UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
under the Securities Exchange Act of 1934

For the month of: November 2025

Commission file number: 001-36578

ENLIVEX THERAPEUTICS LTD.
(Translation of registrant's name into English)

14 Einstein Street, Nes Ziona, Israel 7403618
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

On November 24, 2025, Enlivex Therapeutics Ltd., a company organized under the laws of the State of Israel ("Enlivex"), issued a press release announcing six-month topline data from the Phase IIa stage of ENX-CL-05-001, a multi-center, two-stage Phase I/II double-blind, randomized, placebo-controlled clinical trial evaluating Allocetra™ in patients with moderate-to-severe knee osteoarthritis. A copy of such press release is furnished as Exhibit 99.1 to this Report on Form 6-K and incorporated herein by reference. Also attached as Exhibit 99.2 to this Report on Form 6-K and incorporated herein by reference is a copy of Enlivex's investor presentation in respect of such six-month topline data. The information (i) in the four bullets immediately under the heading "Summary of the 6-month Topline Data" in such press release and (ii) in slides 12 through 25, inclusive, contained in such investor presentation is incorporated by reference into Enlivex's registration statements on Forms S-8, F-3 and F-3MEF (File No. 333-256799, File No. 333-232413, File No. 333-232009, File No. 333-252926 and File No. 333-286956), filed with the Securities and Exchange Commission.

Exhibit No.

99.1	Press Release Issues by Enlivex Therapeutics Ltd. on November 24, 2025
99.2	Investor Presentation

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Enlivex Therapeutics Ltd.
(Registrant)

By: /s/ Oren Hershkovitz
Name: Oren Hershkovitz
Title: Chief Executive Officer

Date: November 24, 2025

Enlivex Announces Positive 6-Month Topline Data –Demonstrating Durable and Persistent Pain Reduction and Improved Function in Primary Age-Related Patients with Moderate to Severe Knee Osteoarthritis

Nes-Ziona, Israel, November 24, 2025 (GLOBE NEWSWIRE) -- Enlivex Therapeutics Ltd. (Nasdaq: ENLV, the "Company"), a clinical-stage macrophage reprogramming immunotherapy company, today announced positive six-month efficacy data from the Phase IIa stage of its randomized, multi-country Phase I/II Allocetra™ trial (ENX-CL-05-001) in patients with moderate to severe knee osteoarthritis (OA). The six-month follow-up has now been completed for all patients. The results re-affirm the three-month data reported previously and substantiate the identification of an age-related primary OA responder population.

Summary of the 6-month Topline Data

- On August 18, 2025, Enlivex announced the 3-month topline data, reporting that Allocetra™ demonstrated, in the primary age group (60+), substantial reduction in pain and improvement in function across multiple efficacy endpoints that were evaluated, compared to placebo. The analysis revealed a robust positive correlation between patients' age and the magnitude of the clinical effect and its statistical significance.

- At 6 months, Allocetra™ continued to demonstrate substantial and durable reduction in pain and improvement in function across multiple efficacy endpoints evaluated in the same primary age group (60+), as compared to placebo. These findings are consistent with the 3-month observations, as well as the robust positive correlation between patients' age and the magnitude of the clinical effect and its statistical significance.

- Allocetra™ demonstrated a clinically meaningful improvement in pain and function, a composite endpoint which we expect will be a key endpoint in the follow-up pivotal studies, reaching statistical significance at 3-month at age 60+ (-26.8 points in the Allocetra™ treated group versus -13.4 points in the placebo group, corresponding to 99% improvement over the placebo group (scale 0-100; p=0.008), and at 6-month at age 61+ (-27.8 points in the Allocetra™ treated group versus -15.5 points in the placebo group corresponding to 80% improvement over the control group (scale 0-100; p=0.02).)

- Allocetra™ continued to demonstrate a favorable safety profile through the six-month follow-up, consistent with the previously reported three-month data.

Professor Philip Conaghan, MBBS, PhD, FRACP, FRCP, is an internationally renowned leader in osteoarthritis and musculoskeletal imaging, and the Consultant Rheumatologist and Director of the NIHR Leeds Biomedical Research Centre. Prof. Conaghan has authored more than 700 publications and chaired multiple global guidelines and trial initiatives and is a member of the Clinical Advisory Board of Enlivex.

Prof. Conaghan commented “The toll of knee osteoarthritis continues to grow with the increasing burden of aging and obesity, and subsequently the need for effective therapies is becoming a major need undertaking. With the understanding that inflammatory mediators play a central role in the progression of knee pain and dysfunction, new treatment strategies can be proposed. I am encouraged by the results demonstrated in the study so far and continue to follow the clinical development of Allocetra™ as an immune modulating agent that could potentially pioneer a new therapeutic approach.”

