

ENLIVEX THERAPEUTICS PHASE IIA TOPLINE RESULTS

Aug 2025



FORWARD-LOOKING STATEMENTS

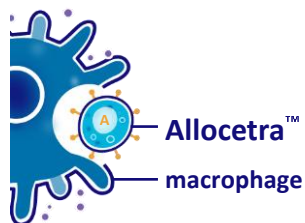
These slides and the accompanying oral presentation contain forward-looking statements and information. Forward-looking statements are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels or activity, performance or achievements 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. Material factors and risks that may cause actual results to differ materially from those expressed in forward-looking statements are detailed under "risk factors" and similar headings in our 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. 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.

MACROPHAGE MODULATION FOR THE TREATMENT OF INFLAMMATORY DISEASES

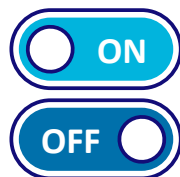
Enlivex is a clinical stage pharmaceutical company developing Allocetra™, a universal, off-the-shelf cell therapy designed to reprogram macrophages into their homeostatic state, for treatment of inflammatory diseases.

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

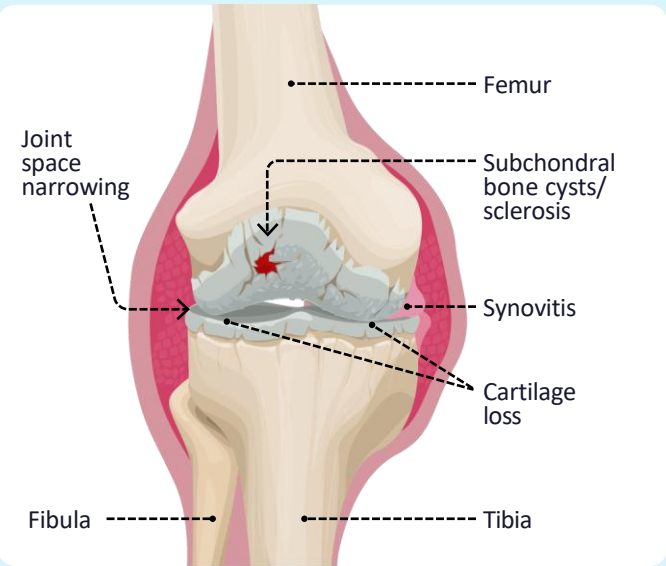
Director

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.

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

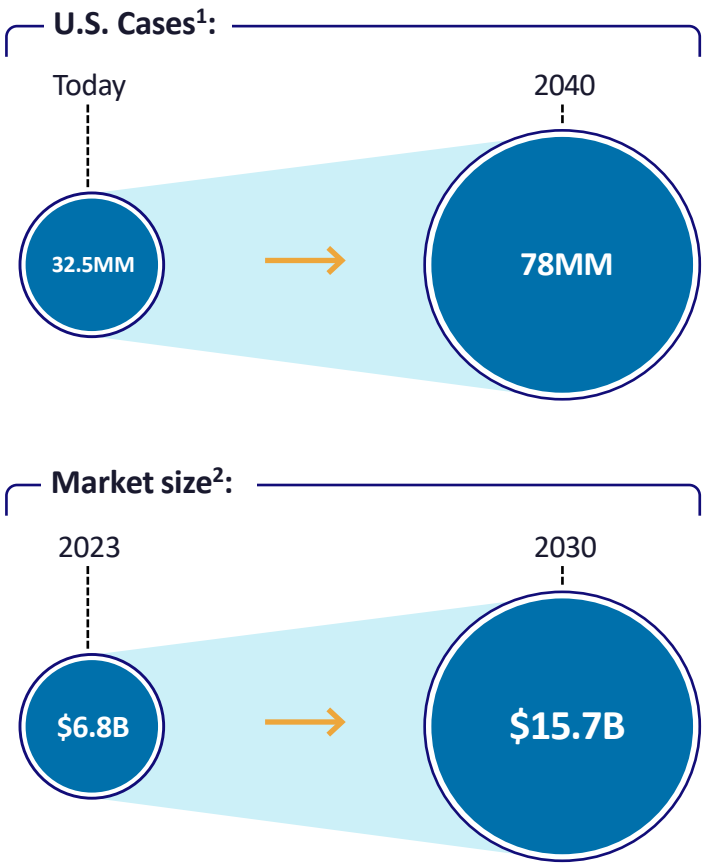
OSTEOARTHRITIS: A GROWING MARKET WITH SIGNIFICANT POTENTIAL AND UNMET MEDICAL NEED

Disease overview

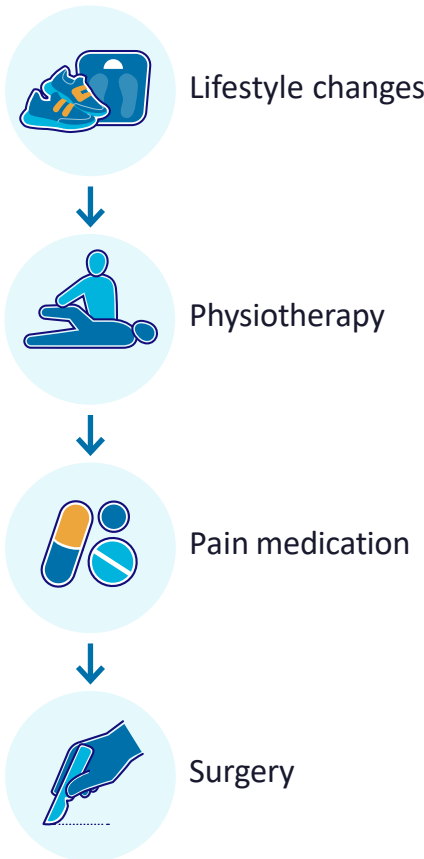


Disease manifestation:
cartilage damage, abnormal bone remodeling, and inflammation of the synovium.

