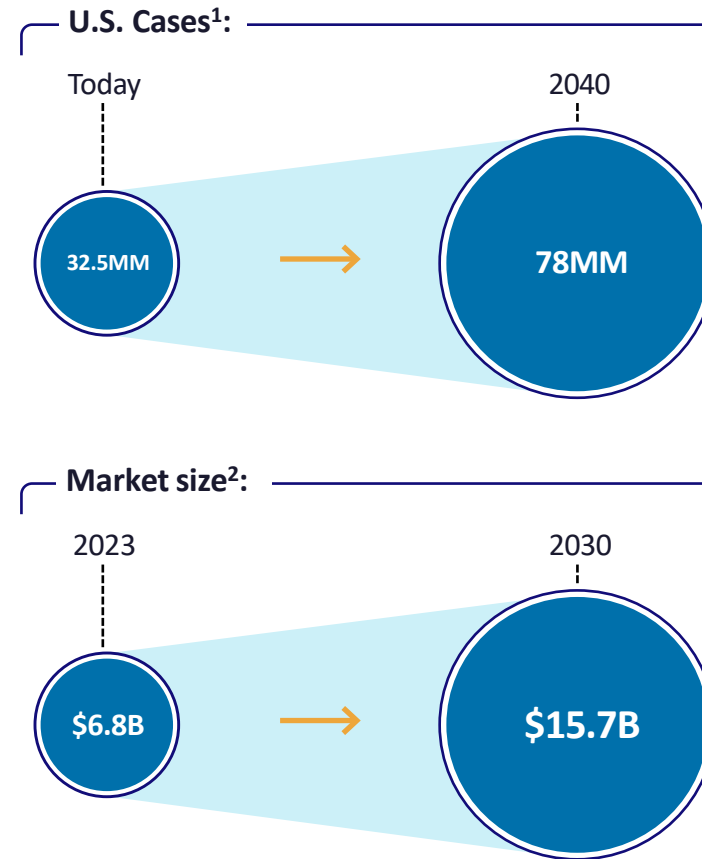
Disease overview



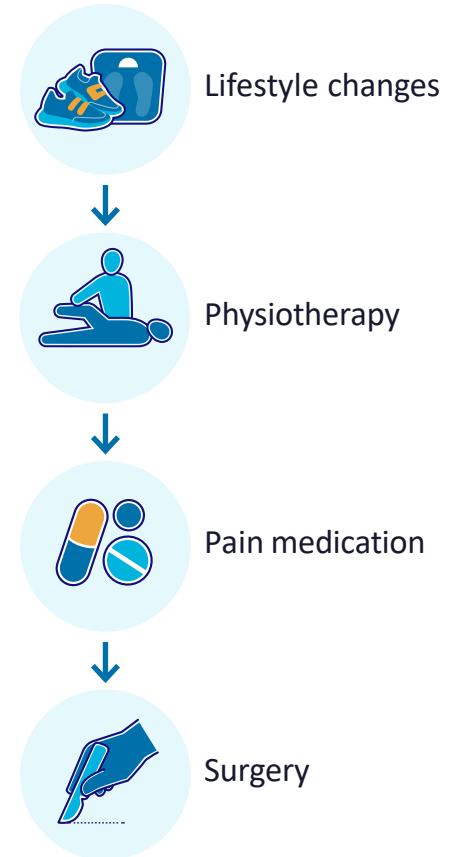
Disease manifestation:

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

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

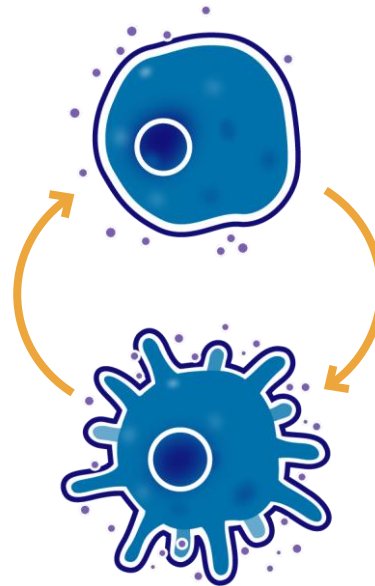
[The Journal of Rheumatology 2015](#)



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](#)



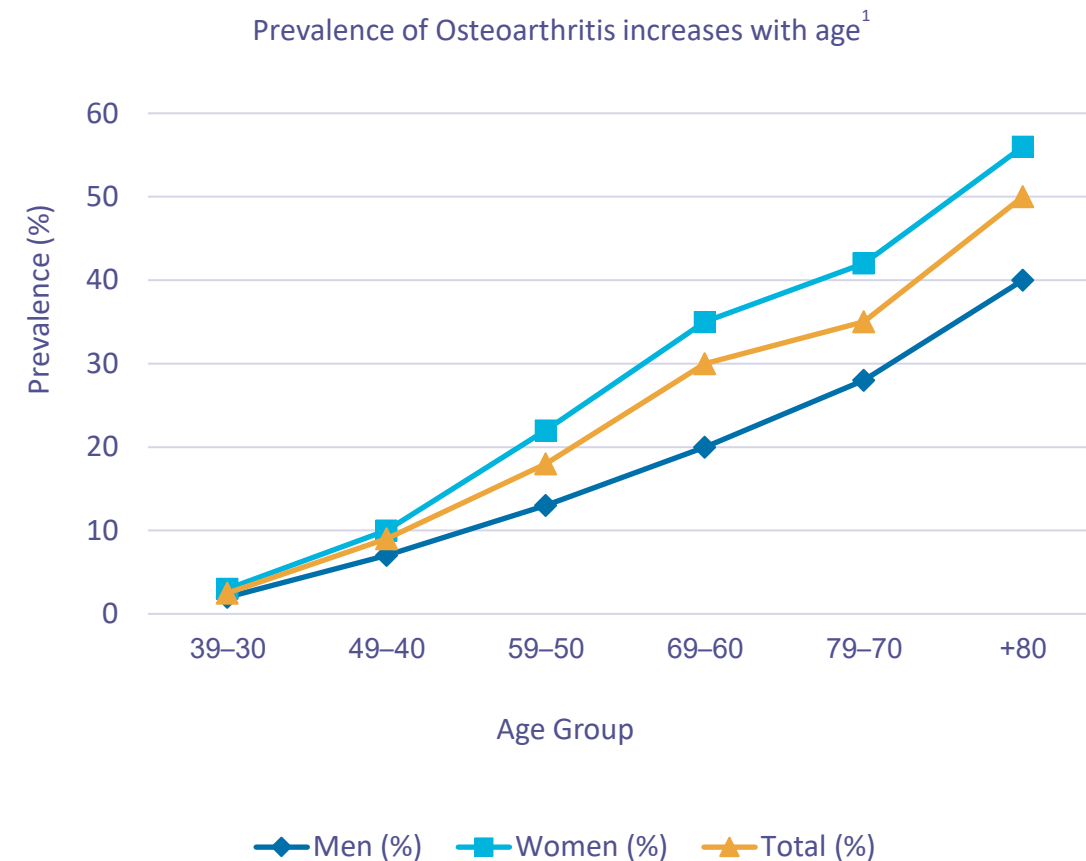
Synovial macrophages in osteoarthritis: the key to understanding pathogenesis?