Oren Hershkovitz, Ph.D., CEO of Enlivex, stated: “We believe the six-month results provide strong evidence that Allocetra™ delivers a durable and clinically meaningful benefit for patients with age-related primary knee osteoarthritis. A single treatment cycle producing at least six months of sustained efficacy represents not only a potentially transformative therapeutic option for patients but also supports a compelling and scalable commercial opportunity for Enlivex.”

Einat Galamidi, M.D., CMO of Enlivex, added: “We are highly encouraged by the durable clinical improvements observed in this patient population. These results pave the way for our upcoming Phase IIb trial evaluating Allocetra™ in age-related primary knee osteoarthritis. We plan to initiate this study in the first half of 2026 and are committed to advancing Allocetra™ as a potential novel treatment to improve the quality of life for millions of patients affected by knee osteoarthritis.”

In-depth analysis of the 6-month results is provided in a separate presentation, available as part of the Companiy’s SEC filings and can be downloaded from its website.

About ENX-CL-05-001

ENX-CL-05-001 is a multi-center Phase I/II clinical trial consisted of two stages. The first stage was a Phase I safety run-in, open-label dose escalation phase to characterize the safety and tolerability of Allocetra™ injections to the target knee, in order to identify the dose and injection regimen or the subsequent Phase IIa stage. The Phase IIa stage is a double-blind, randomized, placebo-controlled multi-centered trial. In addition to evaluating safety, the study protocol was designed to efficiently find a strong signal in a responder population to guide future development, and includes an interim statistical evaluation, conducted by an independent third party and blinded to the Company, to assess the potential value of enrollment of up to 50 patients in addition to the original randomized sample size of 130, and its marginal impact on the p-value of the statistical estimation of the total group and specifically to identify a potential responder sub-group. The trial’s key efficacy endpoints evaluate joint-pain and joint-function in comparison to placebo at three months, six months and 12 months post treatment.

ABOUT KNEE OSTEOARTHRITIS

Osteoarthritis is by far the most common form of arthritis, affecting more than 32.5 million Americans and more than 300 million individuals worldwide. About half of knees with ACL injuries develop osteoarthritis within 5 to 15 years. 78 million Americans are projected to have osteoarthritis by the year 2040. Symptomatic knee osteoarthritis is particularly prevalent and disabling, with 40% of men and 47% of women developing knee osteoarthritis in their lifetimes. Osteoarthritis accounts for over one million hospitalizations annually in the United States, primarily for total joint replacement. The burden of osteoarthritis is enormous, and the need for treatments that reduce pain and attendant disability for persons with osteoarthritis is critical. There are currently no medications approved by either the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA) that have been demonstrated to arrest, slow or reverse progression of structural damage in the joint.

ABOUT ENLIVEX

Enlivex is a clinical stage macrophage reprogramming immunotherapy company developing Allocetra™, a universal, off-the-shelf cell therapy designed to reprogram macrophages into their homeostatic state. Resetting non-homeostatic macrophages into their homeostatic state is critical for immune system rebalancing and resolution of life-threatening and life debilitating conditions. For more information, visit https://enlivex.com/.

Safe Harbor Statement: This press release contains forward-looking statements, which may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "would," "could," "intends," "estimates," "suggests," "has the potential to" and other words of similar meaning, including statements regarding expected cash balances, expected clinical trial results, market opportunities for the results of current clinical studies and preclinical experiments, the effectiveness of, and market opportunities for, ALLOCETRA™ programs. All such forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that forward-looking statements involve risks and uncertainties that may affect Enlivex's business and prospects, including the risks that Enlivex may not succeed in generating any revenues or developing any commercial products; that the products in development may fail, may not achieve the expected results or effectiveness and/or may not generate data that would support the approval or marketing of these products for the indications being studied or for other indications; that ongoing studies may not continue to show substantial or any activity; and other risks and uncertainties that may cause results to differ materially from those set forth in the forward-looking statements. The results of clinical trials in humans may produce results that differ significantly from the results of clinical and other trials in animals. The results of early-stage trials may differ significantly from the results of more developed, later-stage trials. The development of any products using the ALLOCETRA™ product line could also be affected by a number of other factors, including unexpected safety, efficacy or manufacturing issues, additional time requirements for data analyses and decision making, the impact of pharmaceutical industry regulation, the impact of competitive products and pricing and the impact of patents and other proprietary rights held by competitors and other third parties. In addition to the risk factors described above, investors should consider the economic, competitive, governmental, technological and other factors discussed in Enlivex's filings with the Securities and Exchange Commission, including in the Company's most recent Annual Report on Form 20-F filed with the Securities and Exchange Commission. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements, except as required under applicable law.

ENLIVEX CONTACT

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Jack Perkins
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ENLIVEX
CLINICAL DEVELOPMENT

November 2025

Nasdaq: **ENLV**

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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:

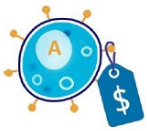
macrophage modulation.