Market

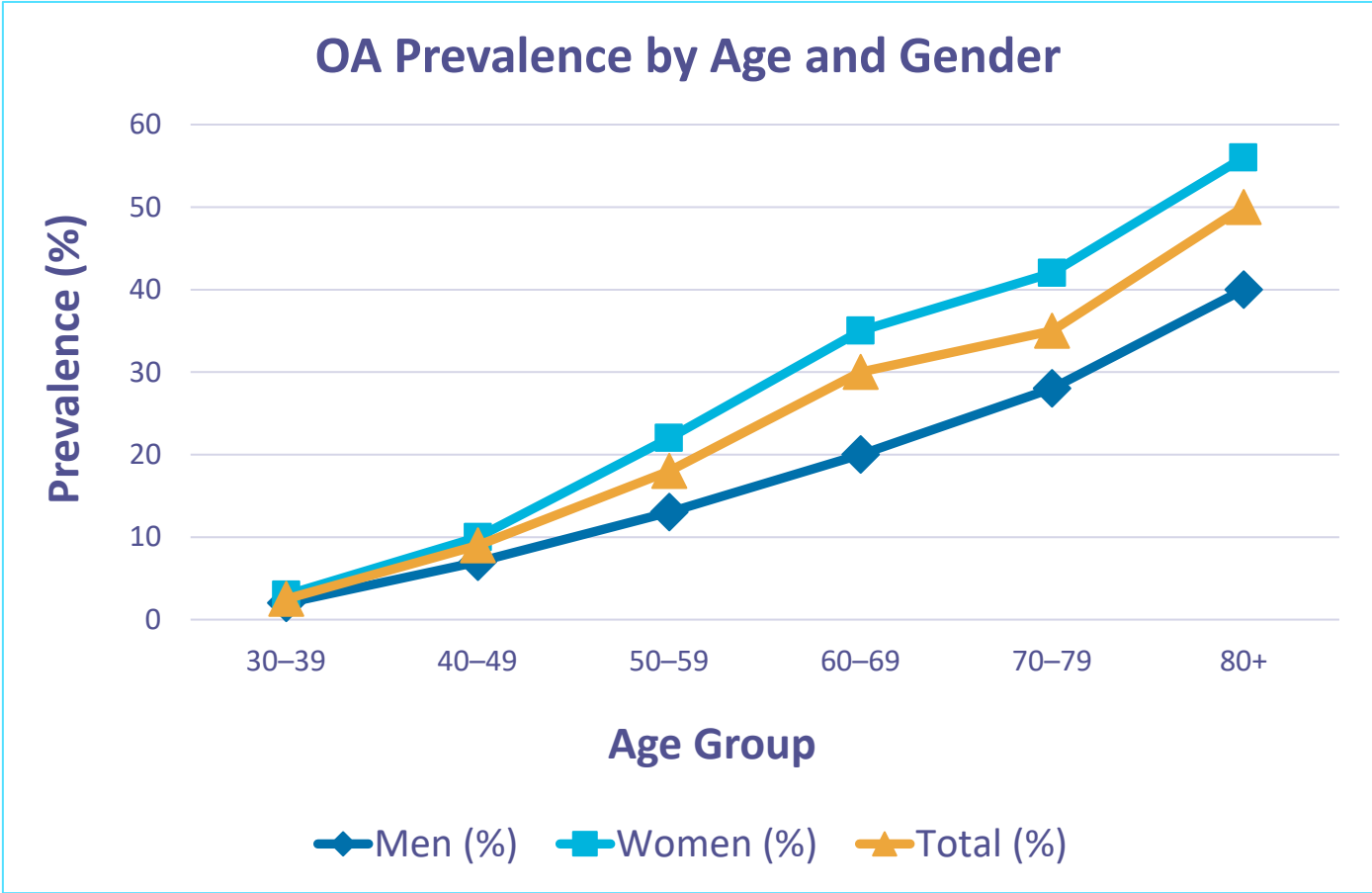


Standard of care



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

PREVALENCE OF OSTEOARTHRITIS INCREASES WITH AGE¹



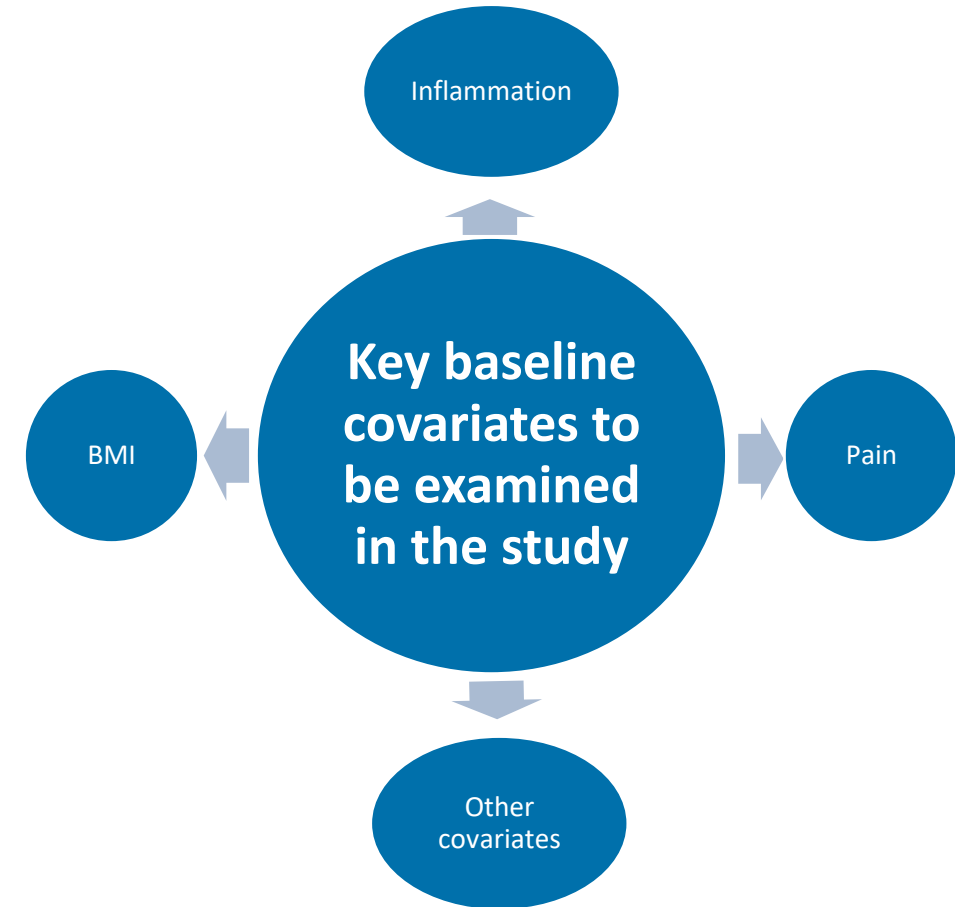