Amanda Thomson and Catharien M. U. Hilkens

[Frontiers in Immunology 2021](#)

KNEE OSTEOARTHRITIS (KOA) MARKET

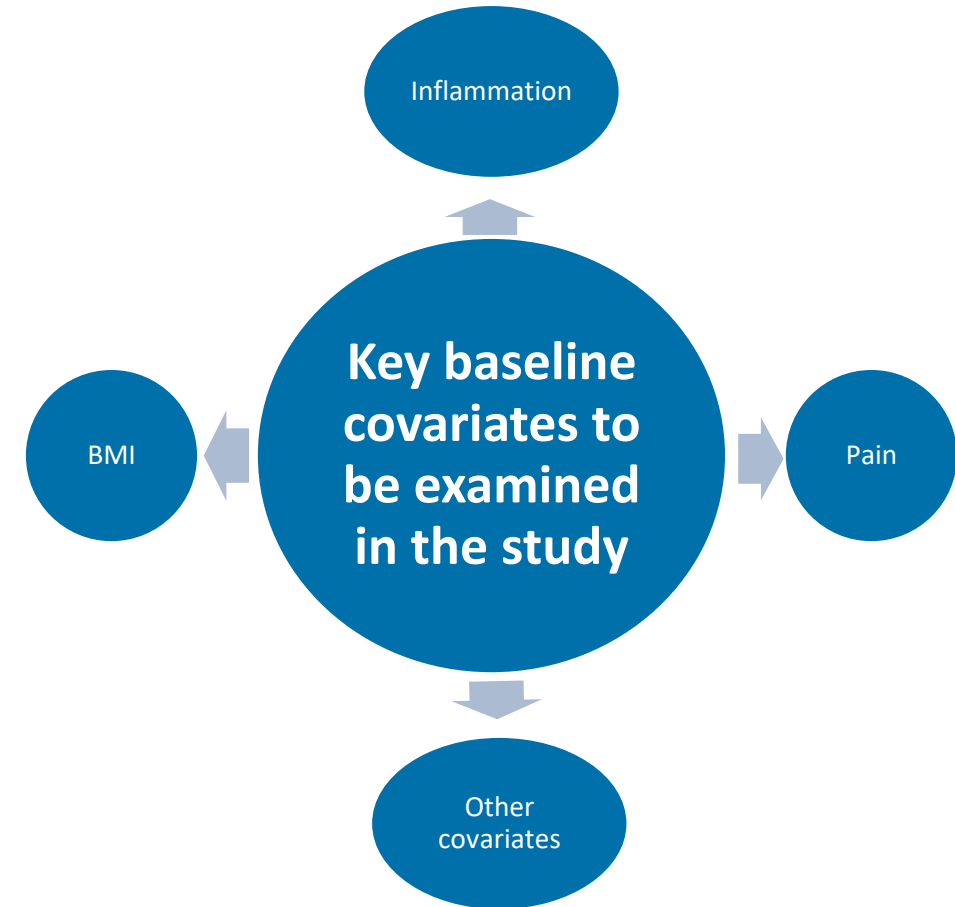
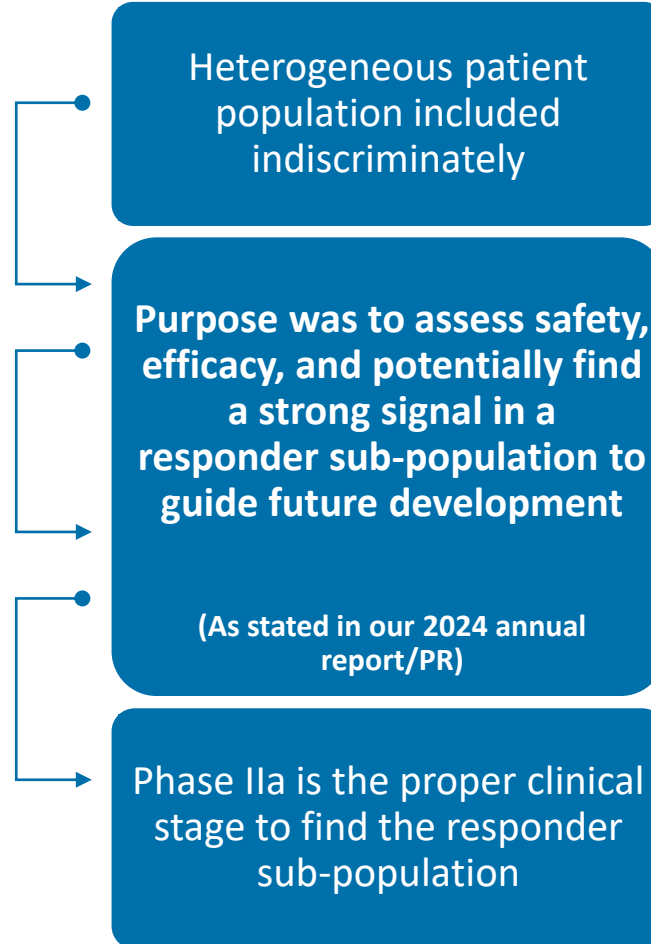
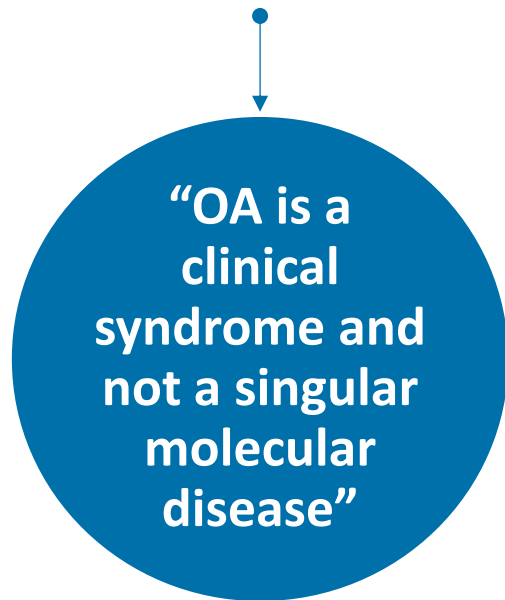
- **High prevalence & burden:**
 - 32M Americans today; projected **78M by 2040**
 - One of the most disabling diseases globally
- **Unmet medical need:**
 - No approved **disease-modifying treatments**
 - Current options: **pain relief, steroids, surgery**
- **Age-related progression:**
 - Prevalence rises to **30% at age 60+**
 - **50% of KOA patients** are 60+
 - As individuals age, the cumulative effects of wear and tear on joint tissues become increasingly evident and induce low grade inflammation mainly mediated by resident macrophages and fibroblasts, and the regenerative capacity of cartilage diminishes
- **Future growth driver:**
 - Rising geriatric population → increasing OA prevalence



