Enlivex to Align with FDA on Allocetra™ Clinical Path to Potential BLA Submission in Knee Osteoarthritis at First RMAT Meeting

- Type B Initial Comprehensive Multidisciplinary RMAT meeting with the FDA scheduled for December 8, 2026 to align on the Allocetra™ development pathway from the ongoing Phase IIb trial toward a potential Biologics License Application (BLA).
- RMAT designation, supported by statistically significant and clinically meaningful three- and six-month Phase I/IIa data in patients with primary age-related knee osteoarthritis, provides all the benefits of the Fast Track and Breakthrough Therapy designation programs.
- 12-month Phase I/IIa data showed a durable treatment response from a single treatment cycle in patients aged 64+, the target population of the ongoing Phase IIb trial (79.2% vs. 47.6% responders; p=0.027).
- Phase IIb trial progressing toward completion of enrollment following a positive interim DSMB safety review; six-month topline data expected by the end of the second quarter of 2027.

Nes-Ziona, Israel, Nov. 23, 2026 (GLOBE NEWSWIRE) -- Enlivex Ltd. (Nasdaq: ENLV) ("Enlivex" or the "Company"), a quality longevity company powered by a prediction markets treasury, today announced that the U.S. Food and Drug Administration (FDA) has scheduled a Type B Initial Comprehensive Multidisciplinary Regenerative Medicine Advanced Therapy (RMAT) meeting with the Company for December 8, 2026 to align on the clinical development path for Allocetra™ from Phase IIb to a potential BLA submission. The Company is also providing an update on its Allocetra™ knee osteoarthritis (OA) clinical program.

The meeting with the FDA is expected to address the overall development plan for Allocetra™ in patients with moderate-to-severe symptomatic primary age-related knee OA, including the scope and design of the clinical program following the ongoing Phase IIb trial required to support a potential BLA submission." The FDA's Initial Comprehensive Multidisciplinary meeting is a meeting type reserved for products with RMAT or Breakthrough Therapy designation, bringing together the FDA's multidisciplinary review team, including senior managers, to discuss the overall development program. It is the first of the interactions with the FDA available to RMAT-designated products as development progresses toward a potential BLA.

"This meeting is the first formal step in coordinating Allocetra™'s development plan with the FDA under our RMAT designation, and we intend to make full use of the access that designation provides," said Dr. Oren Hershkovitz, Chief Executive Officer of Enlivex. "Our Phase I/IIa data supported RMAT designation, and the 12-month results showed a durable benefit from a single treatment cycle in the same population we are now evaluating in our Phase IIb trial. Aligning with the Agency ahead of the topline readout is an important step on Allocetra™'s regulatory path toward a potential BLA."

Allocetra™ Knee Osteoarthritis Program Update

- **Phase I/IIa three- and six-month data supported RMAT designation.** In the randomized, double-blind, placebo-controlled Phase IIa stage of the Phase I/IIa trial, in which 134 patients were randomized and treated, a single three-injection treatment cycle of Allocetra™ produced statistically significant and clinically meaningful improvements in pain and function versus placebo in patients aged 64+ at three and six months (scale 0-100; difference vs. placebo in change from baseline):
  - WOMAC[1] pain: -17.5 points at 3 months (p=0.004) and -15.4 points at 6 months (p=0.012)
  - WOMAC function: -19.3 points at 3 months (p=0.0008) and -19.5 points at 6 months (p=0.0008)
- **12-month data from Phase I/IIa trial showed a durable effect in the Phase IIb target population.** At 12 months following a single treatment cycle, 79.2% of patients aged 64+ in the Allocetra™ group achieved a clinically meaningful response[2] (reduced pain and improved knee function) vs. 47.6% in the placebo group (p=0.027), consistent with the response rates observed at three and six months. No treatment-related serious adverse events

were observed through 12 months. The 12-month data were presented on November 8, 2026 in a poster presentation at the American College of Rheumatology (ACR) Convergence 2026 by Prof. Philip Conaghan, Director of the NIHR Leeds Biomedical Research Centre.

- **Phase IIb trial progressing toward completion of enrollment.** As recently announced, 135 patients, out of a planned total of approximately 182, have been randomized and administered the first study injection in the Phase IIb trial, which is enrolling patients aged 64 and older with moderate-to-severe symptomatic primary age-related knee OA. The trial is actively recruiting at clinical sites in the United States, Denmark and Poland.
- **Positive interim DSMB safety review.** The independent Data and Safety Monitoring Board (DSMB) overseeing the Phase IIb trial completed an interim safety review of data from 85 patients randomized and dosed and confirmed that the safety profile of Allocetra™ allows the trial to continue enrolling patients as designed.
- **Six-month topline data expected by the end of the second quarter of 2027.** As previously announced, the Company expects to report six-month topline data from the Phase IIb trial by the end of the second quarter of 2027.

RMAT Designation

As reported in July 2026, the FDA granted RMAT designation to Allocetra™ for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics. The designation was supported by positive three- and six-month Phase I/IIa data demonstrating statistically significant and clinically meaningful results in patients with primary age-related knee OA. Established under the 21st Century Cures Act, RMAT designation is reserved for regenerative medicine therapies, including cell therapies, intended to treat serious conditions where preliminary clinical evidence indicates the potential to address unmet medical needs. RMAT designation provides all the benefits of the Fast Track and Breakthrough Therapy designation programs, including:

- Early and frequent interactions with the FDA, including the Initial Comprehensive Multidisciplinary meeting and discussion of potential surrogate or intermediate endpoints
- Intensive FDA guidance on an efficient development program, with organizational commitment involving senior FDA managers
- Potential eligibility for accelerated approval, priority review, rolling review and other opportunities to expedite review and approval

About the Phase IIb Trial

The Phase IIb trial (NCT07580716) is a randomized, double-blind, placebo-controlled, global, multicenter clinical trial designed to evaluate the efficacy and safety of three intra-articular injections of Allocetra™ in patients aged 64 and older with moderate-to-severe symptomatic primary age-related knee osteoarthritis. The trial is planned to enroll approximately 182 patients at clinical centers in the United States, Denmark and Poland. Key efficacy endpoints include changes from baseline in pain and physical function compared with placebo, measured at three and six months following treatment. Additional endpoints include changes in quality-of-life measures, functional mobility assessments and durability of response through one year.

About ENX-CL-05-001

ENX-CL-05-001 is a multicenter 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 multicenter trial in which 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 to 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 timing, conduct and outcome of the Company's planned meeting with the FDA; the anticipated benefits of RMAT designation; the timing of enrollment completion and of topline data from the Company's Phase IIb trial; 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 the FDA meeting may not occur as scheduled or may not result in alignment with the FDA on the Company's development plan, and that FDA feedback is not binding and may change; the risk that RMAT designation may not lead to a faster development or regulatory review process and does not increase the likelihood of approval; 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 interim safety reviews may not be predictive of the final safety profile; risks related to the timing, conduct and outcome of clinical trials, including patient enrollment, 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] WOMAC: a widely used, standardized questionnaire to evaluate the condition and quality of life of patients with osteoarthritis of the hip and knee

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



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