

Vital Therapies, Inc. (VTI) is developing the first human cell-based bioartificial liver: ELAD[®] provides support for patients with severe liver failure by processing toxins and synthesizing proteins and metabolites that are key products of normal human liver function. VTI has completed six clinical trials including a pivotal trial in China, which was used to file for marketing approval in China. A US/EU pivotal trial to secure BLA and MAA approval is underway

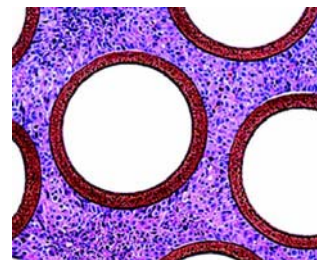
Product ELAD is comprised of four hollow fiber cartridges containing 440 grams of cells and 32,000 fibers mounted on a bedside unit. Immortalized human liver cells are grown outside, and the patient's plasma flows inside of the hollow fibers to allow two-way transfer of metabolites. During ELAD therapy the cells metabolize toxins and synthesize proteins and other liver specific products essential for life, assisting liver function.

Technology The proprietary human hepatocyte cell line, C3A, was licensed from the Wistar Institute in Philadelphia and further developed by Baylor College of Medicine. This immortal cell line, derived from a human hepatoblastoma, can be grown in unlimited quantities, stored and shipped worldwide. A cartridge set is incorporated into the bedside unit, enabling continuous treatment for up to 17 days without the cells losing their ability to perform.

Clinical Development Six human clinical trials have been completed in the USA, UK and China. 132 patients have received ELAD treatment including 14 in compassionate use programs in USA, UK, Saudi Arabia, and Singapore. Phase 1 and two phase 2 controlled, randomized, multicenter trials were run in USA under an FDA IND with promising results. In China, VTI has completed a successful pivotal trial and has filed for market approval. A pivotal US/EU trial to secure BLA and MAA approval is currently underway at over 20 sites.

Regulatory Status ELAD is regulated as a biologic in USA by the FDA's Division of Cellular, Gene and Tissue Therapy in CBER. In the EU, ELAD is an Advanced Therapy and requires a CTA approval in each country. In China, ELAD is regulated as a medical device. The California FDB has certified VTI's San Diego plant as a Drug Manufacturing Facility. It is cGMP compliant. The plant also passed a UK QP audit.

U.S. Market Transplantation is the sole therapy shown to improve survival in liver failure. However, over 17,000 patients are on the transplant waiting list but only 6,400 transplants are performed annually with an average waiting time of about a year. Over 2,000 patients die while waiting for transplantation. There are about 30,000 patients that are not eligible for transplantation and have no therapeutic options available. In a market study done for VTI by Easton Associates, a U.S. market potential for ELAD of \$1.08 billion per year was defined.



ELAD Cross-section (40X)

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China Opportunity Liver disease is pandemic in China. A market study done for VTI by IMS China concluded that 12% of the population is infected with hepatitis B and C and there are more than 400,000 deaths from liver disease annually. In China's urban centers, IMS identified over 1 million patients who would be clinical candidates for ELAD. With the cooperation of eminent physicians who approached VTI through a long time VTI Chinese employee, a 100% owned subsidiary was formed in China to conduct the clinical trial and launch ELAD in China. The trial was completed and the China market application was filed in September 2007. It is under review at SFDA.

Compassionate Use An Expanded Access protocol with cost recovery has been allowed by US FDA and 5 patients have been treated. Compassionate use is also allowed in UK, Singapore and Saudi Arabia.

Manufacturing The bedside system, disposables and cartridges are sourced from reputable medical device suppliers. The cells are grown in the cartridges at VTI's cGMP facility in San Diego, which was recently expanded to 2,000 patient sets/year. All the logistics of growing, storing, shipping and connecting the cartridges to the bedside unit have been proven during the US, UK and China clinical trials.

Competition Liver transplantation is the only therapy currently available that extends survival. However, there are a limited number of livers available, the procedure is very expensive and requires a lifetime of immunosuppressive drugs. Existing toxin removal systems include albumin dialysis, charcoal or resin filtration and plasma exchange. However, none of these has been shown to improve survival, nor are accepted as a standard of care. There are currently no other living cell-based liver support devices in controlled clinical trials anywhere in the world. First mover advantage for VTI will include Orphan Drug, Fast Track and Priority Status in the USA creating substantial technical and regulatory hurdles.

Financing VTI is financed by a syndicate of venture capital funds led by Versant Ventures and MedVenture Associates.



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