¹ Global, regional prevalence, incidence and risk factors of knee osteoarthritis in population-based studies, A. Cui et al. / EClinicalMedicine 2930 (2020) 100587

ENX-CL-05-001 – PHASE IIa STUDY DESIGNED A PRIORI TO IDENTIFY CORRELATION OF TREATMENT EFFECT AND BASELINE FACTORS

OA leading experts forewarned us prior to study design



ENX-CL-05-001: PHASE I/IIa

2-stage trial design - randomized, double-blind, placebo-controlled, multi-country study

Patient criteria:



Patients with symptomatic moderate to severe knee OA who have failed to respond to conventional OA therapy;
Age 45-80 years;
Kellgren-Lawrence (K-L) Grade 2 or 3.



Phase I: Dose escalation & safety



15 patients



Independent safety committee → no negative safety signal, highest dose selected for Phase IIa

Phase IIa: Randomized, double-blind, placebo-controlled



134 patients



- 3 injections (in total) of Allocetra™ or Placebo, each injection 2 weeks from the previous injection

Endpoints:



Primary:

Safety and tolerability.



Secondary:

Change in pain and function assessments (NRS, WOMAC)



Timepoints:

Efficacy: 3-month, 6-month
Safety: 12-month follow-up

Efficacy objectives

- Reduction in pain, increase in function and reduction in stiffness
- Numerical grading based on the patients' assessment using a questionnaire
- The validated questionnaire is named WOMAC
- Aligned with FDA's accepted Phase III endpoints and timepoints

ClinicalTrials.gov Registration: NCT06233474

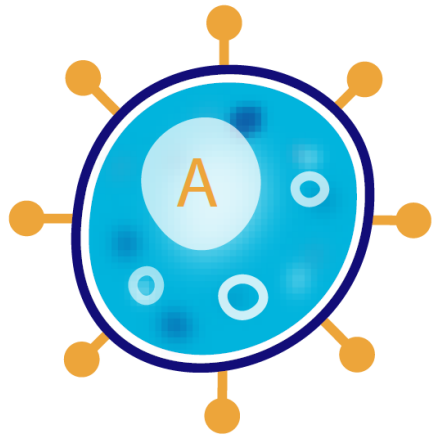
NRS=numerical rating scale. WOMAC= Standard knee questionnaire evaluating pain, stiffness & physical function

ENX-CL-05-001 – PHASE IIa OBJECTIVES MET:

(a) FAVORABLE SAFETY PROFILE & POSITIVE EFFECT,

(b) HIGH RESPONDERS WERE IDENTIFIED (REPRESENTING 50% OF THE KOA MARKET)

- We had clear success in isolating the key molecular disease for which our drug works well
- This finding directly illustrates that our hypotheses were correct – due to the heterogeneity of the patient population, a distinct responder group needs to be identified

