HepaLife(TM) Plans for Phase III Clinical Trial for HepaMate(TM) Bioartificial Liver System

HepaMate's patented technology has previously been tested in Phase I and pivotal Phase II/III clinical studies involving more than 200 patients, making it the most clinically studied bioartificial liver.

BOSTON-- HepaLife Technologies, Inc. (OTCBB: HPLF) (FWB: HL1) (WKN: 500625), developing its cell-based bioartificial liver system, HepaMate(TM), as a potentially lifesaving treatment for liver failure patients, announced today that it plans for a new pivotal Phase III clinical trial in the United States.

The HepaMate(TM) technology has previously been tested in clinical Phase I and pivotal Phase II/III studies involving more than 200 patients. Over 50 scientific papers and book chapters have been published on the technology.

A retrospective statistical analysis of the previous pivotal Phase II/III clinical trial data, adjusted for the impact of liver transplantation on patient survival, revealed a statistically significant survival advantage for patients with fulminant and subfulminant hepatic failure when treated with HepaMate(TM) compared to controls receiving standard medical care alone. The inclusion of a subset of 24 patients who had undergone a prior, failed liver transplant negatively impacted the trial's outcome. Such patients are known to have poor survival rates. Therefore, the previous Phase II/III trial was unable to achieve its primary 30-day survival endpoint in the overall study population.

Based on the retrospective statistical analysis of the clinical trial data, HepaLife expects a new Phase III clinical trial without the inclusion of failed liver transplant patients to be successful.

"I treated 15 acute-liver failure patients with the technology in the previous pivotal clinical trial", says University of California, San Francisco Liver Transplant Physician Philip Rosenthal, MD. "My experience was very good. The patients responded well to the bioartificial liver support therapy; some seriously ill patients even recovered without the need for a liver transplant. The HepaMate system has generated strong and favorable clinical data in acute liver failure patients. I am looking forward to seeing this much needed therapy utilized in the routine clinical setting helping patients with otherwise very limited treatment options."

The retrospective statistical analysis of the HepaMate(TM) treatment demonstrated a
reduction of the risk of pre-transplant death by 47% in fulminant hepatic failure patients (n=121; p<0.043) relative to controls and by 67% in fulminant hepatic failure patients with drug or chemical induced toxicity (n=53; p=0.014). At the same time that bioartificial liver therapy improved outcomes for treated patients, it provided patients with a trend towards additional time for a liver transplant to become available (median of 2 days for all patients). HepaMate(TM) demonstrated clinical activity for a large majority of the enrolled patients (147 out of 171). The FDA previously approved to use identical statistical methodology employed for the retrospective analysis in any subsequent clinical trial and also previously approved to increase the liver cell dose for HepaMate(TM).

As an extracorporeal cell-based bioartificial liver system, HepaMate(TM) is designed to combine blood detoxification with liver cell therapy to provide whole liver function in patients with the most severe forms of liver failure. Liver cells detoxify existing toxins, produce albumin and other liver-specific proteins. A patented liver cell cryopreservation process provides for safe and easy storing and distribution, a significant logistic and commercial advantage. During therapy, the patient’s plasma is separated from whole blood, exposed to the HepaMate(TM) bioartificial liver and returned to the patient. HepaMate(TM) is comprised of a blood plasma separation cartridge, a hollow-fiber bioreactor filled with proprietary porcine liver cells, a charcoal column, an oxygenator, circuit tubing and a plasma reservoir. These components are assembled into a patented blood/plasma circulation system, which is placed on the HepaDrive(TM) perfusion platform.

There are currently no cell-based liver support systems commercially available or in Phase III clinical trials in the US or Europe. HepaLife's patented technology provides for first-mover advantage for an unmet clinical need, and includes fast-track and orphan drug status in the USA. The proprietary cryopreserved pig hepatocyte technology provides a significant logistic advantage. The frozen cells can be stored for years, shipped and handled easily. In contrast fresh cells from cell lines or from liver tissue have a limited life time with decreasing viability and functionality. Thawing, loading and washing of cryopreserved cells is performed at the patient's bedside using a proprietary, FDA-approved technique. Only 90 minutes are required to assemble the system, prime the blood and plasma circuits and to process the liver cells.

In October 2008, HepaLife announced completion of its acquisition of a liver support technology previously knows as HepatAssist.

ABOUT HEPALIFE TECHNOLOGIES, INC.

Based in Boston, Massachusetts, HepaLife(TM) Technologies Inc., is developing its cell-based bioartificial liver system, HepaMate(TM), as a potentially lifesaving treatment for liver failure patients. (OTCBB: HPLF) (FWB: HL1) (WKN: 500625).

Any statements contained in this press release regarding our ongoing research and development and the results attained by us to-date have not been evaluated by the Food and Drug Administration.

For additional information, please visit www.hepalife.com.
To receive future press releases via email, please visit:

http://www.hepalife.com/investor_alerts.php

To view the full HTML text of this release, please visit:


Legal Notice Regarding Forward-Looking Statements

No statement herein should be considered an offer or a solicitation of an offer for the purchase or sale of any securities. This release contains forward-looking statements that are based upon current expectations or beliefs, as well as a number of assumptions about future events. Although the Company believes that the expectations reflected in the forward-looking statements and the assumptions upon which they are based are reasonable, it can give no assurance that such expectations and assumptions will prove to have been correct. Forward-looking statements, which involve assumptions and describe our future plans, strategies, and expectations, are generally identifiable by use of the words "may," "will," "should," "could," "expect," "anticipate," "estimate," "believe," "intend," or "project" or the negative of these words or other variations on these words or comparable terminology. The reader is cautioned not to put undue reliance on these forward-looking statements, as these statements are subject to numerous factors and uncertainties, including but not limited to adverse economic conditions, intense competition, lack of meaningful research results, entry of new competitors and products, adverse federal, state and local government regulation, inadequate capital, unexpected costs and operating deficits, increases in general and administrative costs, termination of contracts or agreements, technological obsolescence of the Company's products, technical problems with the Company's research and products, price increases for supplies and components, litigation and administrative proceedings involving the Company, the possible acquisition of new businesses or technologies that result in operating losses or that do not perform as anticipated, unanticipated losses, the possible fluctuation and volatility of the Company's operating results, financial condition and stock price, losses incurred in litigating and settling cases, dilution in the Company's ownership of its business, adverse publicity and news coverage, inability to carry out research, development and commercialization plans, loss or retirement of key executives and research scientists, changes in interest rates, inflationary factors, and other specific risks.

We currently have no commercial products intended to diagnose, treat, prevent or cure any disease. The statements contained in this press release regarding our ongoing research and development and the results attained by us to-date have not been evaluated by the Food and Drug Administration. There can be no assurance that further research and development, and/or whether clinical trial results, if any, will validate and support the results of our preliminary research and studies. Further, there can be no assurance that the necessary regulatory approvals will be obtained or that HepaLife will be able to develop commercially viable products on the basis of its technologies. In addition, other factors that could cause actual results to differ materially are discussed in the Company's most recent Form 10-Q and Form 10-K filings with the Securities and Exchange Commission. These reports and filings may be inspected and copied at the Public Reference Room maintained by the U.S. Securities & Exchange Commission at 100 F
Street, N.E., Washington, D.C. 20549. You can obtain information about operation of the Public Reference Room by calling the U.S. Securities & Exchange Commission at 1-800-SEC-0330. The U.S. Securities & Exchange Commission also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the U.S. Securities & Exchange Commission at http://www.sec.gov. The Company undertakes no obligation to publicly release the results of any revisions to these forward looking statements that may be made to reflect the events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

Source: HepaLife Technologies