Enlivex Therapeutics Announces Positive Interim Safety and Efficacy Data From Ongoing Trial of Off-The-Shelf Allocetra in Patients with Severe Sepsis

-- Interim Analysis Comparing Allocetra-Treated Patients with 37 Severe Sepsis Patients with Equivalent Source of Infection and Disease Severity Who Were Hospitalized at the Same Hospital, Demonstrates Potential of Allocetra as Therapy for Prevention of Sepsis-Associated Organ Failure and Mortality --

Nes Ziona, Israel, Nov. 04, 2019 (GLOBE NEWSWIRE) -- Enlivex Therapeutics Ltd. (Nasdaq: ENLV), a clinical-stage immunotherapy company, today announced positive interim efficacy data from the Company's ongoing Phase Ib clinical trial in patients with severe sepsis. The interim analysis is based on a dataset of 43 patients with severe sepsis, all hospitalized at Hadassah Medical Center, which is one of the largest and most prestigious hospitals in Israel. Six patients admitted to Hadassah's intensive care unit with sepsis have been administered with off-the-shelf Allocetra ("OTS Allocetra") upon their admission, while 37 patients were matched controls that received standard of care treatment during 2016-2019 but did not receive OTS Allocetra.

The primary safety parameter was 28 days mortality. None (0 of 6) of the OTS Allocetra -treated patients died during this period, compared to 11 of 37 (29%) in the matched control group who died during this period. OTS Allocetra treatment resulted in improved efficacy in all analyzed parameters, which included the sequential organ failure assessment (SOFA) score (the higher the score, the worse the clinical condition of various organs), as well as recovery from sepsis, number of days of hospitalization in the intensive care unit, and others. The interim and efficacy data are as follows:

Sepsis Outcomes	Matched Untreated Group	OTS Allocetra Treated Group
n % of patients that recovered from sepsis within 28 days	***Significant increase in recovery from sepsis in patients that were treated with Allocetra-OTS***	
	48%	100%
n % mortality of patients	29%	0%
n Average organ failure score (SOFA) at admission vs maximal reached during hospitalization	***OTS Allocetra substantially prevents organ failure in severe sepsis patients***	
	Avg. at admission: 3.98 Avg. maximal: 8.11	Avg. at admission: 4.5 Avg. maximal: 4.5
n Median organ failure score (SOFA) at admission vs maximal reached during hospitalization	Median at admission: 4 Median maximal: 8	Median at admission: 4.5 Median maximal: 4.5
n % of patients with organ failure score (SOFA) that increased during 28-day period	***SOFA increase is associated with organ dysfunction and failure, and was prevented in patients treated with OTS Allocetra***	
	78%	0%
n % of patients with organ failure score (SOFA) that increased by 4 or more points during 28 days	***SOFA increase => 4 is associated with high probability of mortality, and was prevented in patients treated with OTS Allocetra***	
	57%	0%
n % of patient mortality among those with organ failure score (SOFA) that increased by 4 or more during 28 days	52%	0%
n % of patients still in the intensive care unit after 6 days	57%	0%

Prof. Dror Mevorach, Chief Medical Officer of Enlivex, commented, "We are pleased with the robust safety and efficacy profile demonstrated by OTS Allocetra in the interim analysis of patients with severe sepsis. Even in a small group of patients, some of the efficacy parameters are already statistically-significant. Our previous analysis showed that no serious adverse events were associated with OTS Allocetra in these patients. Together with our preclinical data, as well as human data from a Phase IIa clinical trial relating to the prevention of GvHD, we believe that OTS Allocetra is positioned as a potentially clinically viable option for treatment of sepsis, which is a clinical condition that has poor clinical outcomes and no currently effective therapy."

Shai Novik, Chairman of Enlivex, stated, "We are encouraged by these interim safety and efficacy analysis results. OTS Allocetra is a significant product candidate for Enlivex, and we look forward to obtaining additional clinical data. We hope to complete the ongoing study by the end of 2019 and provide a final efficacy data analysis shortly thereafter."

The matching of the 37 patients to the OTS Allocetra-treated group was based on similar organ failure clinical SOFA score at admission, overall clinical state, age group, sex, and source of severe sepsis (pneumonia, endovascular, or urinal tract infections). All matched patients were treated at the same hospital as the Allocetra-treated group.

Matching Characteristics	Matched Untreated Group	Treated With OTS Allocetra
• Source of sepsis		
◦ Pneumonia	67%	68%
◦ Endovascular infection (MRSA)	16%	17%
◦ Urinal tract infection	17%	15%
• Age group distribution	Avg. age: 69.2 Median age: 69.0	Avg. age: 69.8 Median age: 70.5
• SOFA at admission (average & median)	Avg. at admission: 3.98 Median at admission: 4	Avg. at admission: 4.50 Median at admission: 4.50
• Sex	All male	All male

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.

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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