

Enlivex Announces Positive Topline Data From Multi-Country, Randomized, Controlled, Phase I/II Trial Evaluating Allocetra in Patients With Moderate-To-Severe Knee Osteoarthritis

ENX-CL-05-001 Trial: 3-months topline data

- In the overall modified intention-to-treat (mITT) population, improvements across all efficacy and secondary endpoints, including 24% reduction in knee pain and 26% improvement in knee function, were observed in the Allocetra™ treatment arm vs placebo; moreover, 72% reduction in knee pain and 95% improvement in knee function were observed for age-related primary osteoarthritis patients compared with placebo - a substantial, clinically meaningful and statistically significant effect in commonly used Phase III primary endpoints for knee osteoarthritis clinical trials.

- Favorable safety profile - No severe adverse events; limited, typically mild to moderate, transient, and treatable side effects occurred in most patients treated with Allocetra™

- Webinar today at 8:00 a.m. Eastern Time

Nes-Ziona, Israel, Aug. 18, 2025 (GLOBE NEWSWIRE) -- Enlivex Therapeutics Ltd. (Nasdaq: ENLV, the "Company"), a clinical-stage macrophage reprogramming immunotherapy company, today announced positive three-month topline data from the Phase IIa stage of ENX-CL-05-001, a multi-center, two-stage Phase I/II double-blind, randomized, placebo-controlled clinical trial evaluating Allocetra™ in patients with moderate-to-severe knee osteoarthritis.

Oren HersHKovitz, Ph.D, CEO of Enlivex, commented, "We are excited to share the topline three-month data from ENX-CL-05-001. We believe these results provide clear indication that Allocetra™ has the potential to become a novel, safe and effective treatment for knee osteoarthritis, a growing market with significant unmet medical need."

The Company will host a webinar today at 8:00 am Eastern Time to provide in-depth analysis of the results. To join the webinar, please click

To join the webinar, please register at: <https://www.redchip.com/webinar/ENLV/87053863717>

It is suggested participants join the webinar at least 15 minutes prior to the scheduled start time to avoid any delays in attendance.

About ENX-CL-05-001

ENX-CL-05-001 is a multi-center Phase I/II 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 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," "target," "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, ALLOCETRATM 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 ALLOCETRATM 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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