Enlivex Therapeutics Announces Plan for Increased Production Capacity of AllocetraTM in Preparation for Potential Treatment of Coronavirus (COVID-19) Patients with Organ Failure

Nes-Ziona, Israel, Feb.24, 2020 (GLOBE NEWSWIRE) -Enlivex Therapeutics Ltd. (Nasdaq: ENLV), a clinical-stage immunotherapy company, today announced that it is initiating a plan to increase its manufacturing capacity of Allocetra™, following the first confirmed coronavirus (COVID-19) case in Israel, in preparation for potential requests for treatment of coronavirus (COVID-19) patients who are hospitalized with diagnosed organ dysfunctions or failures related to coronavirus.

Allocetra™ is an experimental therapy being investigated for treatment of patients with organ failure associated with sepsis, a syndrome whose lethal pathophysiology - cytokine storm followed by organ failure - is similar to that of the coronavirus (COVID-19).

Sepsis is the 3rd leading cause of mortality in the United States. One of every three patients who die in U.S. hospitals dies from sepsis. Organ failure resulting from sepsis, as well as in coronavirus (COVID-19), is considered the result of an exaggerated response of the immune system ("cytokine storm") in the human body to an infection by a virus or a bacteria.

This exaggerated immune response results in organ damage. The immune attacks typically occur in vital organs such as lungs, heart, kidney and liver. When the organs become distressed, they begin to slowly dysfunction, which can result in organ failure, multiple organ failure, and mortality. Mortality rates from sepsis vary upon the degree of organ failure with which the patient arrived at the hospital. The literature describes an average of 20-40% mortality within 28-90 days for sepsis patients admitted to the ICU in a state of organ failure. Similarly, a cytokine storm was recently reported in patients with COVID-19 that were hospitalized in the ICU, (Huang et al. www.thelancet.com Published online January 24, 2020 https://doi.org/10.1016/S0140-6736(20)30183-5) and patients admitted to ICU had higher plasma levels of cytokines and chemokines.

There is no currently approved treatment for sepsis or for complicated corona virus infections. Enlivex recently announced the interim results from its first clinical trial in patients with sepsis. When compared with matched historical controls with sepsis from the same hospital, there were clear differences in (i) mortality -- none of the six Allocetra-treated patients died, vs 29% mortality in 28 days for the matched controls group; (ii) organ failure measures - 78% of the matched controls had an increase of organ failure markers post admission to the hospital, while none (0%) of the six treated patients had any increase in organ failure score, despite similar presentation, and the average organ failure state of the matched controls worsened by a factor of two, while the treated group had not a single case of any organ failure increase; (iii) all the treated patients had their organ failures eliminated and they were subsequently released from the hospital. Each of the patients had organ dysfunction in two to five systems prior to administration of Allocetra. A Full summary of this trial is expected to be published in March 2020.

Enlivex has publicly announced its plan to initiate in 2020 two clinical studies: (i) a Phase II/III clinical trial for sepsis later in the year, and (ii) a Phase II/III for the prevention of GvHD in patients who undergo bone-marrow transplantations. The manufacturing capacity of Allocetra was planned to match the expected recruitment rate of patients in those two clinical trials.

To accommodate potential requests for treatment of COVID-19 patients who are hospitalized with diagnosed organ dysfunctions and/or failures, Enlivex has initiated a plan to increase the production capacity of Allocetra.

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 an out of control immune system (e.g. 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", "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, which 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 under the heading "Risk Factors" contained in Enlivex's most recently filed Annual

Report on Form 20-F. 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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