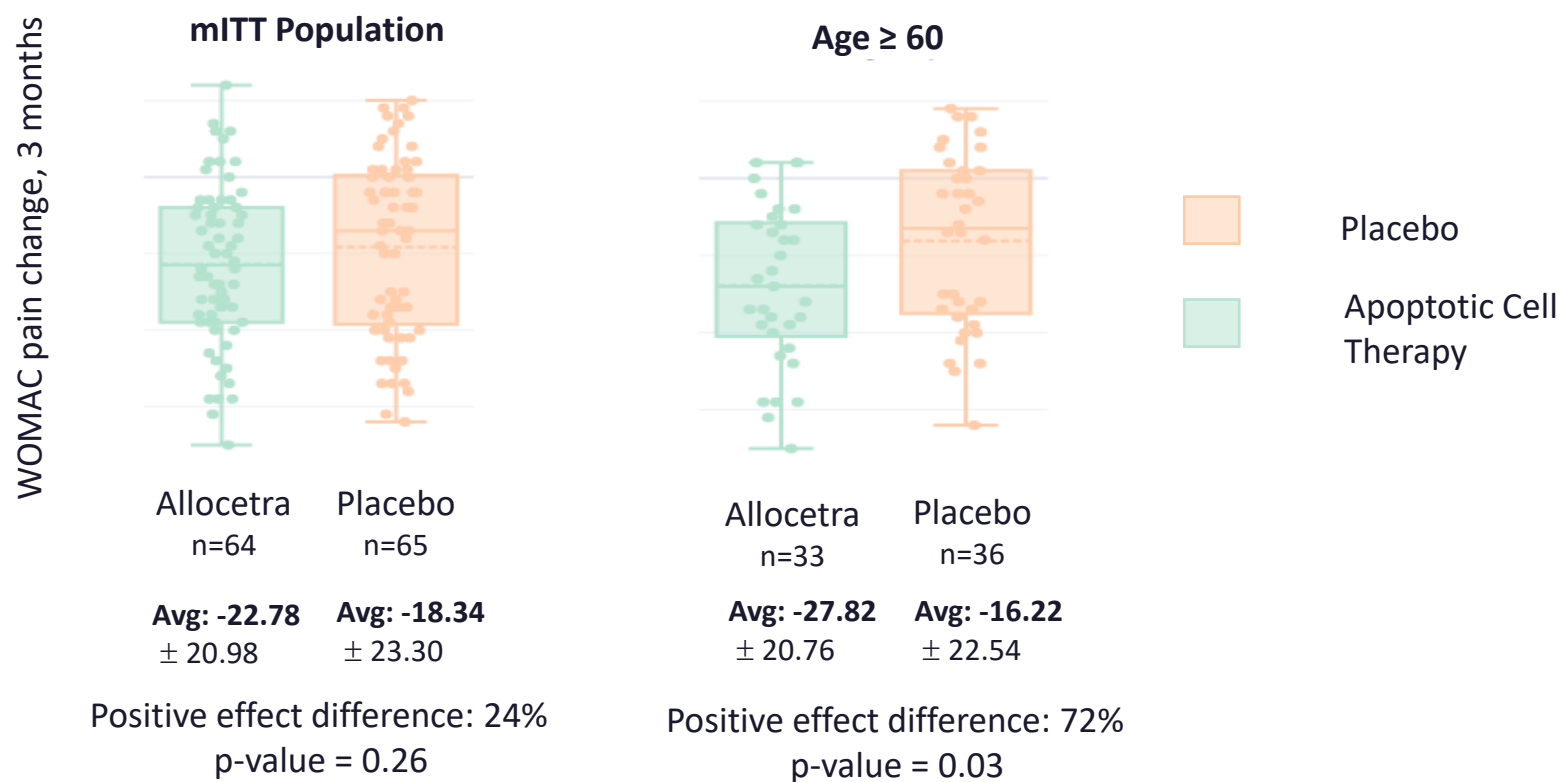


Specific responder profile

- More than 50% of the patients in the study
- Representing more than 50% of the KOA market
- Aligned with the proposed mechanism of action of Allocetra™

24% IMPROVEMENT OF WOMAC PAIN OVERALL; 72% IMPROVEMENT PRIMARY OA PATIENTS – STATISTICALLY SIGNIFICANT AND CLINICALLY MEANINGFUL

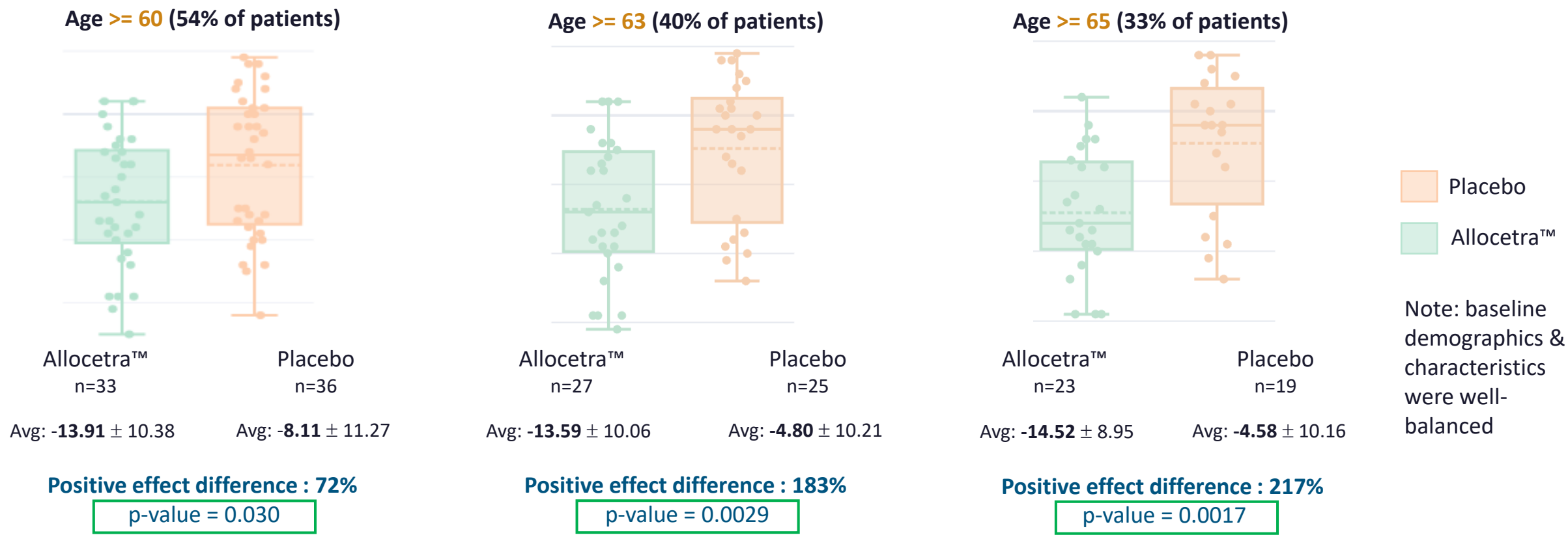
- 54% of the study's population are Primary OA patients (n=69 out of 129)
- The data shows substantial, clinically meaningful, and highly statistically significant difference in treatment effect of Allocetra™ in Primary OA vs placebo



ALLOCETRA™ EFFECT IN PRIMARY OA: CLINICALLY MEANINGFUL, STATISTICALLY SIGNIFICANT, IRRESPECTIVE OF AGE THRESHOLD (REDUCTION IN PAIN)