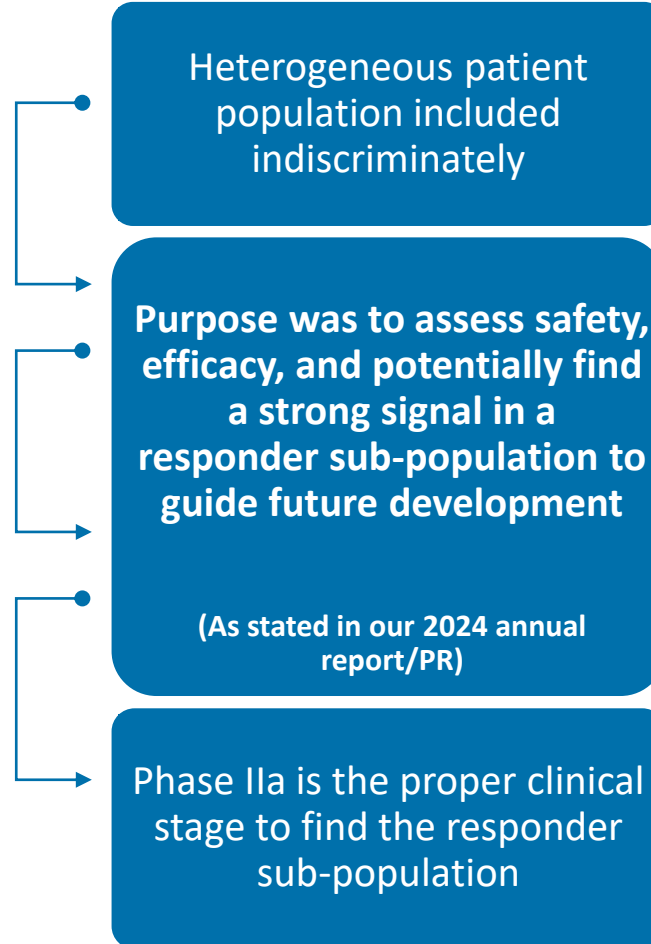
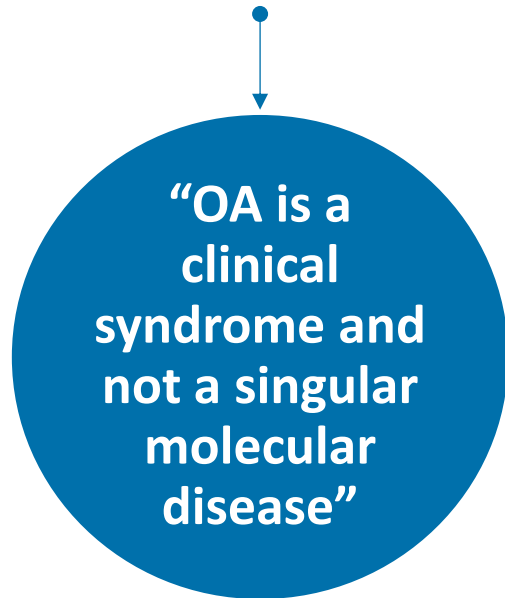
¹ Global, regional prevalence, incidence and risk factors of knee osteoarthritis in population-based studies, A. Cui et al. / EClinicalMedicine 2930 (2020) 100587

