Quality Longevity Company Enlivex Receives Investigational New Drug (IND) Clearance from the FDA for Phase 2b Trial of Allocetra in Age-Related Primary Moderate-to-Severe Knee Osteoarthritis

- Enlivex's first regulatory approval for a late-stage global Phase 2b study in Age-Related Primary Moderate-to-Severe Knee Osteoarthritis following the implementation of its dual-engine value creation model: A clinical-stage quality longevity program powered by a prediction markets treasury strategy.
- IND clearance follows the positive 3 and 6-month data readout from the Company's Phase 1/2a multicenter, randomized, double-blind, placebo-controlled clinical trial, which enrolled 134 patients, and demonstrated a robust, durable, clinically meaningful, and statistically significant treatment effect in older patients with knee osteoarthritis.

Nes-Ziona, Israel, March 23, 2026 (GLOBE NEWSWIRE) -- Enlivex Ltd. (Nasdaq: ENLV) ("Enlivex" or the "Company"), a quality longevity company, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for Allocetra™, the Company's clinical-stage immunotherapy, for the treatment of patients with moderate-to-severe age-related symptomatic primary knee osteoarthritis (OA).

The FDA's clearance enables Enlivex to initiate a global, multicenter, randomized, double-blind, placebo-controlled Phase 2b clinical trial 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.

This is the first regulatory clearance obtained by the Company following the implementation of its dual-engine value creation model, which is centered on the development of a clinical-stage quality longevity program powered by a prediction markets treasury strategy.

Oren Hershkovitz, Ph.D, CEO of Enlivex, commented, "We are very pleased to have received FDA clearance to initiate the Phase 2b clinical trial of Allocetra™ in patients with age-related primary knee osteoarthritis. This milestone represents an important step toward our mission of improving the quality of life of an aging population that is suffering from this debilitating disease with poor availability of treatment options. In our previous clinical study, Allocetra™ demonstrated a robust, durable, and clinically meaningful treatment effect lasting at least six months, with increasing benefit observed in older patient populations. We look forward to enrolling the first patients into the Phase 2b and believe Allocetra™ has the potential to address a major unmet medical need for elderly patients suffering from knee osteoarthritis while supporting a strong commercial opportunity for Enlivex."

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 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-engine structure 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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