Enlivex Announces Second Regulatory Approval for Phase 2b Trial of Allocetra in Age-Related Primary Moderate-to-Severe Knee Osteoarthritis

· Approval by the Danish Medicines Agency (DKMA) for enrolling patients in Denmark follows the recently announced FDA clearance to initiate the Phase 2b study in the United States.

Nes-Ziona, Israel, April 21, 2026 (GLOBE NEWSWIRE) -- Enlivex Ltd. (Nasdaq: ENLV) ("Enlivex" or the "Company"), a quality longevity company, today announced that it has received Clinical Trial Application (CTA) approval by the Danish Medicines Agency (DKMA) for the Phase 2b trial of Allocetra™, the Company's clinical-stage immunotherapy, for the treatment of patients with moderate-to-severe age-related symptomatic primary knee osteoarthritis (OA).

The planned global, multicenter, randomized, double-blind, placebo-controlled Phase 2b clinical trial, recently approved by the FDA, has been designed to evaluate the efficacy and safety of intra-articular injections of Allocetra™ in patients with moderate-to-severe age-related symptomatic primary knee osteoarthritis, which is one of the most prevalent and disabling diseases worldwide, affecting more than 32 million Americans today and projected to impact 78 million Americans by 2040. The clinical trial is designed to enroll patients from clinical centers in the United States, Denmark and Poland.

Oren Hershkovitz, Ph.D, CEO of Enlivex, commented, "Following the recent FDA clearance, the approval in Denmark marks another key step in executing our global Phase 2b strategy for Allocetra ™. Expanding into Europe reflects our commitment to advancing a unified, multinational development program designed to generate robust clinical data. Osteoarthritis remains a highly prevalent and disabling condition with limited disease-modifying treatment options, and we believe Allocetra™'s unique immunomodulatory mechanism has the potential to address the underlying drivers of inflammation and improve the quality of life for aging patients with knee osteoarthritis. We look forward to initiating patient enrollment and further evaluating Allocetra™'s potential to reduce pain, increase function, and improve quality of life for patients."

The Phase 2b trial has been designed to be statistically powered to evaluate key efficacy endpoints, including change from baseline in pain and physical function compared with placebo, measured at three- and six-months periods following treatment. Additional endpoints include changes in quality-of-life measures and functional mobility assessments.

About Enlivex (Nasdaq: ENLV)

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.

About Knee Osteoarthritis

Knee osteoarthritis (KOA) is one of the most prevalent and disabling diseases worldwide, affecting more than 32 million Americans today and projected to impact 78 million Americans by 2040. 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 knee OA patients are 60 years and older. This demographic is expanding with global aging trends, underscoring the need for new, durable therapies.

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 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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