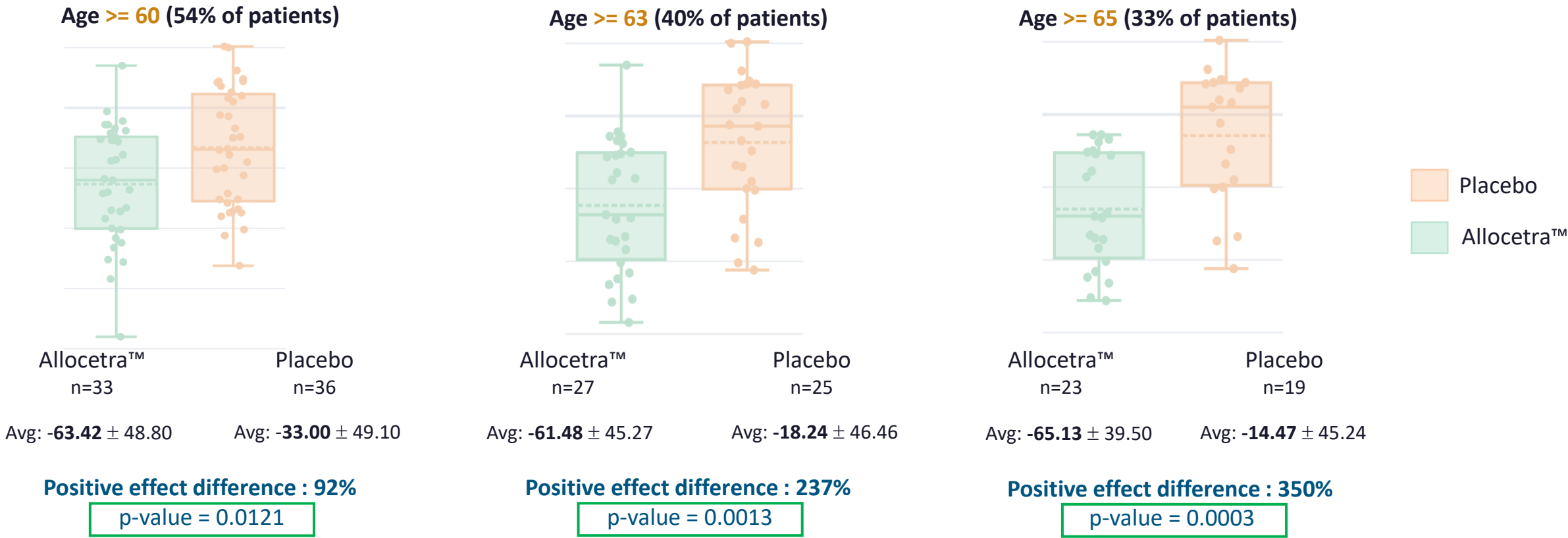
WOMAC pain change 3 months, Primary OA population

WOMAC pain change, 3 months



ALLOCETRA™ EFFECT IN PRIMARY OA: CLINICALLY MEANINGFUL, STATISTICALLY SIGNIFICANT, IRRESPECTIVE OF AGE THRESHOLD (CHANGE IN PAIN, STIFFNESS & FUNCTION)

WOMAC total change 3 months, Primary OA population



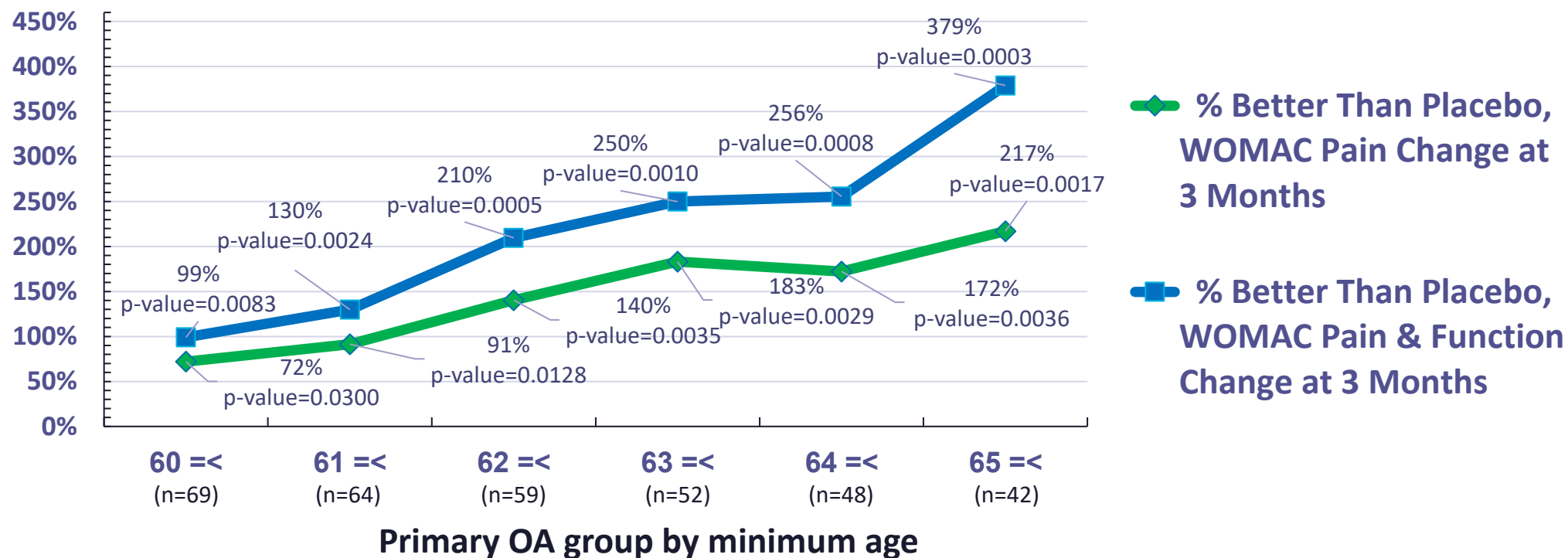
CLINICALLY MEANINGFUL, STATISTICALLY SIGNIFICANT **ACROSS EFFICACY ENDPOINTS** IN PRIMARY OSTEOARTHRITIS PATIENTS

3-month endpoints, Primary OA subjects (**age >=60**, n=69, 54% of enrolled subjects)