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.

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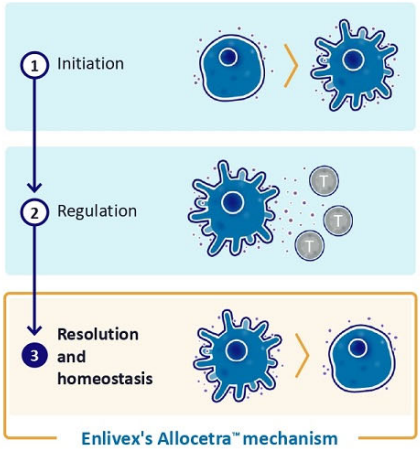
CELLULAR FIRST RESPONDERS: MACROPHAGES AND THEIR CRITICAL ROLE IN INFLAMMATION

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

Main functions:	Role in inflammation:
Recruit other immune cells	Antigen presentation
Defend against pathogens	Cytokine secretion
Cleanup senescent or dead cells	Phagocytosis
Control tissue homeostasis and repair	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.



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PROMOTING BALANCE: APOPTOTIC CELLS FACILITATE MACROPHAGE HOMEOSTASIS

Prof. Dror Mevorach
Scientific Founder

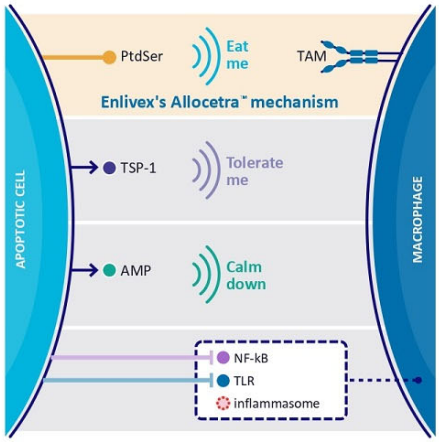
Apoptotic Cells Induce NF-kB and Inflammasome Negative Signaling
Amir Grau, Adi Tabib, Inna Grau, Inna Reiner, Dror Mevorach

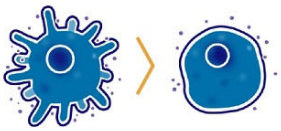
PLOS One, 2015

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.

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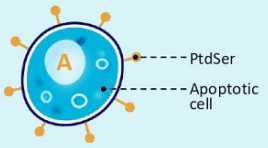
ALLOCETRA™: AN OFF THE SHELF CELL THERAPY DESIGNED TO RESTORE MACROPHAGE HOMEOSTASIS

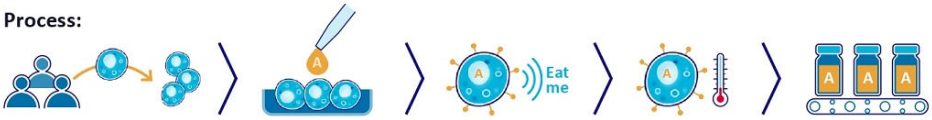


Allocetra™

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

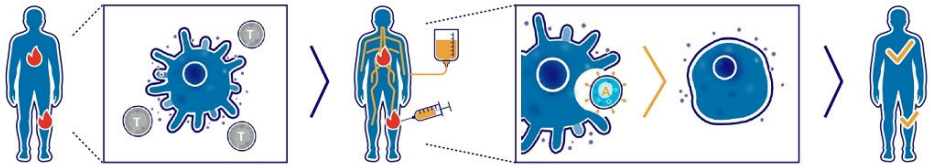
proprietary apoptotic cell modification process

cells express "eat me" signal

cells are frozen

off the shelf, cost effective cell therapy

Mechanism:



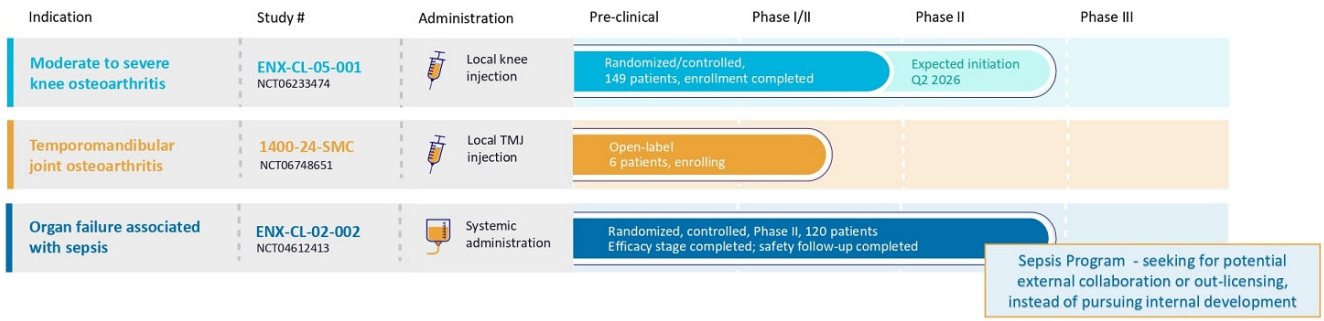
1. Patient with systemic or joint inflammation

