ENLIVEX
CLINICAL DEVELOPMENT

November 2025

Nasdaq: **ENLV**

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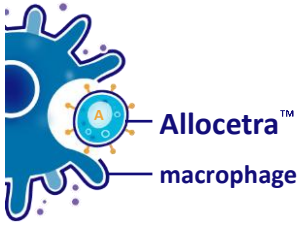
MACROPHAGE MODULATION FOR THE TREATMENT OF INFLAMMATORY DISEASES

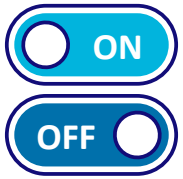
Enlivex is a clinical stage pharmaceutical company developing Allocetra™, a universal, off-the-shelf cell therapy designed to reprogram macrophages into their homeostatic state, for treatment of inflammatory diseases.

About:



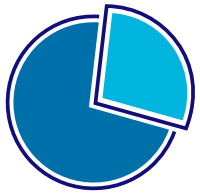
Novel therapeutic modality:

macrophage modulation.



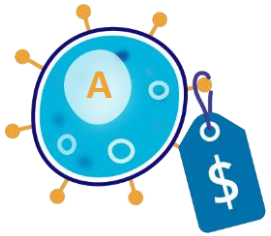
Novel approach:

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.

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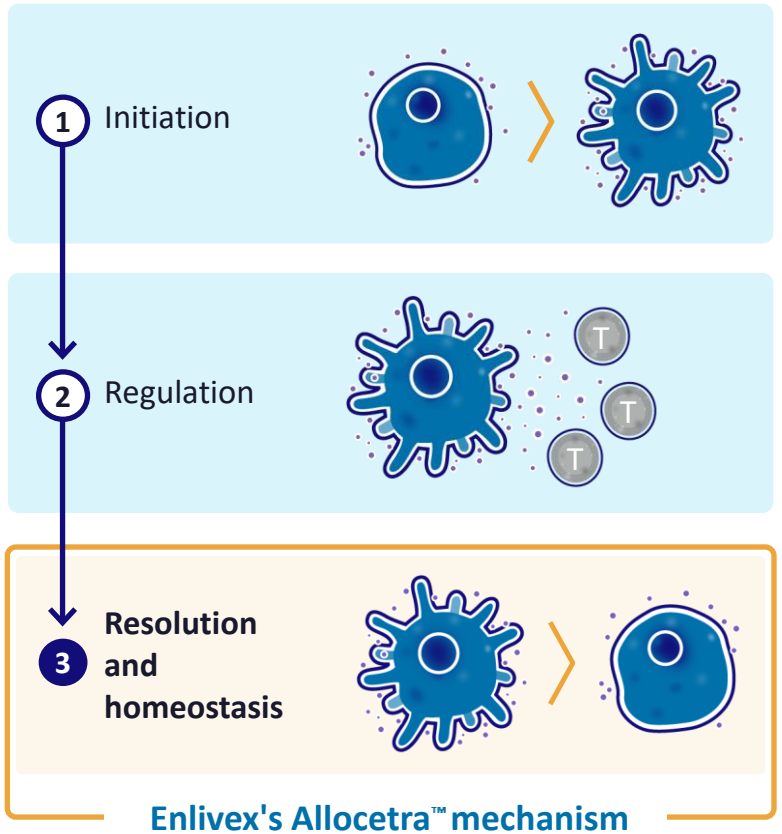
CELLULAR FIRST RESPONDERS: MACROPHAGES AND THEIR CRITICAL ROLE IN INFLAMMATION

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

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.

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PROMOTING BALANCE: APOPTOTIC CELLS FACILITATE MACROPHAGE HOMEOSTASIS

Prof. Dror Mevorach
Scientific Founder

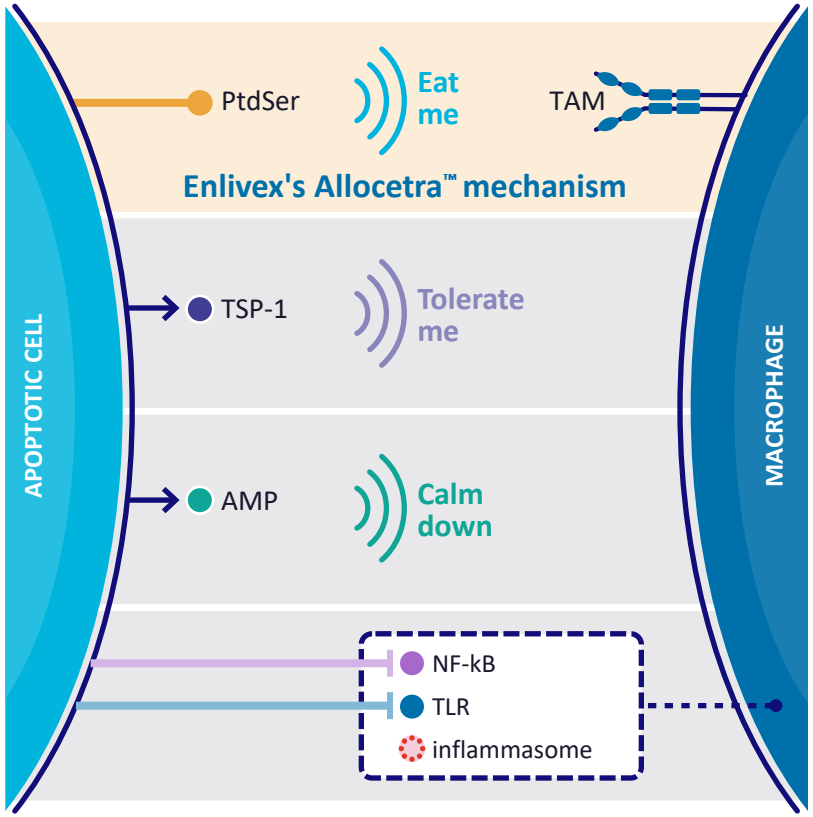
Apoptotic Cells Induce NF-kB and Inflammasome Negative Signaling
Amir Grau, Adi Tabib, Inna Grau, Inna Reiner, Dror Mevorach

