Enlivex Receives FDA Regenerative Medicine Advanced Therapy (RMAT) Designation for Allocetra™ in Age-Related Knee Osteoarthritis

- FDA grant of RMAT designation to Allocetra™ reinforces the potential of this program to deliver a meaningful, disease-modifying impact in age-related primary knee osteoarthritis, where patients face declined quality-of-life and limited treatment options.
- RMAT designation provides the benefit of intensive, early FDA engagement and guidance for efficient drug development including potential eligibility for accelerated approval, priority review and other opportunities to expedite review and approval.

Nes-Ziona, Israel, July 13, 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 granted Regenerative Medicine Advanced Therapy (RMAT) designation to Allocetra™, the Company's clinical-stage immunotherapy, for the treatment of age-related symptomatic knee osteoarthritis (OA) in patients aged 64 and older.

"Receiving RMAT designation for Allocetra™ is an important milestone that we believe underscores the strength of our clinical data in age-related knee osteoarthritis and supports our decision to focus development on the patient population that demonstrated the most pronounced benefit in our Phase I/IIa trial. This designation is expected to provide intensive, early engagement with the FDA as we advance Allocetra™ through its Phase IIb program, and it offers a potential pathway to expedite the development and approval of Allocetra™ for a debilitating condition that affects a large and growing aging population with limited treatment options," said Dr. Oren Hershkovitz, Chief Executive Officer of Enlivex.

RMAT designation is granted by the FDA to potentially accelerate the development of regenerative medicine therapies that show preliminary clinical evidence indicating that the therapy has the potential to address an unmet medical need for the relevant serious condition, such as OA.

The FDA granted RMAT designation for Allocetra™ based on clinical evidence from the Company's completed Phase I/IIa trial, in which patients with primary age-related knee OA treated with Allocetra™ experienced statistically significant and clinically meaningful improvements in knee pain and physical function compared with placebo, with efficacy that was durable through at least six months. Based on these data, the Company initiated a randomized, controlled Phase IIb clinical trial in the United States and in the EU, that plans to enroll 182 primary knee OA patients aged 64 and older. The Company previously announced the dosing of the first patient in the U.S. clinical site and believes that top-line data from this clinical trial will be available by the end of the second quarter of 2027.

In connection with the RMAT designation, the FDA has requested a Type B meeting with the Company to conduct a comprehensive, multidisciplinary discussion of the Allocetra™ development program. The Company intends to schedule this meeting with the FDA to align on key elements of its Phase IIb trial and pivotal development plans.

Osteoarthritis is one of the most prevalent and disabling diseases worldwide, affecting more than 32 million Americans today and projected to affect approximately 78 million Americans by 2040. Treatment options for the underlying disease are limited, and end-stage management commonly requires total knee replacement.

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 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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