Enlivex Reports Positive Allocetra Trial Results in COVID-19 Patients in Severe/Critical Condition

Nes Ziona, Israel, Oct. 01, 2020 (GLOBE NEWSWIRE) -- Enlivex Therapeutics Ltd. (Nasdaq: ENLV, the "Company"), a clinical-stage immunotherapy company, today reported positive top-line results of an investigator-initiated clinical trial of Allocetra™ in COVID-19 patients in severe/critical condition.

The clinical trial included five COVID-19 patients, three in severe condition and two in critical condition. All five patients had complete recovery from their respective severe/critical condition and were released from the hospital after an average of 5.5 days (severe) and 8.5 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.

Therapies such as plasma-based antibodies are typically administered to patients in moderate condition, whereas Allocetra™ was administered in the study to patients in severe or critical condition. The Company believes that Allocetra™, if approved, could potentially cover the gap that currently exists in treating severe or critical COVID-19 patients.

Based on the positive results of the first five COVID-19 patients in severe or critical condition, taken together with the positive safety and efficacy results of Allocetra™ in 10 sepsis patients in a previous study, the Company has determined to shift recruitment of additional patients from the investigator-initiated clinical trial into a larger Phase II clinical trial of COVID-19 patients in severe or critical condition as soon as reasonably practicable, subject to regulatory approval.

Prof. Vernon van Heerden, Head of the Critical Care Medicine Unit at Hadassah Hospital in Israel, and the lead investigator of both the COVID-19 trial and a recently-completed Phase Ib clinical trial of Allocetra™ in sepsis patients stated: "We have now treated 15 patients with Allocetra™ at our hospital, 10 with sepsis, and five with COVID-19. Based on the compelling preliminary results that demonstrated safety and an indication of efficacy of Allocetra™ in these complicated patients, Enlivex's product candidate has the potential to benefit COVID-19 patients in severe or critical condition."

Prof. Dror Mevorach, M.D., Chief Scientific and Medical Officer of Enlivex, added "We believe that the results of Allocetra™ treatment in these severe and critical COVID-19 patients represent a unique opportunity for Enlivex to contribute towards efforts aimed at combating the ongoing global COVID-19 pandemic. Importantly, the initial positive results seen in sepsis patients treated with Allocetra™ are consistent with those observed in COVID-19 patients in severe and critical condition."

Oren Hershkovitz, Ph.D., CEO of Enlivex commented: "We are pleased with the results of this COVID-19 clinical trial. Enlivex will continue to work towards efforts aimed at combating the ongoing global COVID-19 pandemic, while continuing to execute our sepsis clinical development program. The cumulative clinical data to date from the clinical trials in sepsis and COVID-19 are in line with our expectations."

Any COVID-19 trials would be scheduled to run independently of Enlivex's currently planned Phase IIb clinical trial of Allocetra™ for the treatment of organ failures associated with sepsis. The planned Phase IIb trial will be a controlled, randomized study that is expected to commence in the fourth quarter of 2020.

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 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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10/1/2020 6:00:00 AM