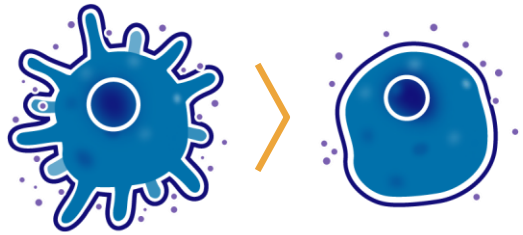
PLOS One, 2015

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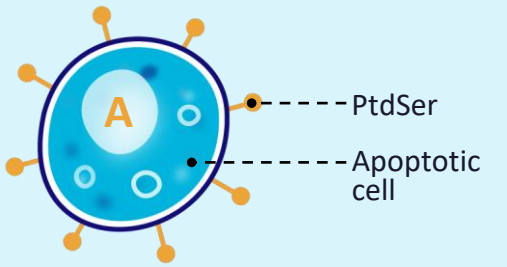
ALLOCETRA™: AN OFF THE SHELF CELL THERAPY DESIGNED TO RESTORE MACROPHAGE HOMEOSTASIS

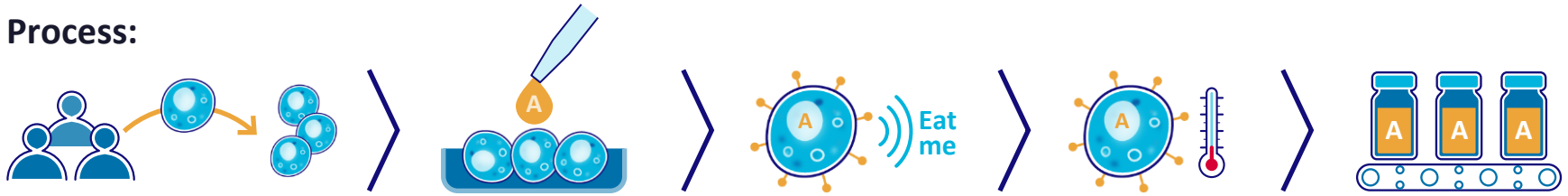


Allocetra™

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

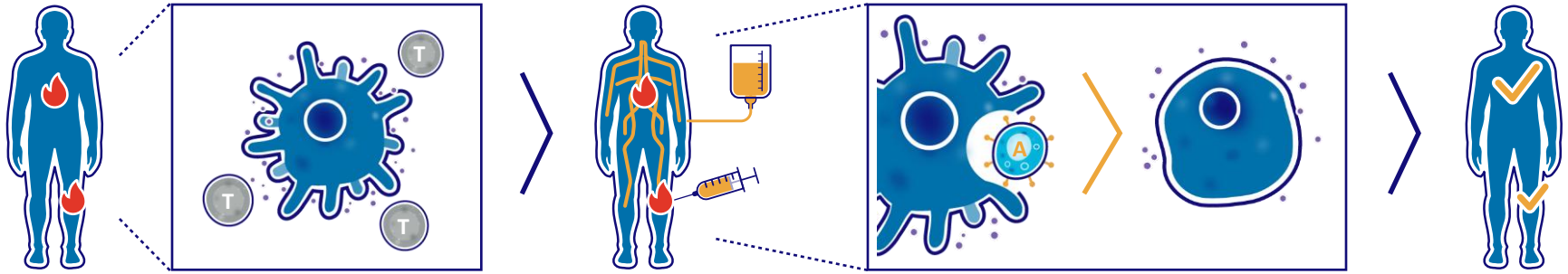
proprietary apoptotic cell modification process

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

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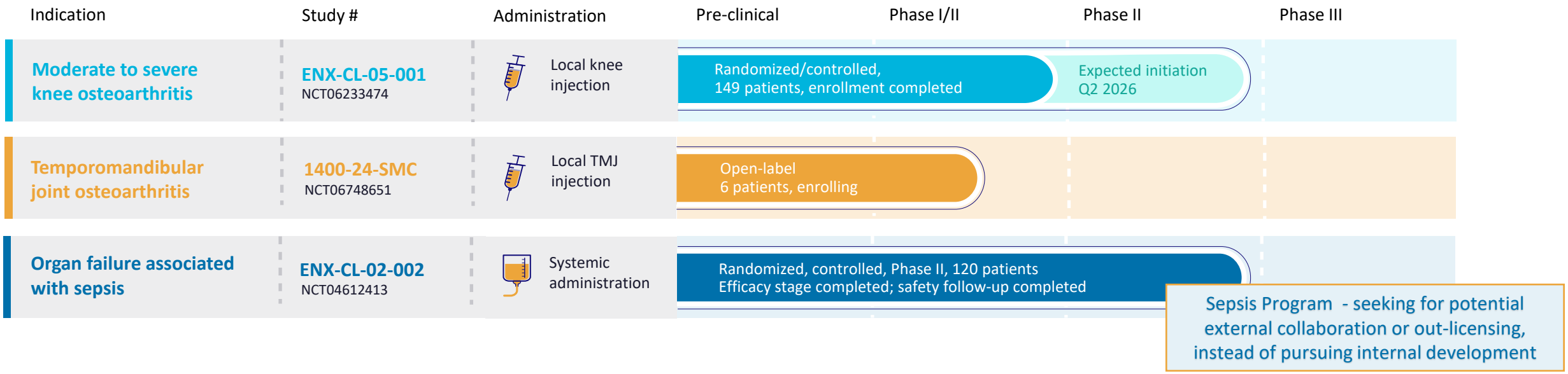
ALLOCETRA™ CURRENT PIPELINE: BUILDING MOMENTUM