ENX-CL-05-001 PHASE I/IIa

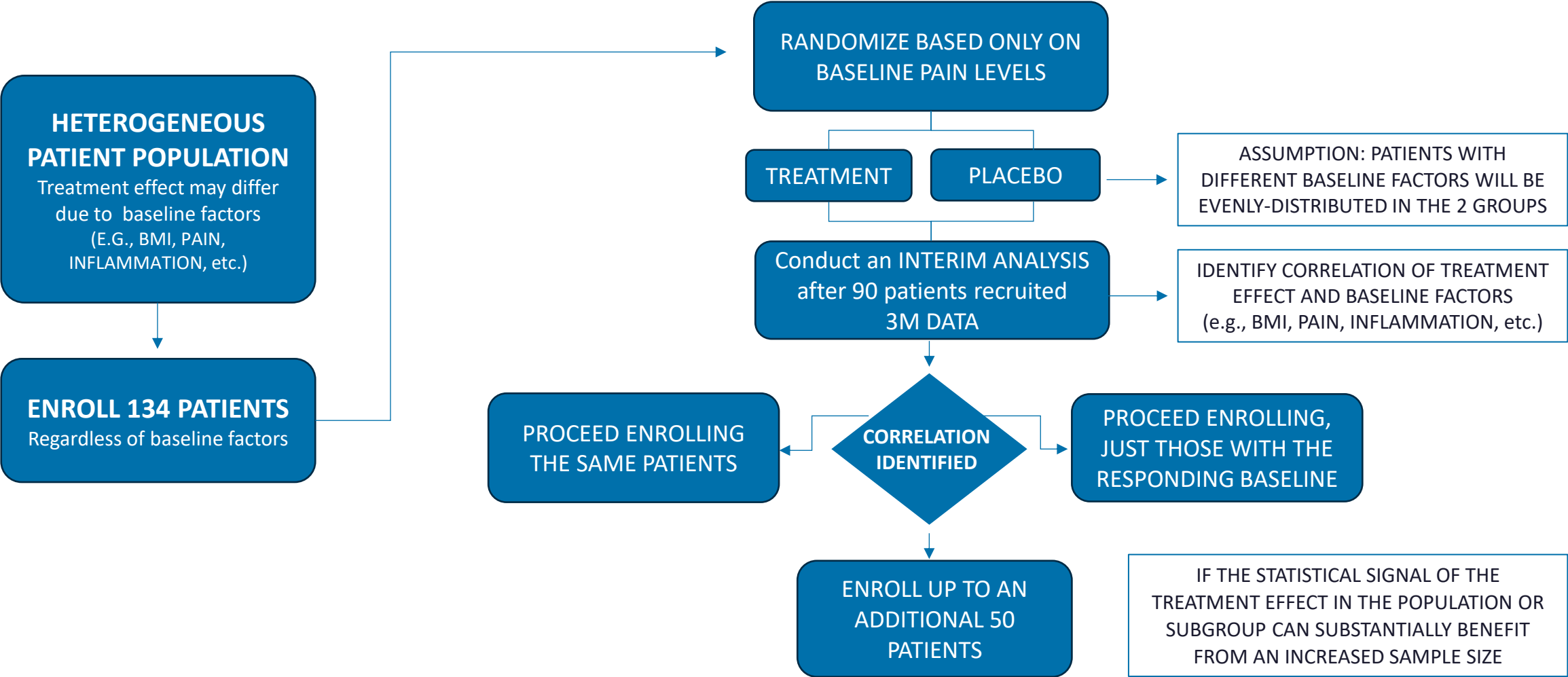
**MULTI-COUNTRY, MULTI-CENTER,
RANDOMIZED, DOUBLE-BLIND, CONTROLLED
TRIAL EVALUATING ALLOCETRA™ IN PATIENTS
WITH MODERATE TO SEVERE KNEE
OSTEOARTHRITIS**

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 – INDEPENDENT, OUTSOURCED INTERIM ANALYSIS AFTER 90 PATIENTS TO IDENTIFY THE RESPONDER SUB-POPULATION



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



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

WELL-BALANCED BASELINE DEMOGRAPHICS & CHARACTERISTICS

ALL RANDOMIZED & TREATED	Allocetra (N=67)	Placebo (N=67)
Age (years)		
Mean (SD)	60.72 (8.31)	61.54 (8.26)
Median (Q1, Q3)	60.00 (54.00, 66.50)	61.00 (55.50, 67.00)
Min - Max	46.00 - 80.00	46.00 - 80.00
Sex		
Female	36 (53.7%)	37 (55.2%)
Male	31 (46.3%)	30 (44.8%)
BMI at baseline		
Mean (SD)	28.79 (3.89)	29.93 (4.29)
Median (Q1, Q3)	28.60 (26.40, 30.65)	29.80 (26.60, 32.30)
Min - Max	19.40 - 39.30	22.20 - 39.70
Target knee		
Left	29 (43.3%)	30 (44.8%)
Right	38 (56.7%)	37 (55.2%)
Kellgren-Lawrence grade (target knee)		
Grade 2	23 (34.3%)	28 (41.8%)
Grade 3	44 (65.7%)	39 (58.2%)
Country		
Denmark	47 (70.1%)	46 (68.7%)
Israel	10 (14.9%)	7 (10.4%)
Moldova	10 (14.9%)	14 (20.9%)