2. Allocetra™ cells are injected into the patient

3. Allocetra™ cells are engulfed by macrophages

4. Macrophage homeostasis is restored

ALLOCETRA™ CURRENT PIPELINE: BUILDING MOMENTUM



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ALLOCETRA™
FOR THE TREATMENT OF OSTEOARTHRITIS

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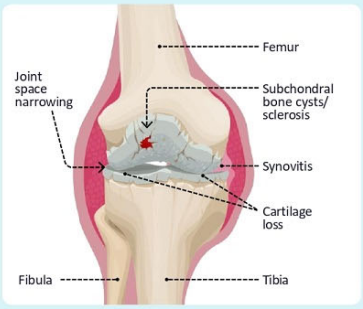
OSTEOARTHRITIS: A GROWING MARKET WITH SIGNIFICANT POTENTIAL

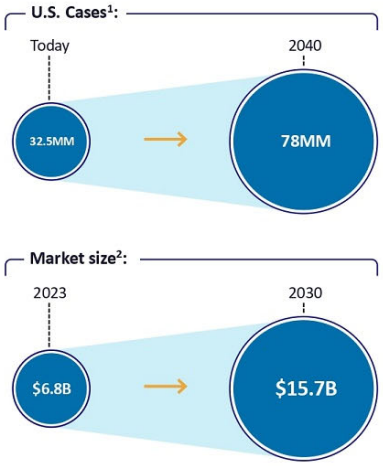
Disease overview



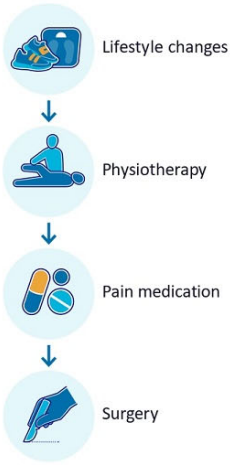
Disease manifestation:

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

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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.

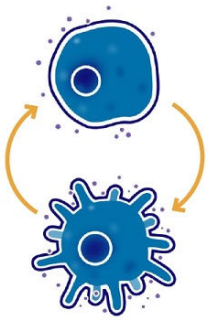
Eric W. Orlowsky and Virginia Byers Kraus

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?

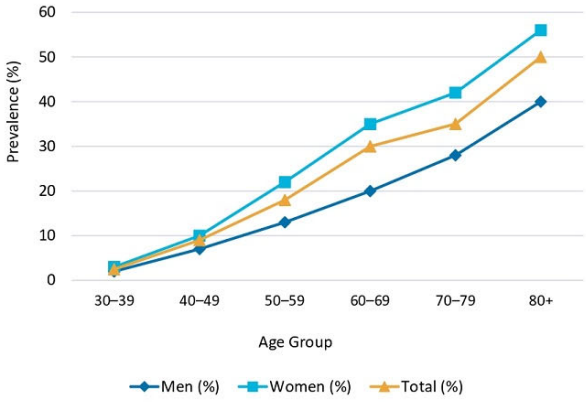
Amanda Thomson and Catharien M. U. Hilkens

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

Prevalence of Osteoarthritis increases with age[1]



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

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RESULTS FROM THE COMPLETED ENX-CL-05-001 – PHASE IIa IN PATIENTS WITH SYMPTOMATIC MODERATE TO SEVERE KNEE OA

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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

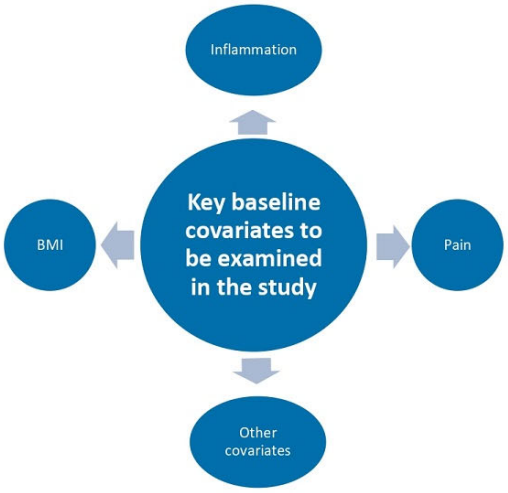
"OA is a clinical syndrome and not a singular molecular disease"

Heterogeneous patient population included indiscriminately

Purpose was to assess safety, efficacy, and potentially find a strong signal in a responder sub-population to guide future development