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ALLOCETRA™
FOR THE TREATMENT OF
OSTEOARTHRITIS

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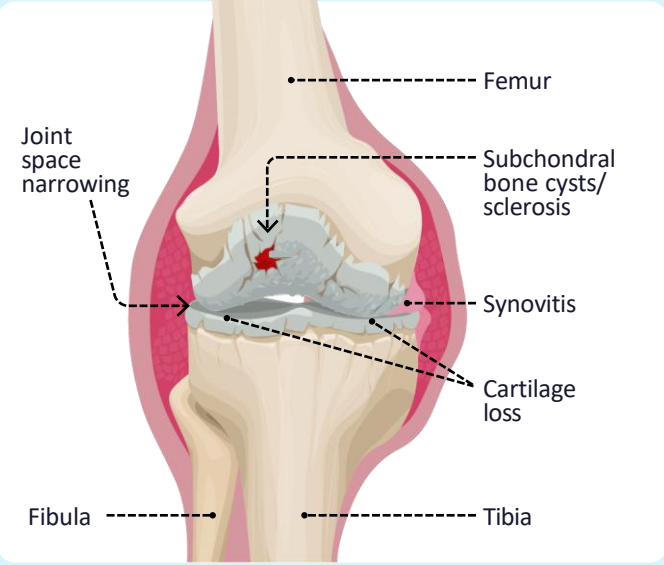
OSTEOARTHRITIS: A GROWING MARKET WITH SIGNIFICANT POTENTIAL

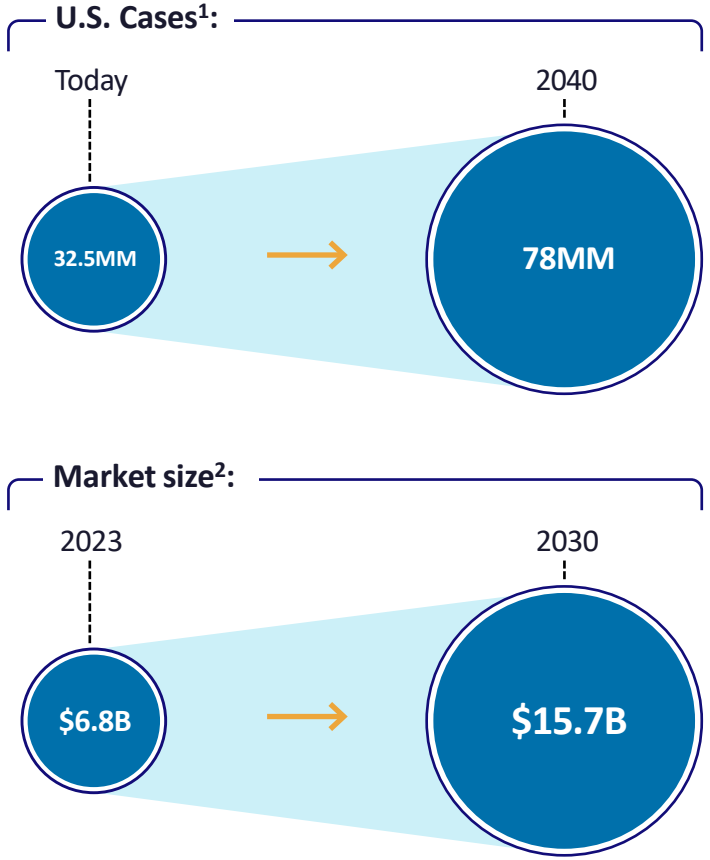
Disease overview



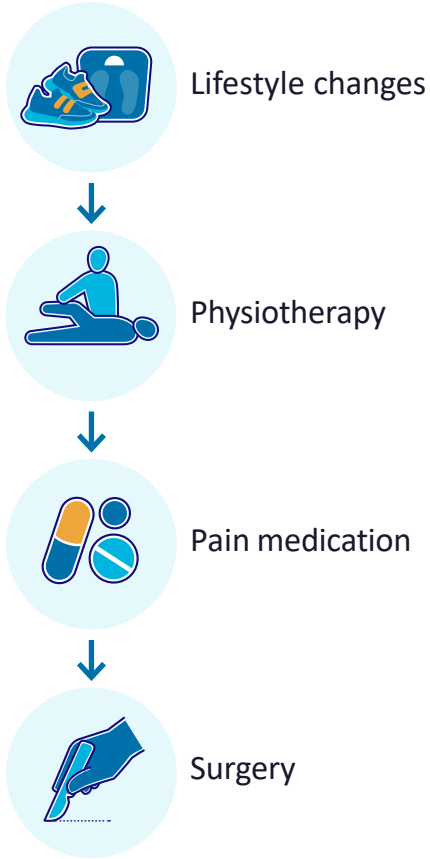
Disease manifestation:

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.

