Enlivex Announces Favorable 12-Month Topline Data from Phase I/IIa Allocetra Trial, Demonstrating Durable Treatment Response

- In patients aged 64+: 79.2% of patients achieved a clinically meaningful response (reduced pain and improved knee function) in the Allocetra™ group vs. 47.6% in the placebo group at 12 months (p=0.027)[1]
- Allocetra™ treatment benefit at 12 months was consistent with the response rates observed at 3 and 6 months, demonstrating a durable effect from a single treatment cycle

- The 12-month data will be presented at the American College of Rheumatology (ACR) Convergence in a poster presentation on November 8, 2026

Nes-Ziona, Israel, Nov. 02, 2026 (GLOBE NEWSWIRE) -- Enlivex Ltd. (Nasdaq: ENLV) ("Enlivex" or the "Company"), a quality longevity company powered by a prediction markets treasury, today announced favorable 12-month topline data from the randomized, double-blind, placebo-controlled Phase IIa stage of the Company's multi-country Phase I/IIa trial (ENX-CL-05-001) evaluating Allocetra™ in patients with moderate to severe knee osteoarthritis. With 12-month follow-up now complete, the data show that a single three-injection treatment cycle of Allocetra™ produced a sustained treatment response through one year in patients with primary age-related knee osteoarthritis, the population being evaluated in the Company's ongoing Phase IIb trial. The one-year safety and efficacy results have been selected for a poster presentation at the American College of Rheumatology (ACR) Convergence 2026 (details below).

Summary of the 12-month Topline Data, Age Group 64+

- **Sustained responder benefit at one year:** The proportion of patients (age 64+) achieving a clinically meaningful response[2] (reduced pain and increased knee function) was 66% higher for the Allocetra™ group than for the placebo group at 12 months, consistent with the treatment benefit observed at the earlier 3- and 6-month timepoints:
  - At 12 months: 79.2% responders in the Allocetra™ group vs. 47.6% in the placebo group (p=0.027)
  - This substantial treatment benefit was consistent with the response rates observed at 3 months (80% higher for the Allocetra™ group than for the placebo group; p=0.019) and 6 months (39% higher for the Allocetra™ group than for the placebo group; p=0.168).
- **Improvement in pain and function maintained through 12 months:** Allocetra™ produced statistically significant and clinically meaningful improvements versus placebo at 3 and 6 months. At 12 months, treatment differences continued to favor Allocetra™ and were reasonably maintained throughout one year (scale 0-100; difference vs. placebo in change from baseline), in the 64+ age group:
  - WOMAC[3] pain: -17.5 points at 3 months (p=0.004), -15.4 points at 6 months (p=0.012), and -12.2 points at 12 months (p=0.113)
  - WOMAC function: -19.3 points at 3 months (p=0.0008), -19.5 points at 6 months (p=0.0008), and -13.1 points at 12 months (p=0.067)
- **Consistent age-related effect:** Across analyses, patient age was the strongest predictor of treatment response, with the treatment effect increasing with age. Improvements in patient-reported outcomes were supported by objective physical performance tests and by exploratory serum biomarker and imaging analyses consistent with Allocetra™'s proposed macrophage-reprogramming mechanism of action.
- **Favorable safety profile through 12 months:** No treatment-related serious adverse events were observed. Adverse events were predominantly transient, mild to moderate local knee reactions, consistent with previously reported data.

12-month data presentation at the ACR convergence

ACR Convergence 2026 is taking place November 6-11, 2026 at the Orange County Convention Center in Orlando,

Florida.

The poster will be presented by Prof. Philip Conaghan, Consultant Rheumatologist and Director of the NIHR Leeds Biomedical Research Centre. Prof. Conaghan is an international leader in osteoarthritis and musculoskeletal imaging who has authored more than 700 publications and chaired multiple global guideline and clinical trial initiatives.