	Allocetra (N=67)	Placebo (N=67)
WOMAC pain score at baseline		
Mean (SD)	26.67 (7.20)	26.42 (9.40)
Median (Q1, Q3)	26.00 (22.00, 32.50)	27.00 (23.00, 32.00)
Min - Max	9.00 - 40.00	2.00 - 43.00
Pain medication tablets during baseline		
Mean (SD)	1.85 (4.27)	3.28 (9.01)
Median (Q1, Q3)	0.00 (0.00, 2.00)	0.00 (0.00, 2.00)
Min - Max	0.00 - 20.00	0.00 - 42.00
Baseline NRS pain (target knee)		
Mean (SD)	6.19 (0.94)	6.16 (0.95)
Median (Q1, Q3)	6.20 (5.43, 6.77)	6.00 (5.43, 6.86)
Min - Max	4.57 - 8.14	4.71 - 8.43
Baseline NRS pain (contralateral knee)		
Mean (SD)	2.37 (1.41)	2.44 (1.42)
Median (Q1, Q3)	2.50 (1.43, 3.38)	2.43 (1.50, 3.62)
Min - Max	0.00 - 5.00	0.00 - 4.71

PRIMARY VS SECONDARY OA: DIFFERENCE IN MEDIATION OF INFLAMMATION

- **Primary OA**

- 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
- This is primarily due to the age-related decline in the quality and quantity of chondrocytes, the cells responsible for maintaining cartilage integrity
- We defined patients in the age group of ≥ 60 as [Primary OA patients](#)

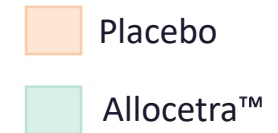
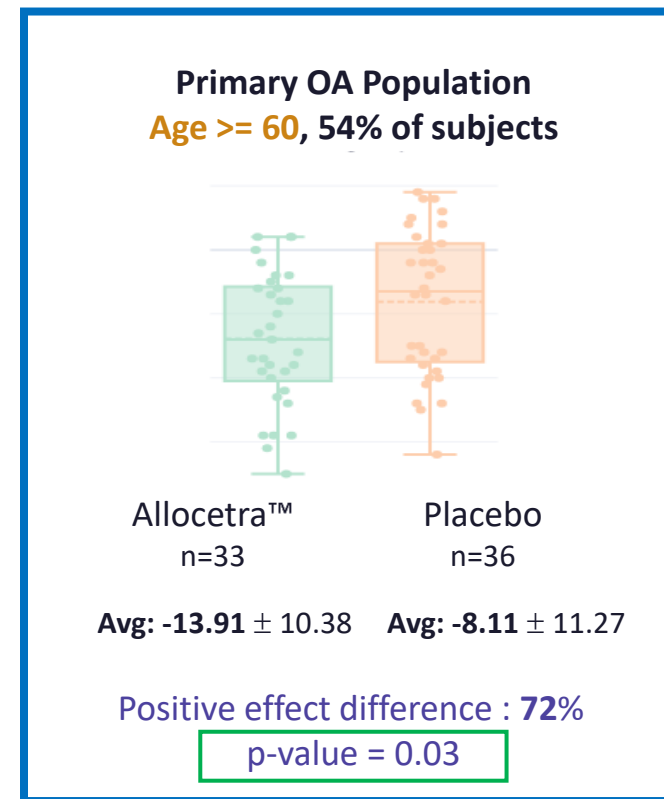
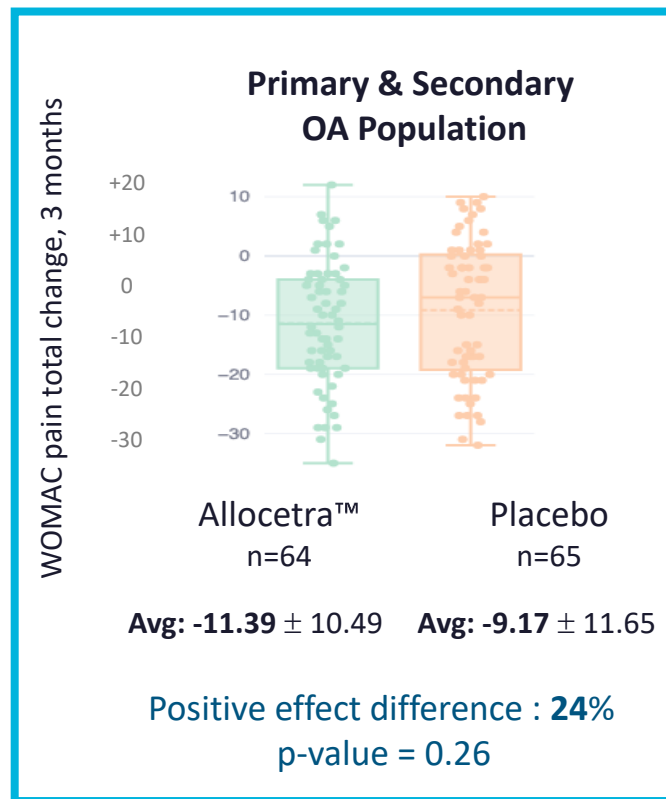
- **Secondary OA**

- Joint trauma with incomplete repair or other conditions such as chronic misalignment of the joint, characterize younger patients, with average onset in the 30s–40s and symptoms by 40s–50s. Secondary OA presents additional mechanisms that include chronic immune response in the joint that is different from the classical low-grade inflammation seen in primary OA, driven by accumulation of circulating monocytes, T cells, neutrophils, and complement activation
- We defined patients in the age group of < 60 as [Secondary OA patients](#)

- Muthu S, et al. Failure of cartilage regeneration: emerging hypotheses and related therapeutic strategies. *Nat Rev Rheumatol.* 2023;19(7):403–416.
- Matthew J. Wood. Macrophage proliferation distinguishes 2 subgroups of knee osteoarthritis patients. *Osteoarthritis and Cartilage* 27 (2019)
- K. McCulloch. Accelerated post traumatic osteoarthritis in a dual injury murine model