Efficacy measure	Allocetra™	Placebo	Difference	% Better than placebo	p-value	Reduction from baseline in Allocetra™ group
WOMAC total change	-26.43 (n=33)	-13.75 (n=36)	-12.68	92%	0.012	-48%
WOMAC pain change	-27.82 (n=33)	-16.22 (n=36)	-11.60	71%	0.030	-50%
WOMAC function change	-26.45 (n=33)	-12.63 (n=36)	-13.82	109%	0.007	-49%
WOMAC pain & function change	-26.76 (n=33)	-13.45 (n=36)	-13.32	99%	0.008	-49%
WOMAC stiffness & function change	-26.06 (n=33)	-13.10 (n=36)	-12.96	99%	0.012	-48%
NRS pain change	-2.89 (n=32)	-1.99 (n=36)	-0.90	45%	0.094	-46%

PHASE III ENDPOINTS: CLINICALLY MEANINGFUL, STATISTICALLY SIGNIFICANT, SUBSTANTIAL EFFECT SIZE, TRENDING WITH AGE

% Excess reduction of pain, pain & function in Allocetra™ group
vs reduction in the placebo group



SAFETY PROFILE: ALLOCETRA™ DEMONSTRATED A FAVORABLE SAFETY PROFILE, NO RELATED SERIOUS ADVERSE EVENTS WERE REPORTED

- As observed also in earlier clinical data in severe OA subjects, some patients injected with Allocetra™ experienced local responses following injection (84% of patients treated with Allocetra™, vs. 36% for placebo)
- Local responses mostly involved some knee pain or discomfort (73% of patients treated with Allocetra™, vs. 79% for placebo), and might have included knee swelling or limitation in range of motion (79% of patients treated with Allocetra™, vs. 33% for placebo)
- The events usually presented within 1-2 days following injection (average 1 day), and were mostly mild to moderate (93% of events), and transient (average duration 6 days for Allocetra™, vs. 10 days for placebo)
- Patients were advised of the possibility of such reactions to occur, and guided that symptoms may be alleviated with rest, ice packs on the knee, compression bandages, and knee elevation. If needed, they were allowed to take NSAIDs for a few days
- Overall, patients' willingness to continue with treatments was minimally impacted by the side effects, only 7.5% of patients treated with Allocetra™ opted to discontinue subsequent injections due to adverse events

SUMMARY: 3-MONTH TOPLINE DATA – ENX-CL-05-001

- Study objectives met
 - Allocetra™ demonstrated a favorable safety profile, no related serious adverse events were reported
 - 72% avg positive effect in pain reduction, 99% in increased function (Phase III endpoints) for Primary OA patients
 - Clinically meaningful with high statistical significance of intended Phase III endpoints in the planned Phase III population, as well as multiple secondary endpoints
 - Positive effect vs placebo exceeds FDA's effectiveness thresholds by more than 65%
 - Robust and consistent effect, aligned with the proposed MOA of Allocetra™
- Osteoarthritis: a growing market with significant potential and unmet medical need with Primary OA responders representing more than 50% of the ~\$7BN KOA market
- Simple manufacturing process, highly attractive KOA treatment cycle at estimated total COGS (3 injections) of ~\$450, allowing competitive pricing well within the range of high-end solutions
- We believe Allocetra™ has strong potential to become the therapy of choice for primary knee osteoarthritis patients

ENX-CL-05-002: PHASE IIb

Randomized, double-blind, placebo-controlled, multi-country study

Patient criteria:



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

Age 60/65-80 years;

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

Phase IIb: Randomized, double-blind, placebo-controlled

- Allocetra™ (1 or 2 doses) Vs. Placebo , 3 injections in total, each injection 2 weeks from the previous injection
- 75 patients per arm

Endpoints:



Primary:

3-month change in WOMAC pain

OR

3-month change in WOMAC pain & function

Safety and tolerability



Secondary:

3 & 6-month change in WOMAC total, NRS pain, and response assessments

NRS=numerical rating scale. WOMAC= Standard knee questionnaire evaluating pain, stiffness & physical function

ADDITIONAL CLINICAL STUDIES IN OA

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;

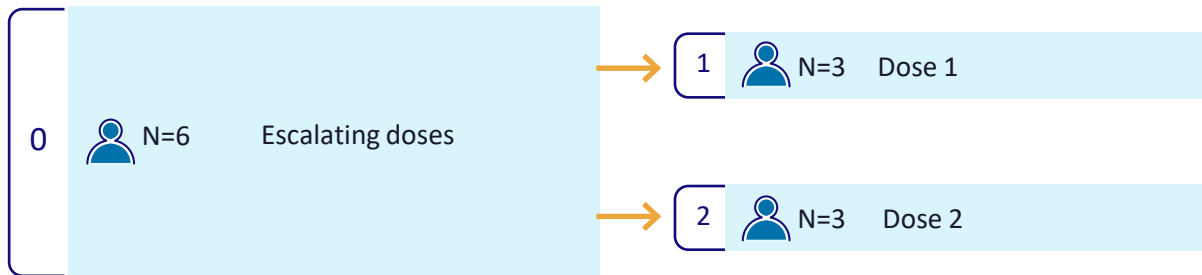
Age >40 years;

Eaton classification Grade 2 or 3.

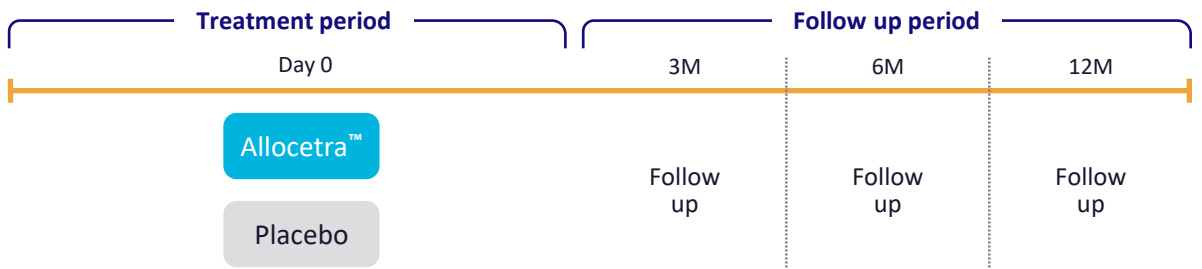


Local thumb Injection

Part 1: Safety (run-in) 6 patients



Part 2: Randomization >40 patients



Endpoints:



Primary:
Safety and tolerability.