(As stated in our 2024 annual report/PR)

Phase IIa is the proper clinical stage to find the responder sub-population



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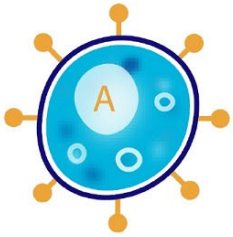
ENX-CL-05-001 – PHASE IIa OBJECTIVES MET:

(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™

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ENX-CL-05-001 KNEE-OSTEOARTHRITIS PHASE IIa
RESULTS - 3 & 6-MONTH TOPLINE DATA ANALYSIS

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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

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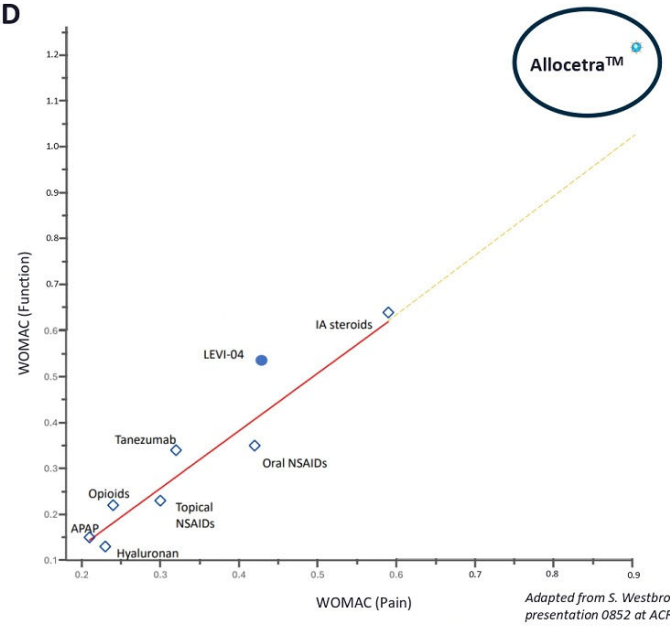
COMPETITIVE COMPARISON OF STANDARDIZED EFFECT SIZES

Efficacy Endpoint	Standardized Effect Size		
	mITT	≥60	≥65
NRS Pain Change from Baseline (scale 0-10)			
3 Months	-0.22	-0.41	-0.76
6 Months	-0.08	-0.30	-0.80
WOMAC Pain Change from Baseline (randomized 0-100)			
3 Months	-0.20	-0.53	-1.05
6 Months	-0.05	-0.25	-0.88
WOMAC Function Change from Baseline (randomized 0-100)			
3 Months	-0.21	-0.67	-1.22
6 Months	-0.15	-0.48	-1.22
WOMAC Total Change from Baseline (randomized 0-100)			
3 Months	-0.19	-0.62	-1.20
6 Months	-0.11	-0.41	-1.14



Adapted from S. Westbrook presentation 0852 at ACR 2025

Dobson et al. Osteoarthritis Cartilage. 2013;21(8):1042-52; Bannuru et al. Ann Intern Med. 2015;162(1):46-54; Conaghan et al. J Bone Joint Surg Am. 2018;100(8):666-677; Katz et al. Postgrad Med. 2010;122(4):112-28; Berenbaum et al, Ann Rheum Dis. 2020;79(6):800-810; Chevalier et al. Ann Rheum Dis. 2010;69(1):113-9

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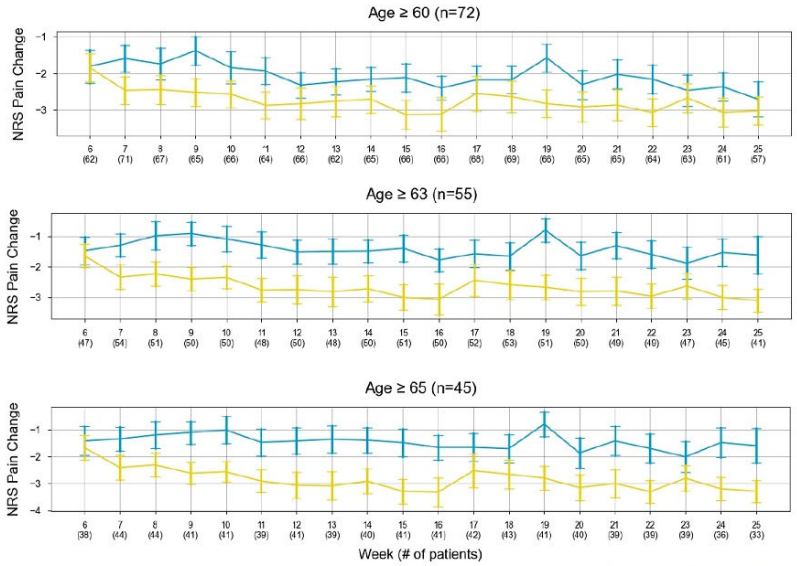
PAIN NRS WEEKLY CHANGE OVER TIME

Substantial and durable weekly pain NRS reduction compared to placebo, with increased effect trending with age.