24% POSITIVE EFFECT ON WOMAC PAIN ACROSS STUDY PATIENTS; 72% IN 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™ (pain reduction, the FDA's chosen Phase III endpoint) in Primary OA vs placebo, and reduced effect of Allocetra™ in Secondary OA



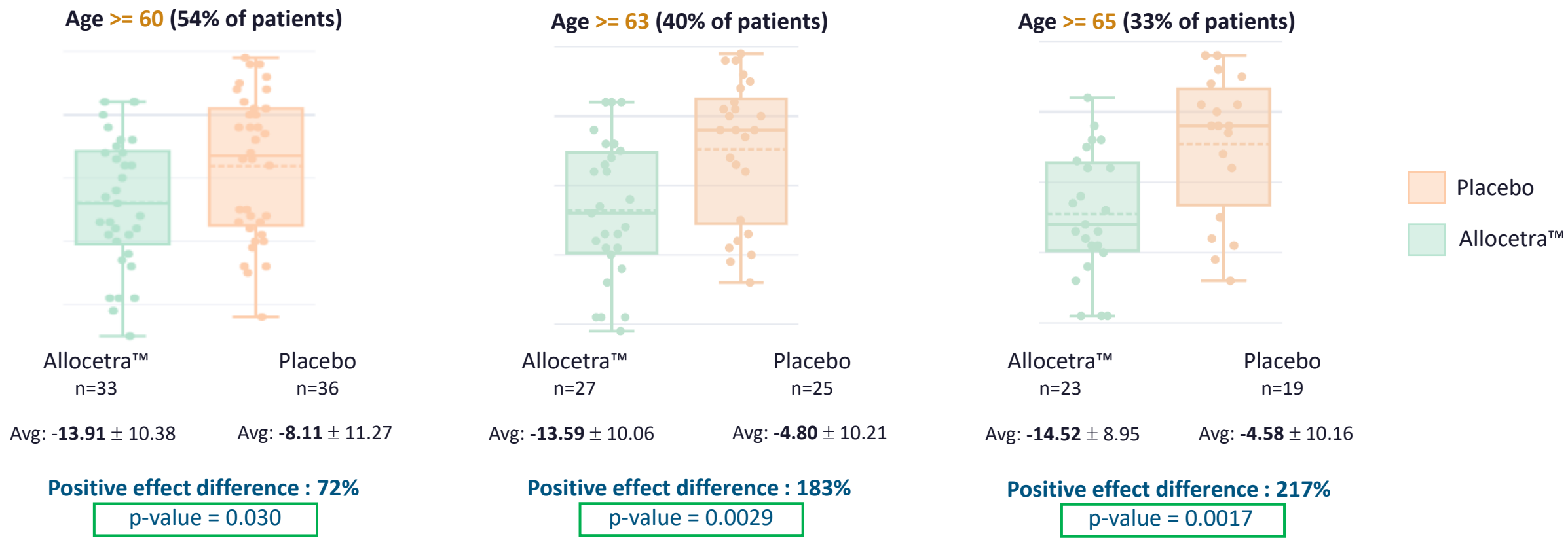
CLINICALLY MEANINGFUL, STATISTICALLY SIGNIFICANT **ACROSS EFFICACY ENDPOINTS** IN PRIMARY OSTEOARTHRITIS PATIENTS

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	Delta between groups expressed as % from FDA's threshold for clinical significance (-10% to -15%)
Phase III primary endpoint →	WOMAC total change	-63.42 (n=33)	-33.00 (n=36)	-30.42	92%	0.012	-48%	
	WOMAC pain change	-13.91 (n=33)	-8.11 (n=36)	-5.80	72%	0.030	-49%	-65%
	WOMAC function change	-44.97 (n=33)	-21.47 (n=36)	-23.50	109%	0.007	-50%	
Phase III primary endpoint →	WOMAC pain & function change	-58.88 (n=33)	-29.58 (n=36)	-29.30	99%	0.008	-49%	-90%
	WOMAC stiffness & function change	-49.52 (n=33)	-24.89 (n=36)	-24.63	99%	0.013	-47%	
	NRS pain change	-3.04 (n=34)	-2.06 (n=37)	-0.98	48%	0.070	-49%	