Poster Presentation

- **Title:** *Durable Clinical Efficacy of an Innovative Intra-Articular Apoptotic Cell Therapy in Knee Osteoarthritis: Age-Related Effect Through One Year*
- **Abstract ID:** 24454477
- **Session:** Poster Session A (0632-0644): Osteoarthritis - Clinical Poster A
- **Date & Time:** November 8, 2026 | 10:30 AM - 12:30 PM ET

"The 12-month results show that a single treatment cycle of Allocetra™ delivered a clinically meaningful benefit in older patients with knee osteoarthritis that was sustained through one year. In a disease with no approved disease-modifying therapies, where treatment is largely limited to symptom management or surgery, a durable response from a single treatment cycle could offer a differentiated profile for patients, physicians and payers. We are pleased that these data were selected for presentation at ACR Convergence 2026, and we look forward to topline data from our Phase IIb trial, which is enrolling this same population, by the end of the second quarter of 2027," said Dr. Oren Hershkovitz, Chief Executive Officer of Enlivex.

About ENX-CL-05-001

ENX-CL-05-001 is a multi-center Phase I/IIa clinical trial consisting 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 for the subsequent Phase IIa stage. The Phase IIa stage was a double-blind, randomized, placebo-controlled multi-centered trial where 134 patients were randomized and treated.

About Knee Osteoarthritis

Osteoarthritis (OA) is one of the most prevalent and disabling diseases worldwide, affecting more than 32 million Americans today and projected to continue and grow substantially, with knee OA (KOA) being the most prevalent form. There are currently no approved disease-modifying therapies; treatment is largely limited to pain relief, intra-articular steroids, or surgery, and the burden increases sharply with age. By age 60, KOA affects roughly 30% of the population, and about half of KOA patients are 60 years of age or older. This demographic is expanding with global aging trends, underscoring the need for new, durable therapies.

About Enlivex

Enlivex is a quality longevity company powered by a prediction markets treasury. The Company is advancing Allocetra™, an advanced clinical-stage immunotherapy targeting inflammatory conditions associated with aging, with a primary focus on age-related osteoarthritis. In addition to its clinical programs, Enlivex operates a prediction markets treasury strategy built around the Rain Protocol, the leading decentralized prediction markets infrastructure on Arbitrum. This dual strategy combines the development of quality longevity therapeutics with exposure to the emerging prediction markets ecosystem.

Forward-looking statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should,"

"would," "could," "intends," "estimates," "suggests," "target," "has the potential to," "goal," and other words of similar meaning, including statements relating to the anticipated benefits of the Company's digital asset treasury strategy; the assets to be held by the Company; the expected future market, price, trading activity, and liquidity of the RAIN token; the impact of expanded exchange listings and increased token liquidity on market participation and accessibility; the potential effects of digital asset liquidity on the liquidity of the Company's ordinary shares; macroeconomic, political, and regulatory conditions surrounding digital assets; the Company's plans for value creation and strategic positioning; market size and growth opportunities; regulatory conditions; competitive position; technological and market trends; future financial condition and performance; expected clinical trial results; market opportunities for the results of current clinical studies and preclinical experiments; and the effectiveness of, and market opportunities for, ALLOCETRA™ programs.

Each forward-looking statement contained in this press release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the risk that results from subgroup analyses and small patient populations, including those described in this press release, may not be replicated in larger trials, including the Company's ongoing Phase IIb trial; the risk that topline data may change following a more comprehensive review of the data; the risk that RMAT designation may not lead to a faster development or regulatory review process and does not increase the likelihood of approval; risks related to the timing, conduct and outcome of clinical trials and regulatory submissions; the risk of failure to realize the anticipated benefits of the Company's digital asset treasury strategy; changes in business, market, financial, political, and regulatory conditions; risks relating to the Company's operations and business, including the highly volatile nature of the price, trading volume, and liquidity of RAIN and other cryptocurrencies; risks associated with digital asset exchange listings, trading venues, and market infrastructure; the risk that the price and liquidity of the Company's ordinary shares may be correlated with the price or liquidity of the digital assets it holds; risks related to increased competition in the industries in which the Company operates; risks relating to significant legal, commercial, regulatory, and technical uncertainty regarding digital assets generally; risks relating to the treatment of crypto assets for U.S. and foreign tax purposes; and those risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission. The forward-looking statements in this press release speak only as of the date of this document, and the Company undertakes no obligation to update or revise any of these statements, except as required by applicable law.

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[1] Summary of the 12-month Topline Data, Age Group 64+

[2] Under the OMERACT-OARSI responder criteria, the established standard for osteoarthritis trials

[3] WOMAC: a widely used, standardized questionnaire to evaluate the condition and quality of life of patients with osteoarthritis of the hip and knee