Placebo

Allocetra™

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RESPONDER RATES (OMERACT-OARSI CRITERIA) – WOMAC PAIN

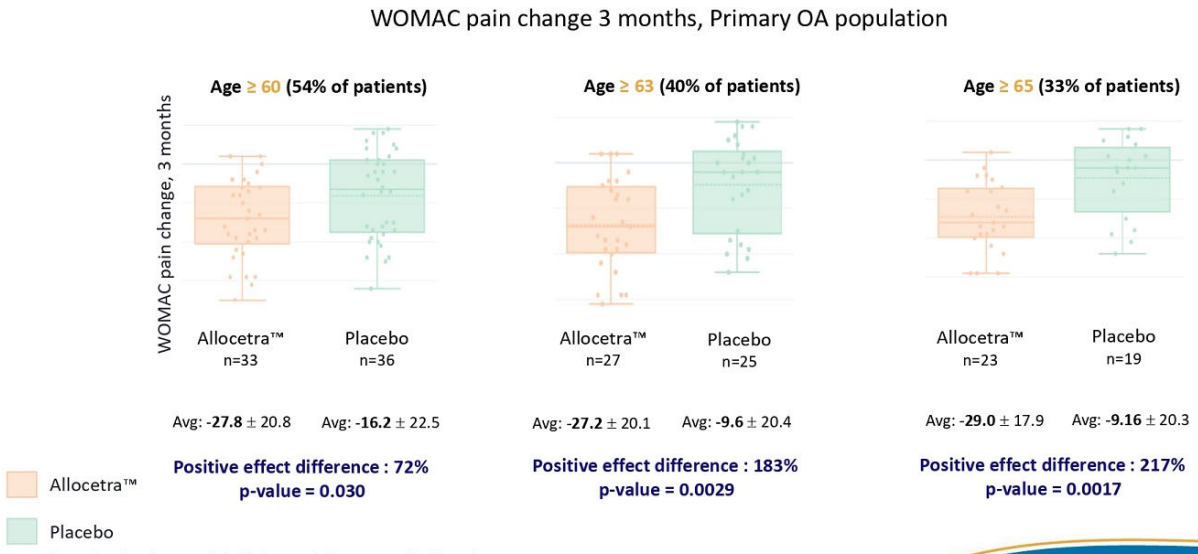
High responder rates compared to placebo, with increasing percentages trending with age

Age threshold		3m	6m
≥ 60	Placebo	50%	58%
	Allocetra	71%	65%
	% better than placebo	41%	12%
	p-value	0.0773	0.5604
≥ 63	Placebo	37%	44%
	Allocetra	68%	64%
	% better than placebo	83%	45%
	p-value	0.0219	0.1448
≥ 65	Placebo	33%	38%
	Allocetra	75%	63%
	% better than placebo	125%	64%
	p-value	0.0042	0.1069

Responders were defined as patients that met the OMERACT-OARSI criteria
(Outcome Measures in Arthritis Clinical Trials-Osteoarthritis Research Society International)

ENLIVEX

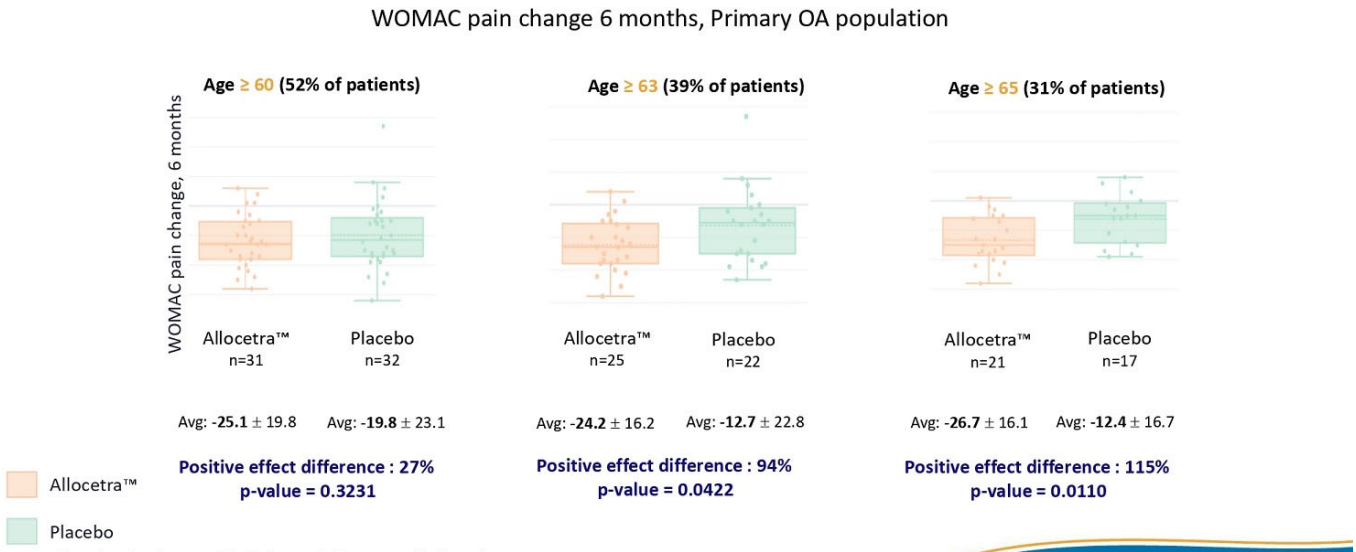
ALLOCETRA™ EFFECT IN PRIMARY OA: CLINICALLY MEANINGFUL, STATISTICALLY SIGNIFICANT, TRENDING WITH AGE (REDUCTION IN PAIN)