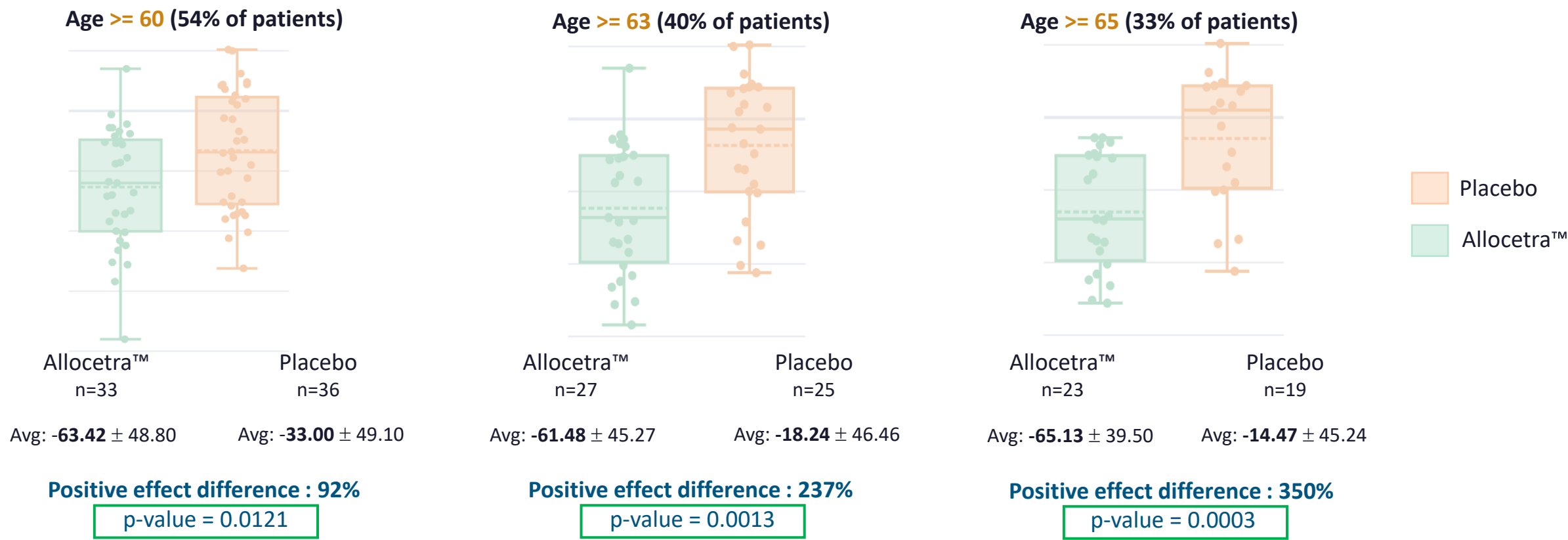
ALLOCETRA™ EFFECT IN PRIMARY OA: CLINICALLY MEANINGFUL, STATISTICALLY SIGNIFICANT, IRRESPECTIVE OF AGE THRESHOLD (REDUCTION IN PAIN)

WOMAC pain change 3 months, Primary OA population



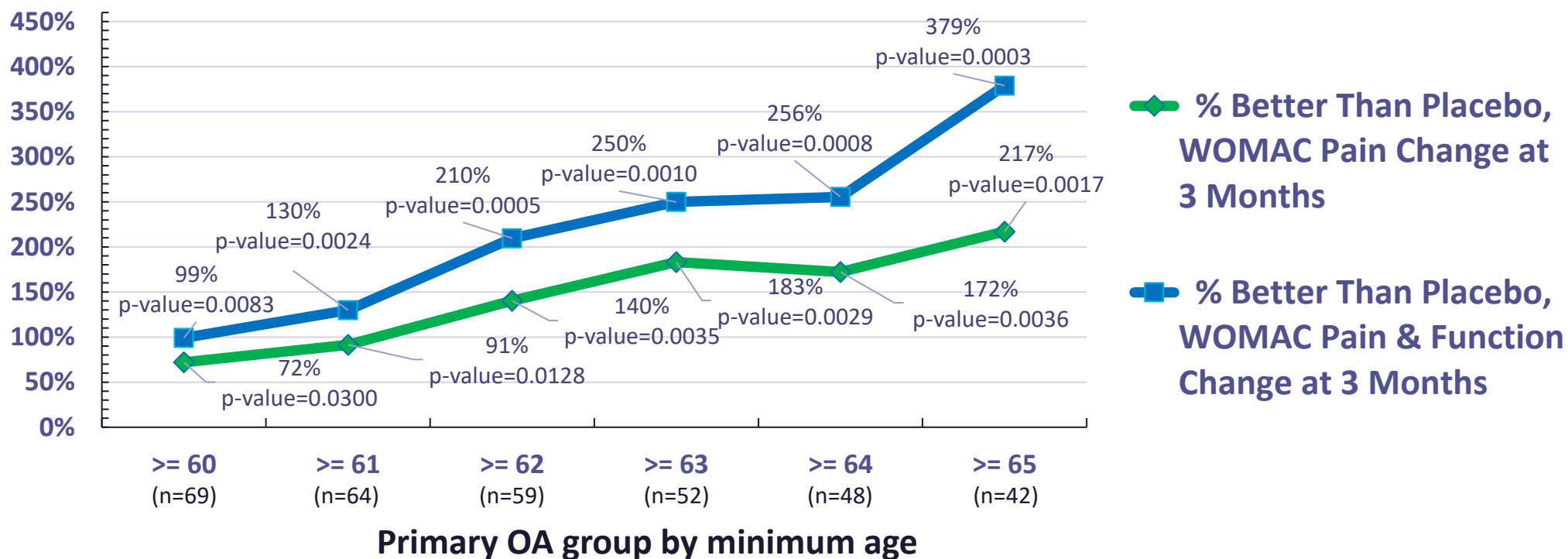
ALLOCETRA™ EFFECT IN PRIMARY OA: CLINICALLY MEANINGFUL, STATISTICALLY SIGNIFICANT, IRRESPECTIVE OF AGE THRESHOLD (CHANGE IN PAIN, STIFFNESS & FUNCTION)