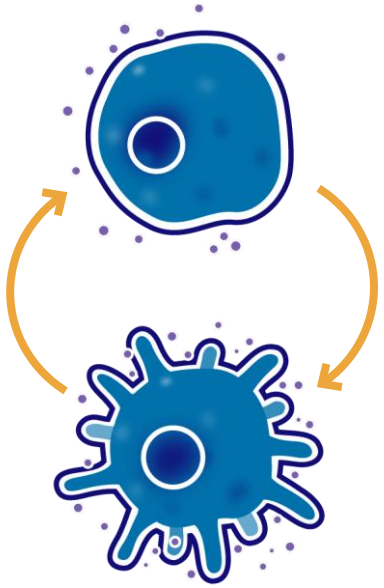
Eric W. Orlowsky and Virginia Byers Kraus

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?

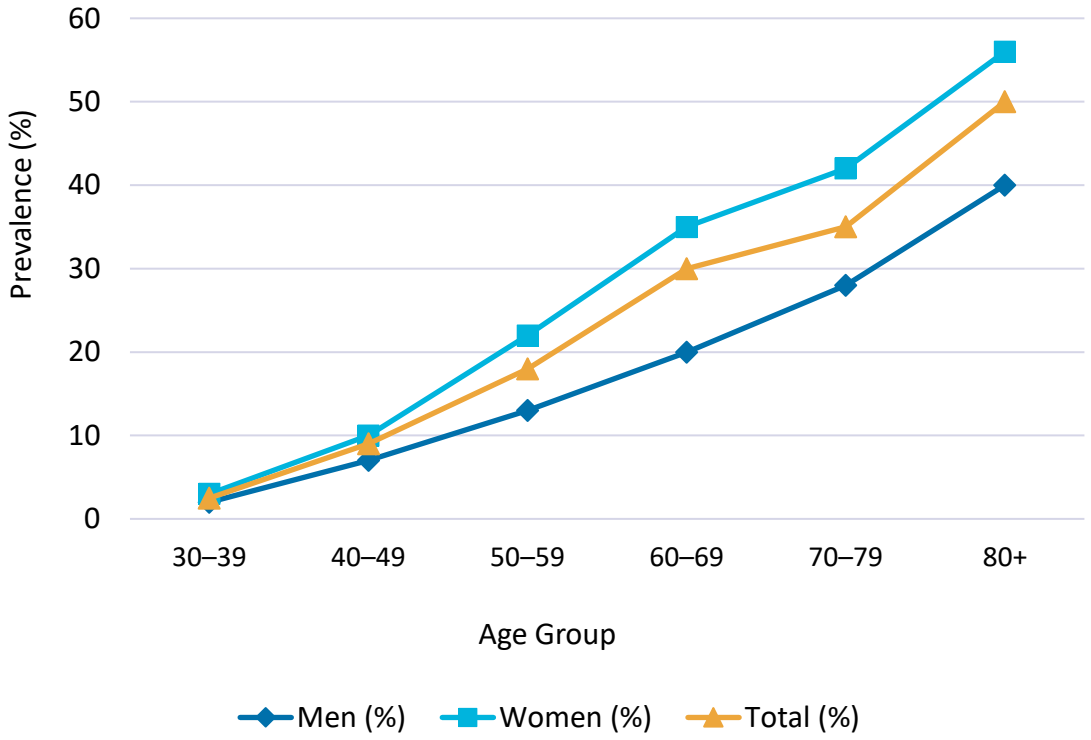
Amanda Thomson and Catharien M. U. Hilkens

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

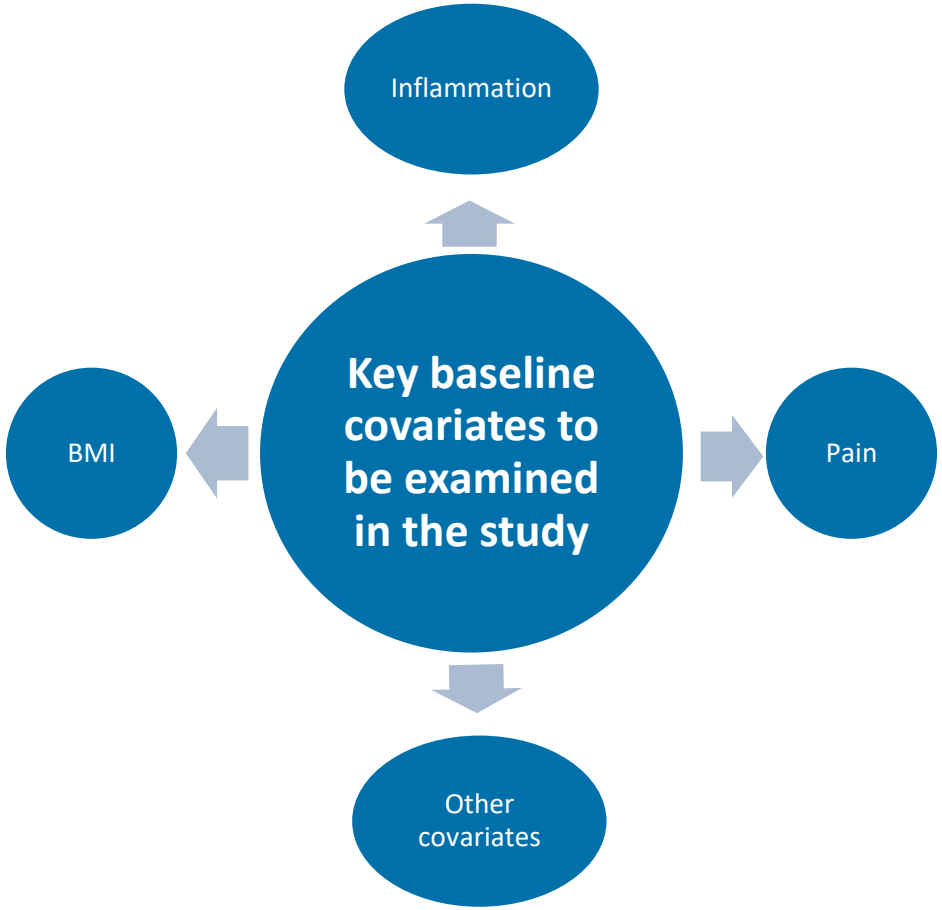
“OA is a clinical syndrome and not a singular molecular disease”

