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Vital Therapies Announces Characteristics of Early Subjects in VTL-308 Pivotal Study of ELAD System in Severe Alcoholic Hepatitis

SAN DIEGO, June 05, 2017 (GLOBE NEWSWIRE) -- Vital Therapies, Inc. (Nasdaq:VTL), a biotherapeutic company developing ELAD®, a cell-based therapy targeting the treatment of acute forms of liver failure, today released data describing the baseline characteristics of the 67 subjects enrolled as of the Company's last quarterly report on May 9, 2017 in study VTL-308, the Company's ongoing pivotal phase 3 study in subjects with severe alcoholic hepatitis.

The enrollment criteria for VTL-308 were devised based on extensive analysis of prior clinical data for the ELAD System, including the 203 subject randomized dataset from VTI-208, a prior Phase 3 trial. Based on pre-specified exploratory analyses, it was determined from VTI-208 that younger subjects, as well as those with severe liver disease but without evidence of other organ dysfunction at baseline, would comprise the population most likely to exhibit improved survival in the prospectively designed VTL-308 clinical trial. In particular, an optimized post-hoc subgroup (N=60) of the VTI-208 population provided guidance on the specific inclusion and exclusion criteria that should be applied.

As part of routine quality control of study conduct, the critical baseline characteristics of subjects enrolled in the VTL-308 study are monitored. As previously reported, 67 subjects were enrolled as of May 9, 2017, of a total anticipated cohort of at least 150 subjects. The characteristics of the first 67 subjects are shown below, in comparison to the characteristics of the subgroup population from VTI-208 on which the inclusion criteria were based:

	Data	Age (years)	MELD	Bilirubin (mg/dL)	INR	Creatinine (mg/dL)
VTL-308 enrollment limits		<50 yrs	≤30	≥16 mg/dL	≤2.5	<1.3mg/dL
VTI-208 reference population (n=60)	Mean (range)	40.10 (28-49)	25.60 (20-29)	26.62 (16.6 - 52.6)	1.86 (1.0 - 2.5)	0.71 (0.10-1.30)
VTL-308 (n=67)	Mean (range)	38.94 (25-49)	25.33 (19-29)	25.32 (16.0 - 42.8)	1.84 (0.95 - 2.50)	0.75 (0.36- 1.27)

No subjects outside the enrollment criteria have been enrolled in VTL-308 to date and, as can be seen from these data, the subject characteristics are closely tracking the reference VTI-208 subset.

Jan Stange, M.D., Ph.D., VTL's Chief Medical Officer noted, "In order for clinical trials to be successful it is essential that subjects enrolled are carefully monitored to ensure compliance with all inclusion and exclusion criteria. It is remarkable how closely the baseline characteristics of the first 67 subjects enrolled in VTL-308 compare with the population from VTI-208 on which the study design is based. We look forward to obtaining data from this prospective trial in this poorly-served, high-mortality population."

About Vital Therapies, Inc.

Vital Therapies, Inc. is a biotherapeutic company developing a cell-based therapy targeting the treatment of acute forms of liver failure. The Company's ELAD System is an extracorporeal human allogeneic cellular liver therapy currently in phase 3 clinical trials. Vital Therapies, Inc. is based in San Diego, California. Vital Therapies® and ELAD® are trademarks of Vital Therapies, Inc.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements concerning or implying the conduct of our clinical trials and the final baseline characteristics which could differ from the baseline characteristics to date. Forward-looking statements are based on management's current expectations and are subject to various risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such forward-looking statements. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements. Risks and uncertainties include, but are not limited to, difficulty obtaining or maintaining regulatory approval in the United States or Europe, in particular for a combination product and open-label clinical trials; our limited experience in conducting pivotal clinical trials and significant issues regarding our clinical trials, including, but not limited to, the successful opening and the continued participation of clinical sites and their ongoing

adherence to protocols, assumptions regarding enrollment rates, timing and availability of subjects meeting inclusion and exclusion criteria, changes to protocols or regulatory requirements, the need to comply with and meet applicable laws and regulations, and unexpected adverse events or safety issues. There can be no assurance that data from any of our clinical trials will be sufficient to support an application for marketing in any country or that any such application will ever be approved. These and other risks regarding our business are described in detail in our Securities and Exchange Commission filings, including in our Annual Report on Form 10-Q for the quarter ended March 31, 2017. These forward-looking statements speak only as of the date hereof, and Vital Therapies, Inc. disclaims any obligation to update these statements except as may be required by law.

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