WOMAC total change 3 months, Primary OA population



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

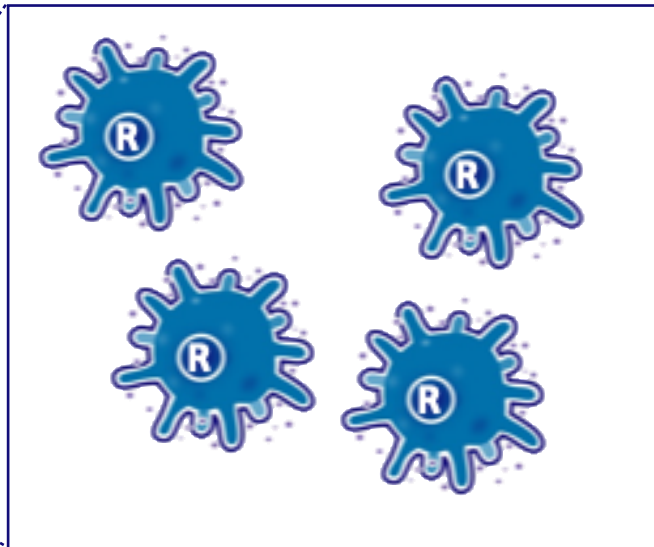
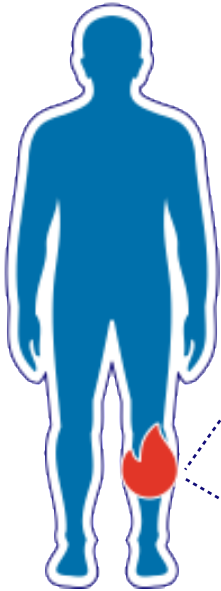
% Excess reduction of pain, pain & function in Allocetra™ group
vs reduction in the placebo group



SUPERIOR ACTIVITY IN PRIMARY OA CONSISTENT WITH THE PROPOSED MECHANISM OF ACTION OF ALLOCETRA™

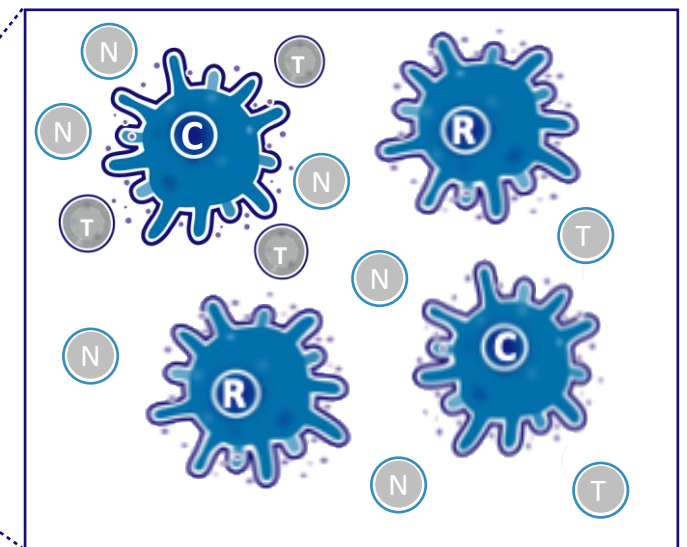
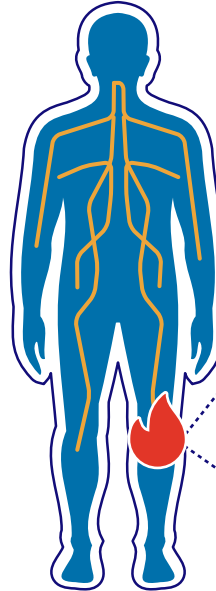
Primary Osteoarthritis

Inflammation-mediation
via **resident macrophages**



Secondary Osteoarthritis

Inflammation-mediation
via **multiple cell types**



Resident macrophage,
interacts well with Allocetra™



Circulating macrophage, may **interact differently** with Allocetra™



Neutrophil cell



T-cell

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

ENX-CL-05-001: PLANNED 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

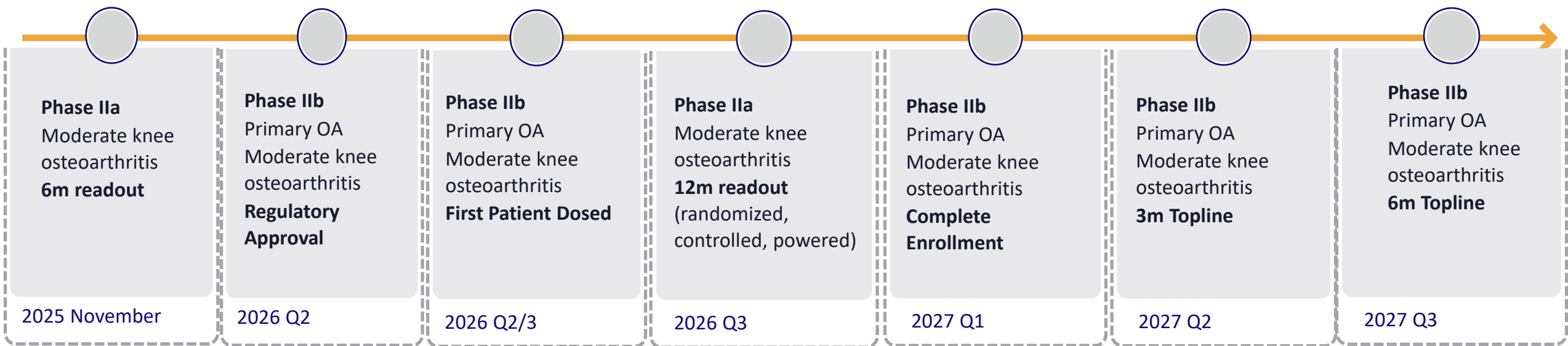


Secondary:

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

SHORT AND LONG TERM TARGET MILESTONES



Initiation and potential finalization of partnership discussions

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

THANK YOU