Note: baseline demographics & characteristics were well-balanced
Results are normalized to 0-100 scale

ENLIVEX

ALLOCETRA™ EFFECT IN PRIMARY OA: CLINICALLY MEANINGFUL, STATISTICALLY SIGNIFICANT, TRENDING WITH AGE (REDUCTION IN PAIN)

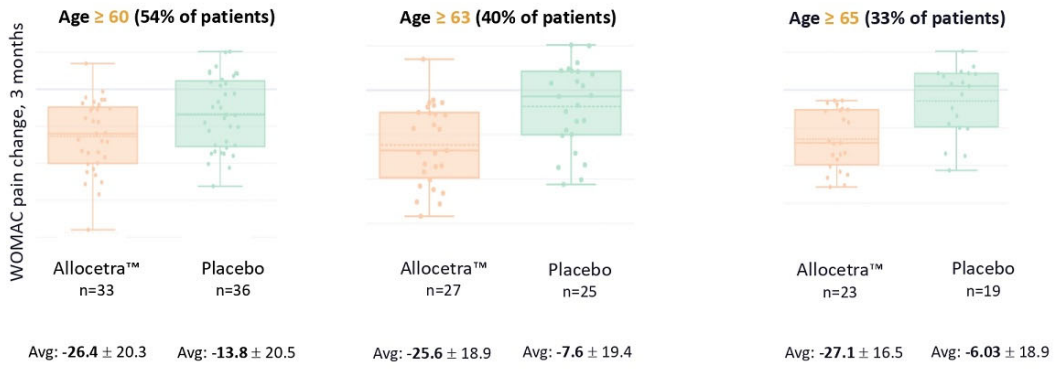


Note: baseline demographics & characteristics were well-balanced
Results are normalized to 0-100 scale

ENLIVEX

ALLOCETRA™ EFFECT IN PRIMARY OA: CLINICALLY MEANINGFUL, STATISTICALLY SIGNIFICANT, TRENDING WITH AGE (REDUCTION IN PAIN & STIFFNESS, AND INCREASE IN FUNCTION)

WOMAC total change 3 months, Primary OA population

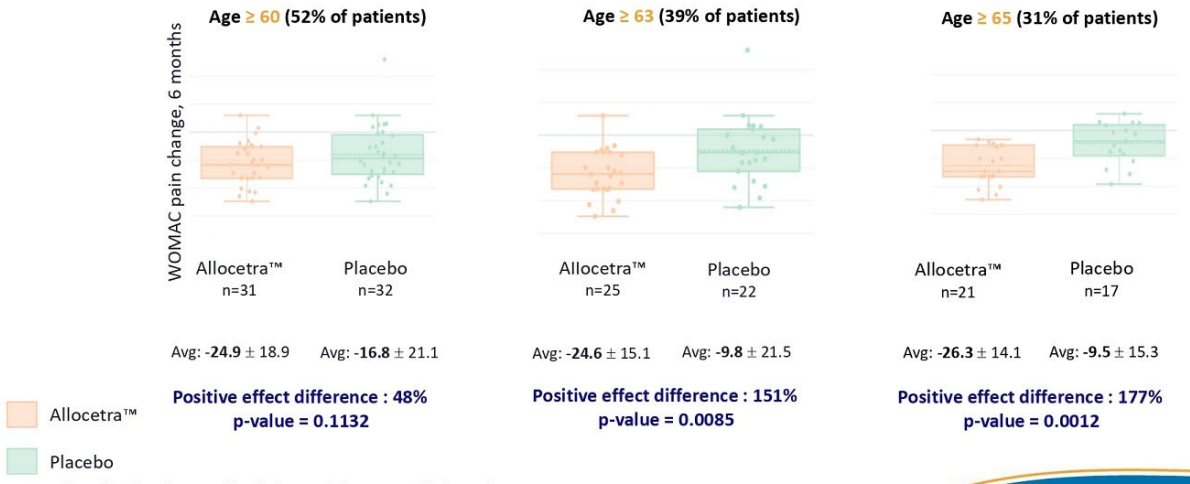


Note: baseline demographics & characteristics were well-balanced
Results are normalized to 0-100 scale