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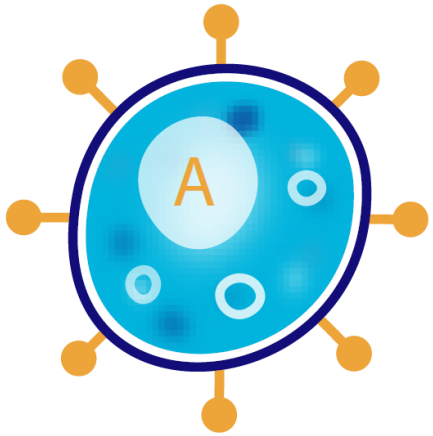
ENX-CL-05-001 – PHASE IIa OBJECTIVES MET:

(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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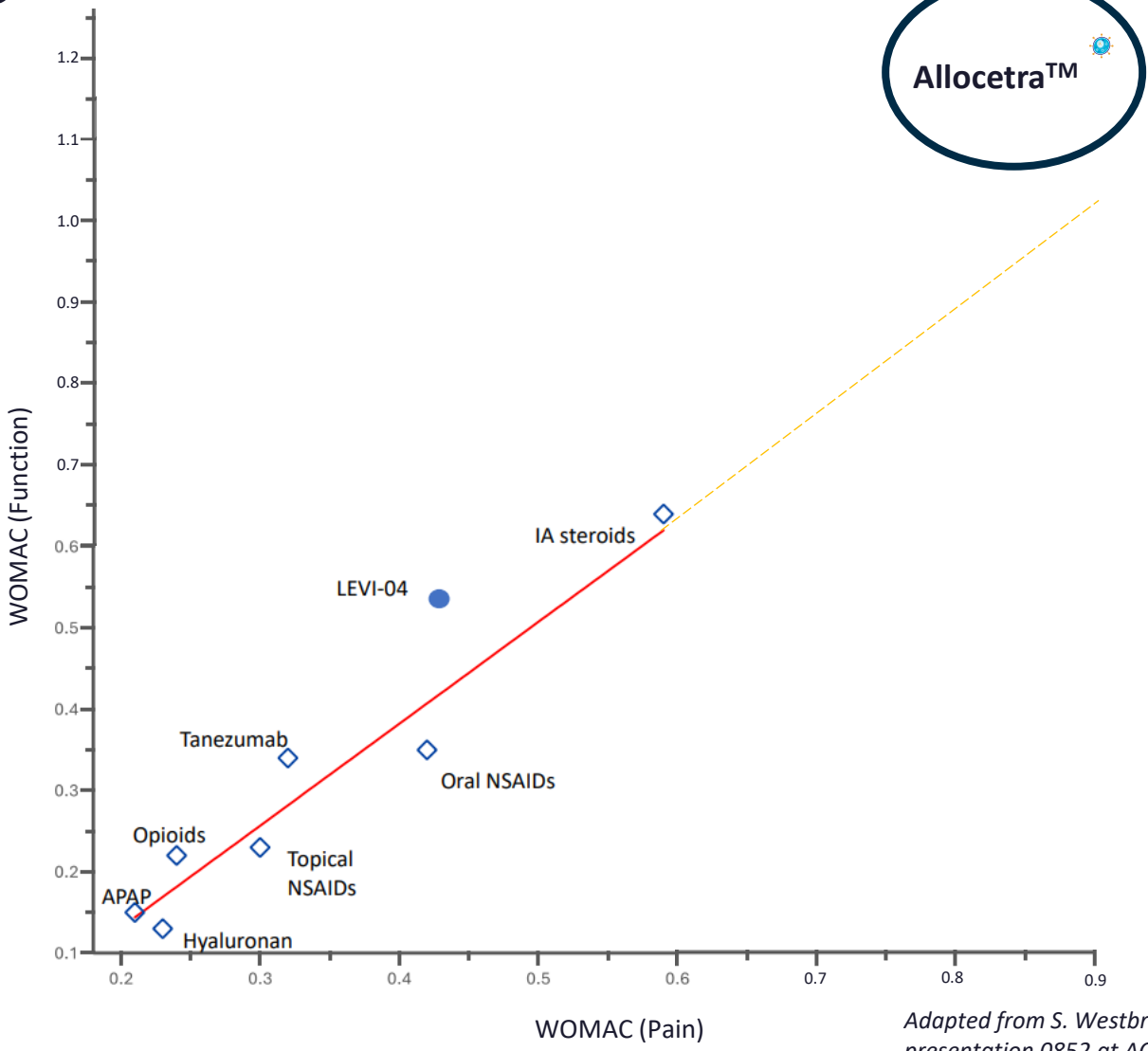
COMPETITIVE COMPARISON OF STANDARDIZED EFFECT SIZES

