Enlivex Reports Dosing of First Two Patients in Phase II Clinical Trial Evaluating Allocetra in Severe and Critical COVID-19 Patients

Nes Ziona, Israel, Oct. 22, 2020 (GLOBE NEWSWIRE) -- Enlivex Therapeutics Ltd. (Nasdaq: ENLV, the "Company"), a clinical-stage immunotherapy company, today reported that the first two patients have been dosed in an investigator-initiated Phase II clinical trial evaluating Allocetra™ in severe and critical COVID-19 patients.

This COVID-19 study is designed as a multi-center, investigator-initiated, Phase II clinical trial. The trial is expected to recruit up to twenty-four COVID-19 patients in severe or critical condition and is designed to assess Allocetra™ in combination with standard of care treatment. The trial plans to evaluate safety, tolerability, cytokine profile and efficacy parameters. Each patient in the clinical trial will be observed for 28 days following administration of Allocetra™.

The newly initiated Phase II study follows recently reported positive top-line results from a Phase Ib investigator-initiated clinical trial of Allocetra™ in COVID-19 patients in severe and critical condition. The Phase Ib study took place in Hadassah Hospital, one of the largest hospitals in Israel, and included five COVID-19 patients, three in severe condition and two in critical condition. All five patients completely recovered from their respective severe/critical condition and were released from the hospital after an average of 5 days (severe) and 9 days (critical), following administration of Allocetra™, at which time they were all COVID-19 PCR negative. There were no reported severe adverse events relating to the administration of Allocetra™ in the patients, and the therapy was well-tolerated.

ABOUT THE ALLOCETRA COVID-19 PHASE II CLINICAL TRIAL

The COVID-19 study is a multi-center investigator-initiated, Phase II clinical trial. The trial is expected to recruit up to twenty-four COVID-19 patients in severe or critical condition, as defined by the U.S. National Institute of Health (NIH), and is designed to assess Allocetra™ in combination with standard of care treatment. Safety, tolerability, cytokine profile and efficacy parameters are planned to be evaluated. Up to twenty-four patients are expected to be recruited, subject to each patient's eligibility and signing of an informed consent to participate and receive treatment. Eligibility criteria include an existing illness with at least one of (a) radiographic infiltrates by imaging (chest x-ray, CT scan, etc.), or (b) Sp/O_2 ratio lower or equal to 94% on room air, or (c) requiring supplemental oxygen (low flow or high flow), with a P/F ratio of below 350 but higher than 150. Exclusion criteria include (a) pregnancy, lactation and childbearing potential woman who are not willing to use acceptable contraceptives measures for the entire study duration, (b) illness combined with other organ failure requiring organ support other than a respirator, including Stage 4 severe chronic kidney disease or requiring dialysis (i.e. estimated glomerular filtration rate (eGFR) < 30), (c) intubated patients (due to inability to sign an informed consent), (d) patients with malignant tumor, other serious systemic diseases and psychosis, (e) patients who are participating in other clinical trials or treated with any experimental agents that may contradict this trial, (f) co-infection of HIV or tuberculosis, (g) known immunocompromised state or medications known to be immunosuppressive, and (h) patients with P/F ratio or S/F ratio of <150 or a change in status of eligibility manifested by a rapid decline of P/F ratio between eligibility status and actual drug delivery.

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) such as sepsis and COVID-19, as well as solid tumor 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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