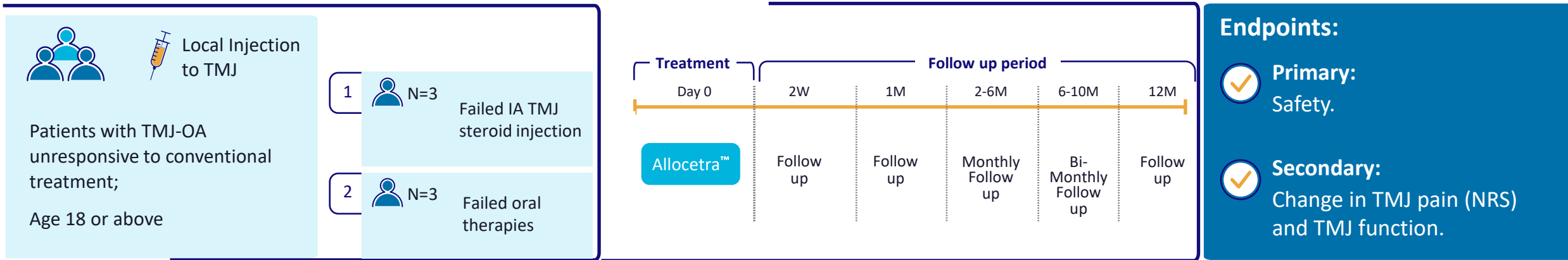


Secondary:
Change from baseline in pain and function.

ClinicalTrials.gov Registration: NCT06459063

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

Investigator-initiated Phase I study



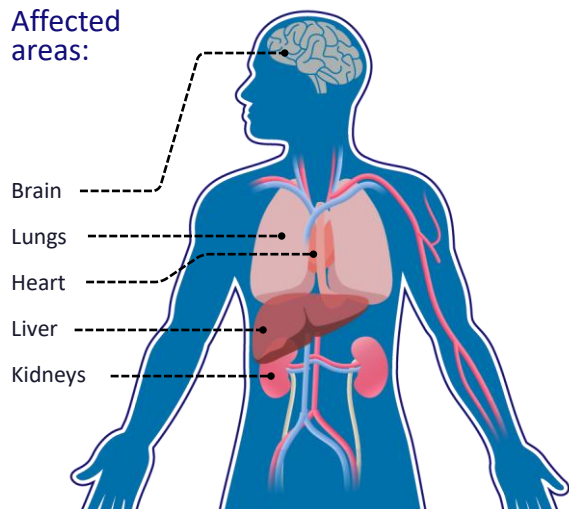
ClinicalTrials.gov Registration: NCT06748651

ALLOCETRA™ FOR THE TREATMENT OF SEPSIS

SEPSIS: A GLOBAL HEALTH CHALLENGE WITH SUBSTANTIAL MARKET OPPORTUNITY

Disease

Affected areas:



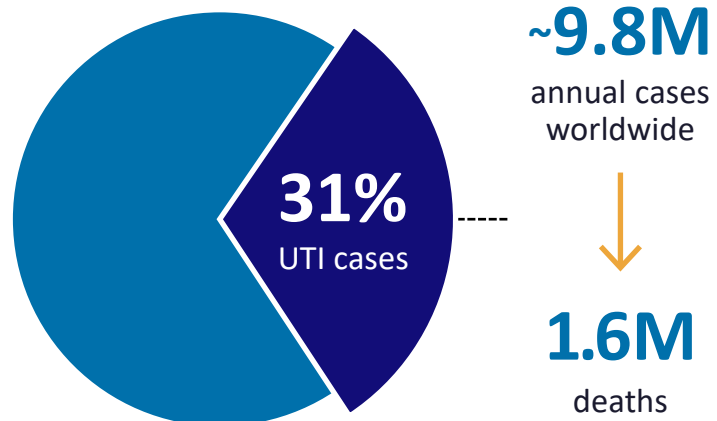
A life-threatening overactive immune response to infection that attacks the body and leads to:

- tissue damage,
- organ failure,
- death.

Market

\$33B Global market (severe Sepsis only²)

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

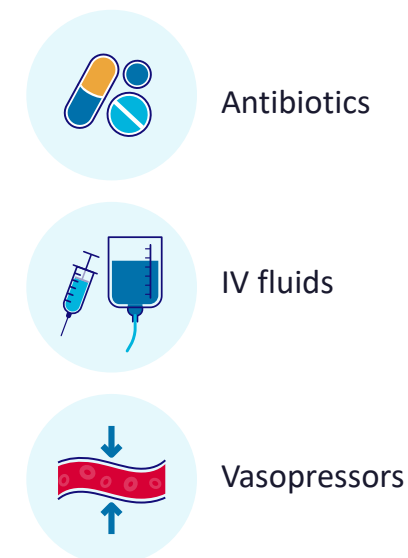


Standard of care

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:

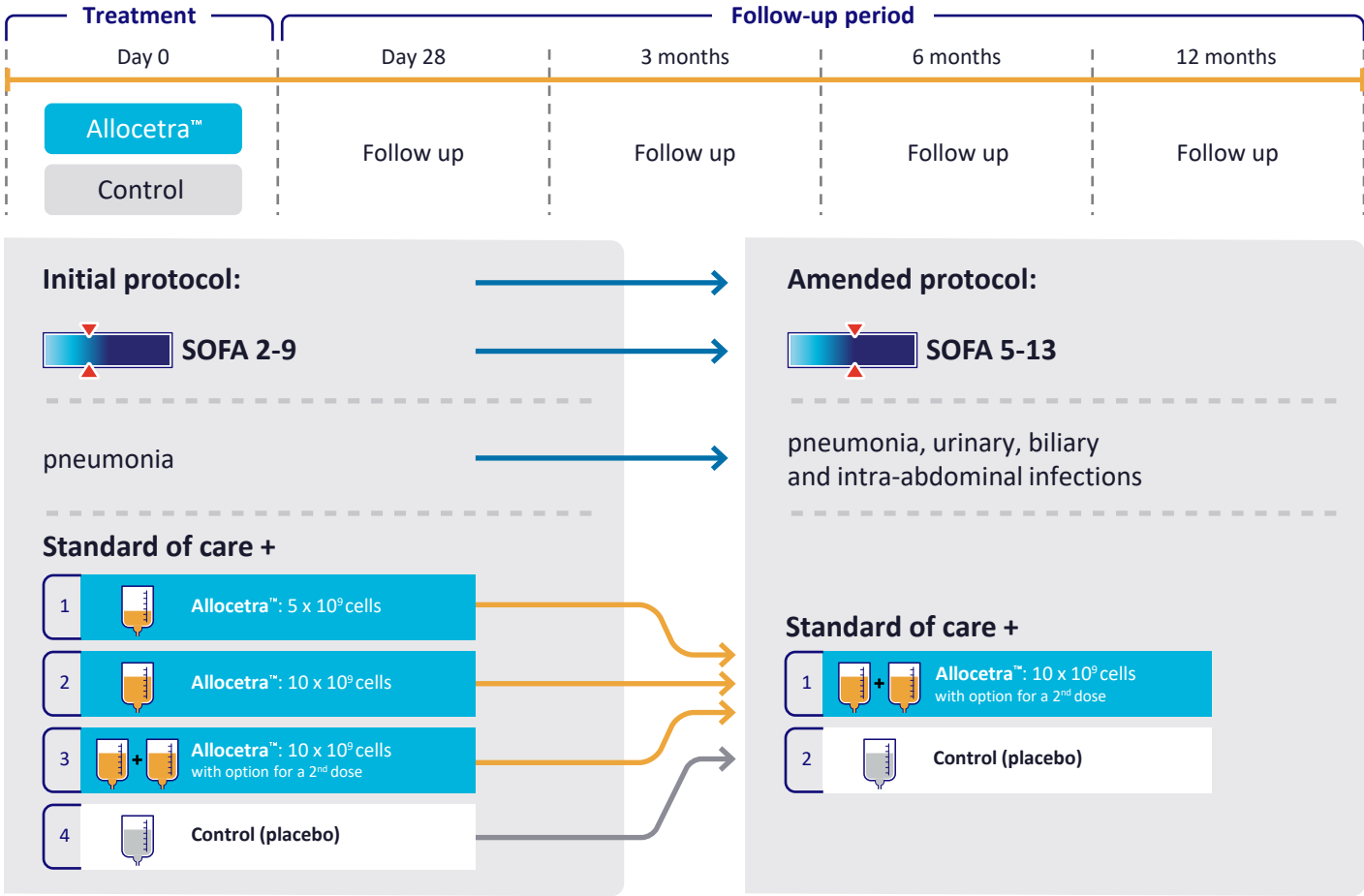


1 - Management of Urosepsis in 2018, Bonkat et. Al. , European Urology Focus Volume 5, Issue 1, (2019)

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

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.

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 II²	21.1 (6-44)	20.5 (6-47)
Septic shock	24 (65%)	31 (78%)
Invasive ventilation	16 (43%)	23 (58%)
Pneumonia	14 (38%)	16 (40%)
Urinary (UTI)	9 (24%)	9 (22.5%)
Intra-abdominal	5 (14%)	10 (25%)
Skin and soft tissue infections	4 (11%)	3 (7.5%)
Acute 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.

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

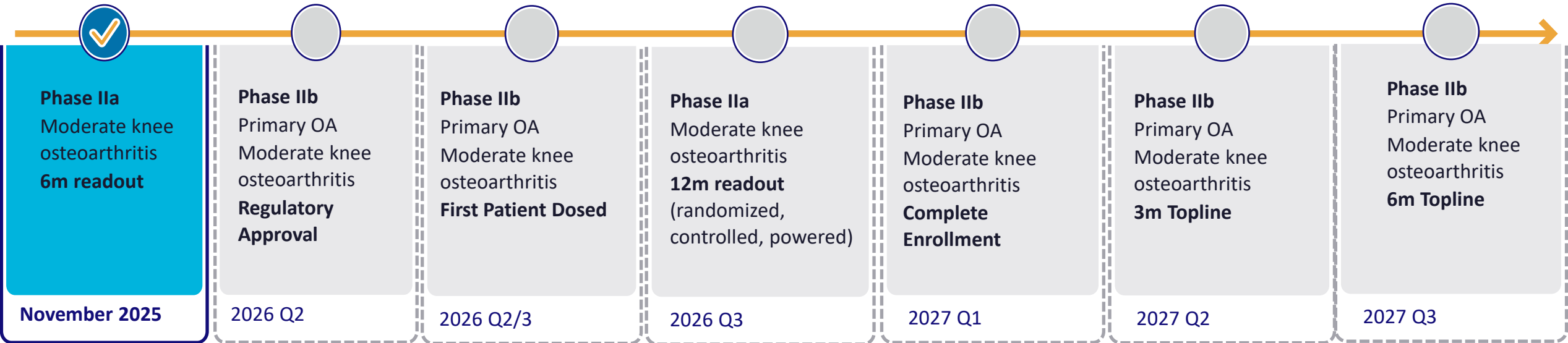
UTI	Population: screening SOFA ≥7		D1-14	D1-28
 N=9	 Control	Average reduction in SOFA score:	-7.22	-6.75
		Stdev:	2.28	2.12
 N=6	 Allocetra™	Average reduction in SOFA score:	-9.00	-8.40
		Stdev:	2.28	2.61
		% over control:	25%	24%
		p-value:	0.0814	0.1181

→ Despite higher risk of the Allocetra™-treated group

	Septic shock	Respiratory SOFA ≥3	Coagulation SOFA ≥3	Cardiovascular SOFA =4	Renal SOFA ≥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).

SHORT AND LONG TERM TARGET MILESTONES



Initiation and potential finalization of partnership discussions

EXTENSIVE IP PROTECTION



Expected protection up to

2043

FINANCIAL SUMMARY

NASDAQ GS
ENLV

Cash & equivalents
\$19.5 MM (June. 30, 2025)

Debt
none

Shares outstanding
23.8 MM (June 2025)

Estimated cash runway through
Dec. 31, 2026

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 200+ patients
- ✓ Clinical data supportive of proposed MOA

THANK YOU