	Standardized Effect Size		
Efficacy Endpoint	**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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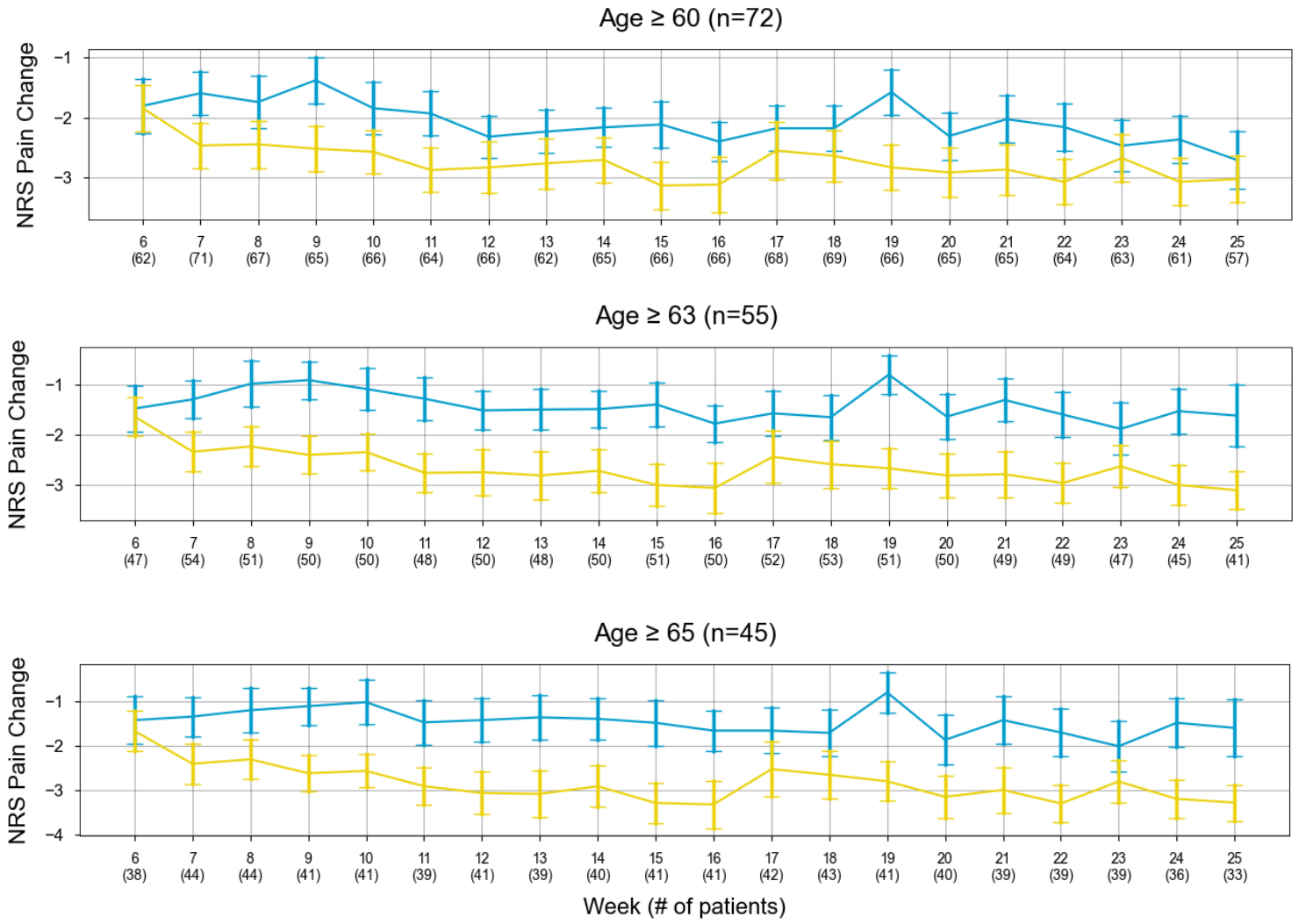
PAIN NRS WEEKLY CHANGE OVER TIME

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)