ENLIVEX

ALLOCETRA™ EFFECT IN PRIMARY OA: CLINICALLY MEANINGFUL, STATISTICALLY SIGNIFICANT, TRENDING WITH AGE (REDUCTION IN PAIN & STIFFNESS, AND INCREASE IN FUNCTION)

WOMAC total change 6 months, Primary OA population



Note: baseline demographics & characteristics were well-balanced
Results are normalized to 0-100 scale

ENLIVEX

CLINICALLY MEANINGFUL, STATISTICALLY SIGNIFICANT POSITIVE EFFECT, HIGHLY CORRELATED WITH PRIMARY OA AGE THRESHOLD

The positive effect of Allocetra™ on pain & function is substantial, with at least 6-month durability

Age cutoff	Change from baseline - 3 months					Change from baseline - 6 months				
	Allocetra™ Mean (SD)	**Placebo** Mean (SD)	**Difference**	**% Better than placebo**	**p-value**	**Allocetra™** Mean (SD)	**Placebo** Mean (SD)	**Difference**	**% Better than placebo**	**p-value**
≥ 60	**-26.8** (±20.0)	**-13.4** (±20.6)	-13.3	**99%**	**0.0083**	**-25.3** (±18.6)	**-16.6** (±21.6)	-8.7	**52%**	**0.0927**
≥ 61	**-28.2** (±20.7)	**-12.3** (±19.6)	-16.0	**130%**	**0.0024**	**-27.8** (±18.3)	**-15.5** (±21.0)	-12.3	**80%**	**0.0215**
≥ 62	**-28.2** (±20.7)	**-9.1** (±19.4)	-19.1	**210%**	**0.0005**	**-27.8** (±18.3)	**-12.9** (±21.9)	-14.9	**116%**	**0.0095**
≥ 63	**-25.8** (±18.6)	**-7.4** (±19.6)	-18.4	**250%**	**0.0010**	**-24.9** (±14.6)	**-9.7** (±22.3)	-15.2	**156%**	**0.0076**
≥ 64	**-26.3** (±16.5)	**-7.4** (±20.0)	-18.9	**255%**	**0.0008**	**-26.5** (±13.4)	**-7.9** (±21.1)	-18.6	**235%**	**0.0013**
≥ 65	**-27.3** (±16.2)	**-5.7** (±19.2)	-21.6	**379%**	**0.0003**	**-26.5** (±13.8)	**-9.6** (±15.1)	-16.9	**175%**	**0.0009**

Trending with age

Results are normalized to 0-100 scale

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, similar to 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

DATA SUMMARY: 3 AND 6-MONTH TOPLINE DATA – ENX-CL-05-001

- Study objectives met
  - Allocetra™ demonstrated an encouraging safety profile, no related serious adverse events were reported
  - In primary age-related osteoarthritis patients, Allocetra™ treatment resulted in substantial, clinically meaningful, and durable effect, with high statistical significance of established Phase III endpoints, as well as multiple secondary endpoints
    - Positive effect vs placebo exceeds FDA's effectiveness thresholds required for commercial approval
    - 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%[1] 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

[1] Chen et al., Global burden of knee osteoarthritis from 1990 to 2021, PLoS One 2025

NEXT STEP: INITIATE ENX-CL-05-002, a PHASE IIb in primary KOA patients

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

Endpoints:

Primary:
3-month change in WOMAC pain
OR
3-month change in WOMAC pain & function

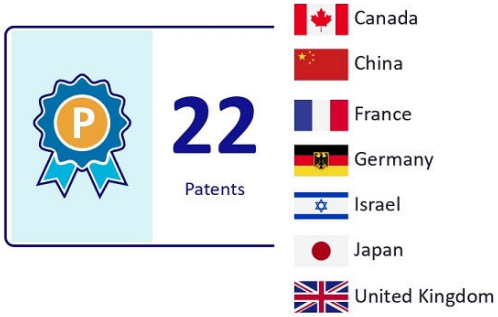
Safety and tolerability

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

ENLIVEX

EXTENSIVE IP PROTECTION



Expected protection up to

2043

CLINICAL 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
- Clinically meaningful and statistically significant results in age-related knee osteoarthritis supporting late-stage development

THANK YOU