Enlivex Therapeutics Completes Recruitment In Phase Ib Trial Evaluating Safety And Efficacy Of Universal Off-The-Shelf Allocetra In Patients With Severe Sepsis

Nes Ziona, Israel, November 18, 2019 (GLOBE NEWSWIRE) -- Enlivex Therapeutics Ltd. (Nasdaq: ENLV), a clinical-stage immunotherapy company, today reported completion of patient recruitment into the Company's Phase Ib clinical trial in patients with severe sepsis. The study was designed to recruit ten patients, including six treated with a single dose of Allocetra, and four patients treated with two doses of Allocetra.

Enlivex announced on November 4, 2019 positive interim safety and efficacy data from an ongoing trial of off-the-shelf universal Allocetra in patients with severe sepsis. The interim analysis comparing the first six Allocetra-treated patients with 37 severe sepsis patients with equivalent source of infection and disease severity who were hospitalized at the same hospital, demonstrated the potential of single dose Allocetra infusion as therapy for prevention of sepsis-associated organ failure and mortality.

Sepsis is defined as a life-threatening organ dysfunction caused by a dysregulated immune response to infection. Sepsis has been identified by the World Health Organization as a global health priority and currently has no FDA-approved pharmacologic treatment. Sepsis is the third leading cause of mortality in the United States after cardiovascular and cancer diseases and affects approximately 1.7 million adults in the United States each year. Various studies have estimated that up to 50% of severe sepsis hospitalizations culminate in death.

ALLOCETRA™ by Enlivex was designed to provide a novel immunotherapy mechanism of action that targets life-threatening clinical indications that are defined as "unmet medical needs", including prevention or treatment of complications associated with bone marrow transplantations (BMT) and/or hematopoietic stem cell transplantations (HSCT); organ dysfunction and acute multiple organ failure associated with sepsis; and enablement of an effective treatment of solid tumors via immune checkpoint rebalancing.

ABOUT ENLIVEX

Enlivex is a clinical stage immunotherapy company, developing an allogeneic drug pipeline for immune system rebalancing. Immune system rebalancing is critical for the treatment of life-threatening immune and inflammatory conditions which involve hyper-expression of cytokines (Cytokine Release Syndrome) and for which there are no approved treatments (unmet medical needs), as well as solid tumors immune-checkpoint rebalancing. For more information, visit http://www.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, 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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