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, Nov. 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^{TM} 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^{TM} 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.

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