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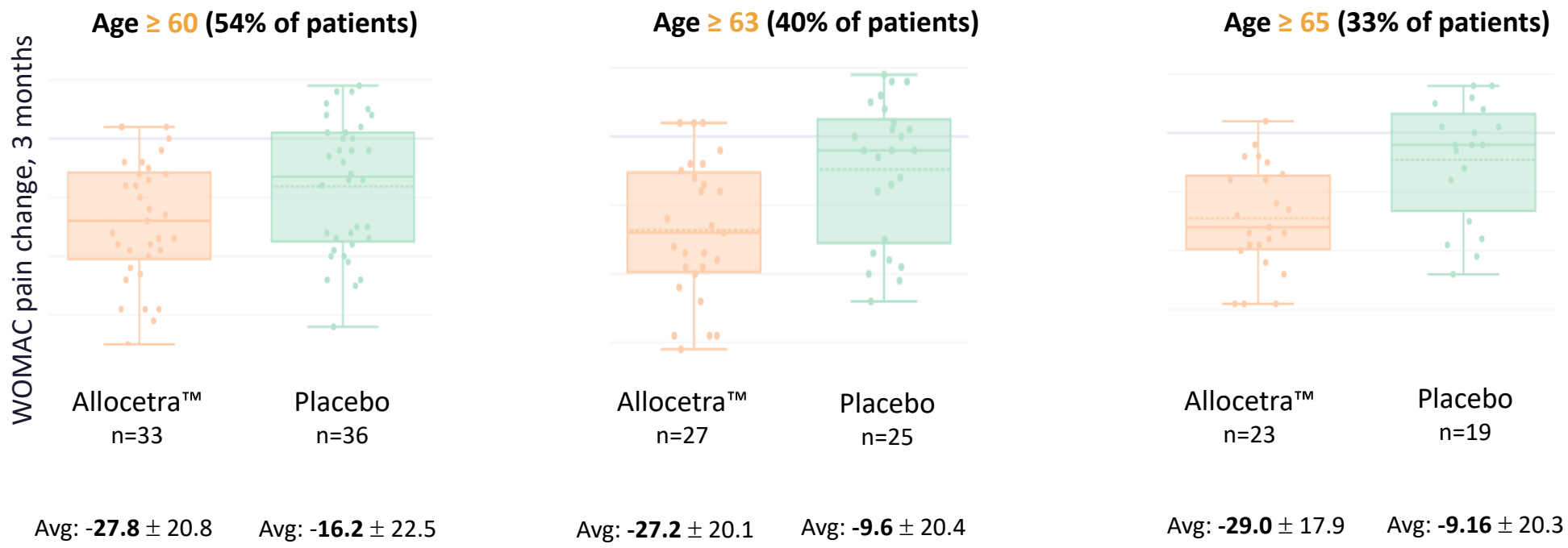
ALLOCETRA™ EFFECT IN PRIMARY OA: CLINICALLY MEANINGFUL, STATISTICALLY SIGNIFICANT, TRENDING WITH AGE (REDUCTION IN PAIN)

WOMAC pain change 3 months, Primary OA population



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

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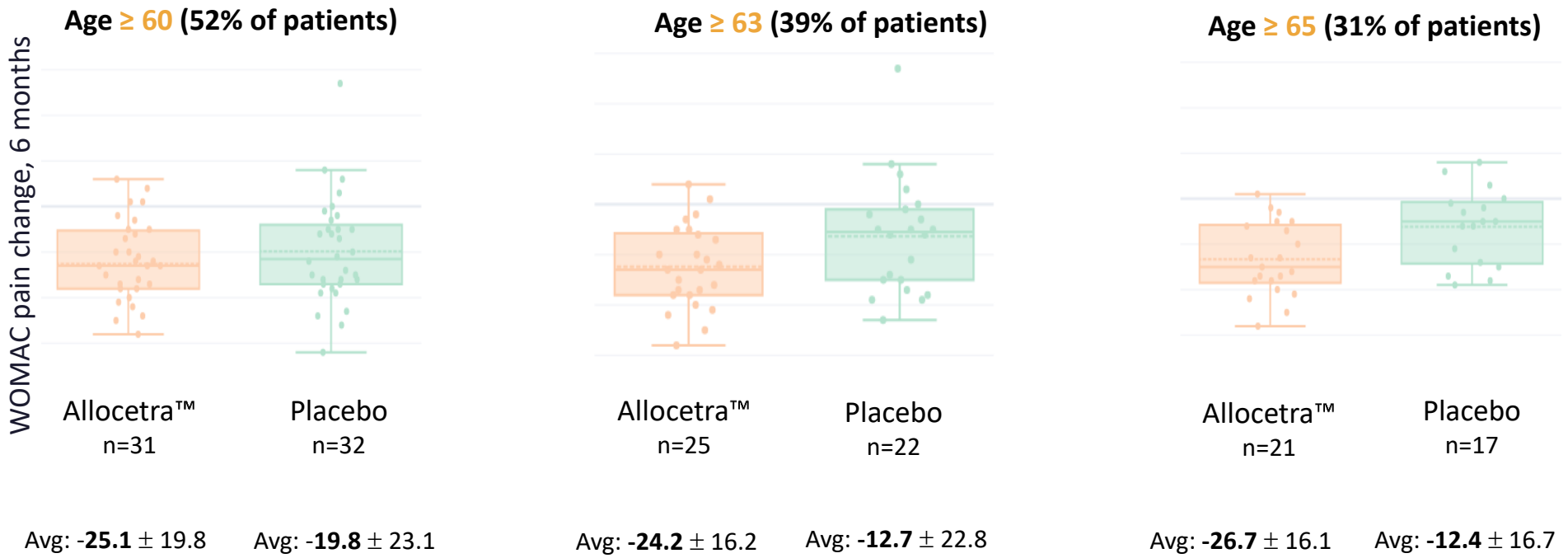
ALLOCETRA™ EFFECT IN PRIMARY OA: CLINICALLY MEANINGFUL, STATISTICALLY SIGNIFICANT, TRENDING WITH AGE (REDUCTION IN PAIN)

