Enlivex Reports Positive Interim Results From Phase II Clinical Trial Evaluating Allocetra in Severe and Critical COVID-19 Patients

Nes Ziona, Israel, Dec. 03, 2020 (GLOBE NEWSWIRE) -- Enlivex Therapeutics Ltd. (Nasdaq: ENLV, the "Company"), a clinical-stage immunotherapy company, today reported positive interim results of an investigator-initiated Phase II clinical trial evaluating Allocetra™ in severe and critical COVID-19 patients.

The interim clinical results relate to eight COVID-19 patients who were treated with Allocetra™ in the Phase II clinical trial , six of whom were in severe condition and two of whom were in critical condition. Key results and conclusions from both the ongoing Phase II clinical trial, as well as a previously-reported investigator-initiated Phase Ib study include:

- Seven out of seven (100%) patients treated through November 26, 2020 had complete recovery from their respective severe/critical condition and were discharged from the hospital, after an average of 4.7 days following Allocetra™ administration.
- Taken together with previously-treated patients in the concluded Phase Ib study, twelve out of twelve patients (100%) through November 26, 2020 had complete recovery from their respective severe/critical condition and were discharged from the hospital, after an average of 5.5 days following Allocetra™ administration.
- The eighth treated patient in the Phase II study (and 13th treated patient overall), who enrolled in the Phase II study in critical condition on November 27, 2020, has experienced a clinical improvement following treatment with Allocetra™ and is classified as moderate/severe condition on the date of this press release. The patient remains hospitalized six days after treatment (results from patients enrolled in the prior Phase Ib investigator-initiated study showed an average of nine days to hospital discharge following Allocetra™ administration to critical patients).
- Allocetra™ treatment has been well tolerated with no treatment-related serious adverse events.

Data from both the previously-reported investigator-initiated Phase Ib study and the ongoing investigator-initiated Phase II COVID-19 trials are shown below:

Clinical Trial	# Patients enrolled	Disease Severity	Clinical Outcome		Hospitalization Post Administration of Allocetra™	
			Recovered	Mortality	Discharged	Duration (days, avg.)
Phase Ib Patients						
Phase Ib	3	Severe	3/3 (100%)	0/3 (0%)	3/3 (100%)	5
Phase Ib	2	Critical	2/2 (100%)	0/2 (0%)	2/2 (100%)	9
Total	5		5/5 (100%)	0/5 (0%)	5/5 (100%)	6.6
Phase II, Patients Enrolled Through November 26, 2020						
Phase II	6	Severe	6/6 (100%)	0/6 (0%)	6/6 (100%)	4.5
Phase II	1	Critical	1/1 (100%)	0/1 (0%)	1/1 (100%)	6
Total	7		7/7 (100%)	0/1 (0%)	7/7 (100%)	4.7
Summary of Phase Ib + Phase II Patients Enrolled Through November 26, 2020						
Total	12		12/12 (100%)	0/12 (0%)	12/12 (100%)	5.5
Phase II, Patients Enrolled After November 26, 2020						
Phase II	1	Critical	Patient enrolled Nov 27, 2020. Following treatment, clinical status improved from *Critical* to *Severe/Moderate*. Patient is currently hospitalized. Results from Phase Ib study showed an average of nine days to hospital discharge following Allocetra™ administration to critical patients			

Prof. Vernon van Heerden, Head of the Critical Care Medicine Unit at Hadassah Hospital in Israel and the lead investigator of both the prior Phase Ib and the current Phase II COVID-19 clinical trials stated, "Thirteen COVID-19 patients have been treated to date with Allocetra™. The Phase II patients that have been discharged from the hospital are currently healthy. We believe that these compelling preliminary results have demonstrated safety and an indication of efficacy of Allocetra™ in these complicated patients, highlighting the potential of Enlivex's product candidate to benefit severe and critical COVID-19 patients as well as others suffering from cytokine storms and organ dysfunctions across various clinical indications."

Prof. Dror Mevorach, M.D., Chief Scientific and Medical Officer of Enlivex, added, "We believe the results from the COVID-19 clinical trials of Allocetra™ represent a unique opportunity for Enlivex in this COVID-19 patient population, and suggest that Allocetra™ may have utility as a safe and efficacious treatment for resolving states of organ failures across different life-threatening, high mortality clinical indications with high unmet medical needs."

Oren Hershkovitz, Ph.D., CEO of Enlivex commented, "We are pleased with the interim results of this COVID-19 Phase II clinical trial. We believe that Allocetra™, if approved, could potentially cover the void that currently exists in treatments for severe or critical COVID-19 patients. The upcoming anticipated regulatory approval of various COVID-19 vaccines is a game-changer in the fight against the pandemic, yet with various surveys demonstrating 33% of the U.S. population unwilling to get vaccinated, and studies showing that vaccines are not 100% effective, our commercial model

estimates continued demand for the treatment of severe or critical COVID-19 patients for years to come."

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 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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