WOMAC pain change 6 months, Primary OA population



Allocetra™

Placebo

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

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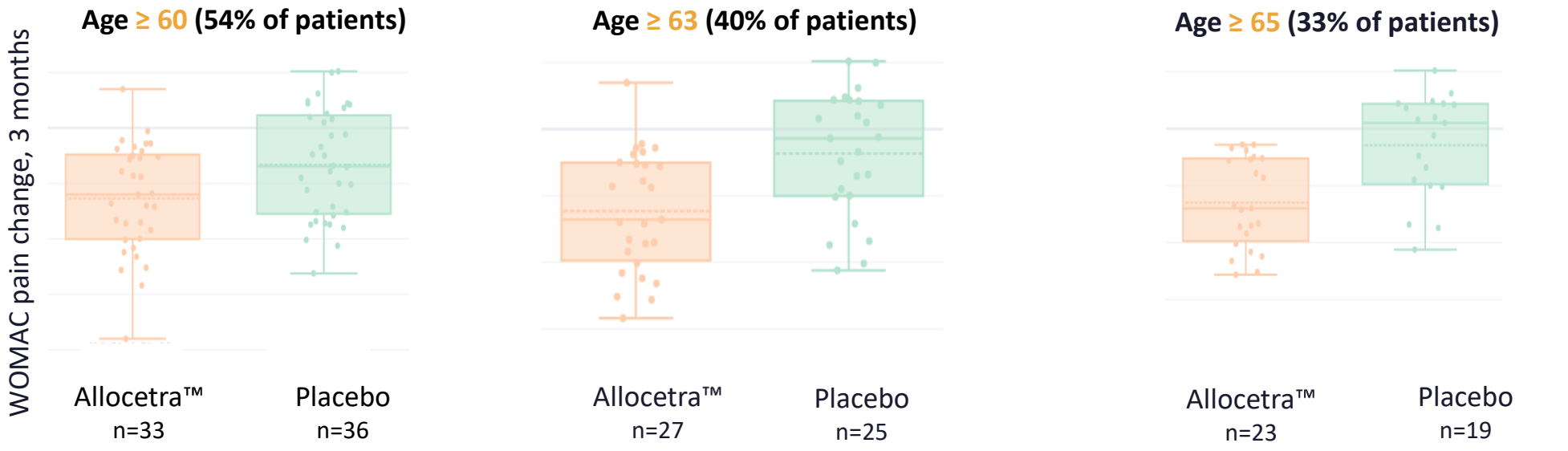
ALLOCETRA™ EFFECT IN PRIMARY OA: CLINICALLY MEANINGFUL, STATISTICALLY SIGNIFICANT, TRENDING WITH AGE (REDUCTION IN PAIN & STIFFNESS, AND INCREASE IN FUNCTION)

WOMAC total change 3 months, Primary OA population



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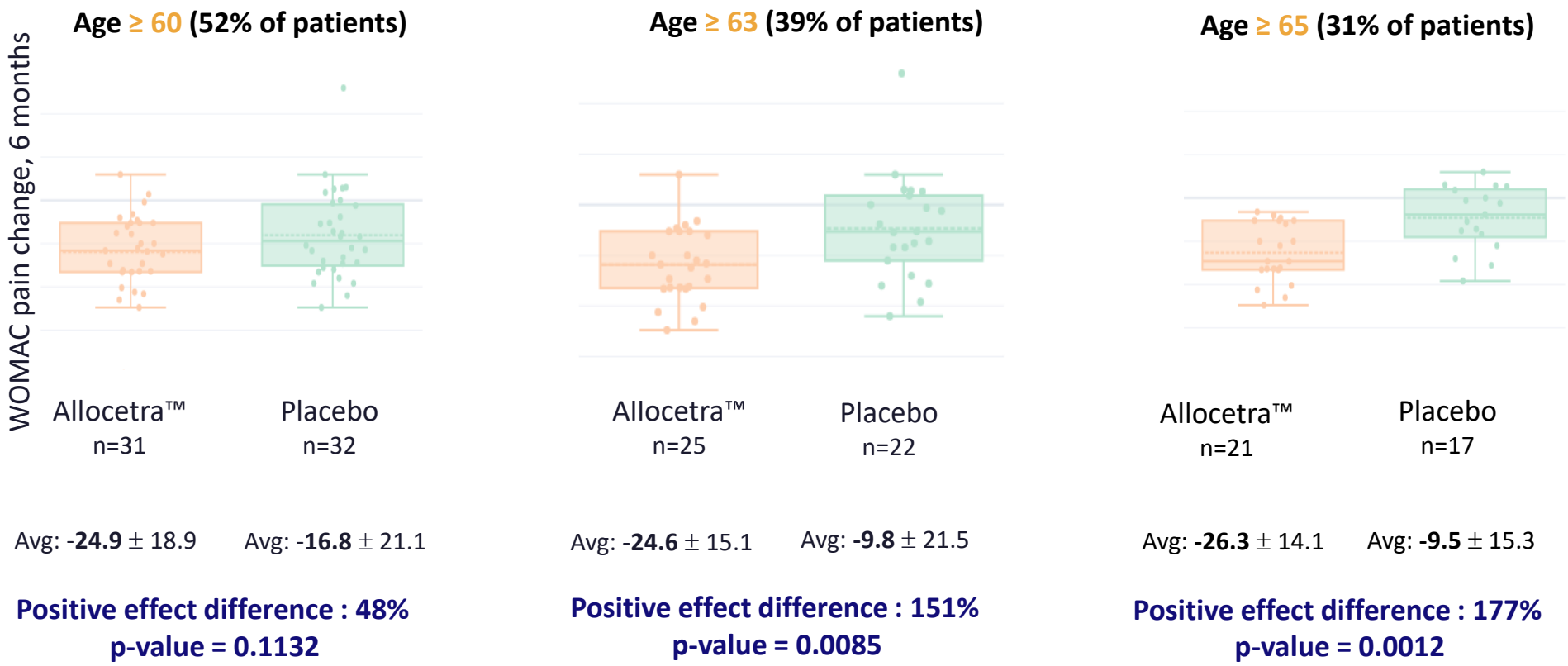
ENLIVEX

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

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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

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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

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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

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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

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EXTENSIVE IP PROTECTION

11 Patents — USA

22 Patents

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

Expected protection up to

2043

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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