

# News Release

## Accomplished Executive with Regulatory Affairs/Quality Systems & Bioartificial Liver Device Expertise Joins HepaLife™

**HepaLife expands team with addition of regulatory expert; Company continues development of first-of-its-kind bioartificial liver device following positive research outcomes.**

**Boston, MA – March 13, 2008** – HepaLife Technologies, Inc. (OTCBB: HPLF) (FWB: HL1) (WKN: 500625), developers of the first-of-its-kind artificial liver device, today announced the addition of Dr. Zorina Pitkin -- an accomplished expert in regulatory affairs/quality systems related to cell-based products and bioartificial liver devices -- to the Company's Scientific Advisory Board.

Dr. Zorina Pitkin is an internationally renowned expert and lecturer on the development and implementation of delivery and quality system programs, regulatory strategies for cellular therapies, xenotransplantation (life-saving cell and organ transplantation from different species), and biologic/device combination products, including bioartificial devices for the kidney and liver.

In addition to her current appointment to the Board of Directors of the Regulatory Affairs Professional Society, she previously served as an Advisor to the World Health Organization Committee on Xenotransplantation. Dr. Pitkin designed and directed training programs for the first-ever multinational clinical trials for an early cell-based liver assist device, and has been successful in implementing the regulatory strategy for the development of new compounds, therapeutics and medical devices in accordance with the Food and Drug Administration's (FDA) approval process.

"Dr. Pitkin brings us nearly twenty years of hands-on biotechnology experience, and a particular know-how of cell-based biologic/device combination products and bioartificial devices," stated Mr. Frank Menzler, President and CEO of HepaLife Technologies, Inc.

"Dr. Pitkin's input will be extremely valuable in developing our strategy for initial in-vivo trials and, ultimately, in moving towards obtaining FDA product approval for our first-of-its kind bioartificial liver device, the active development of which has been bolstered by encouraging research outcomes."

Positive results from recent in-vitro tests of HepaLife's proprietary bioartificial liver were announced last month. Researchers 'seeded' the Company's patented PICM-19 liver cells inside its artificial liver device and favorably demonstrated the important ability to reduce levels of toxic ammonia by 75% in fewer than 24 hours, a feature considered necessary to the successful treatment of acute liver failure using an artificial liver. In contrast to HepaLife's early preclinical results, published in-vivo data from clinical trials of systems utilizing liver cells other than the Company's PICM-19, have only reported ammonia reduction levels between 0 to 44%.

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According to researchers, biochemical improvement as a result of artificial liver device treatment in clinical application is judged not only by the elimination of ammonia, but also by the production of urea. Importantly, HepaLife's PICM-19 cells synthesized 80% of the ammonia present into urea, the normal pathway of ammonia reduction of the human liver. HepaLife's patented PICM-19 cell line is the only known liver stem cell line of its kind with this ability to produce substantial amount of urea.

"As we move forward with the development of our artificial liver device technology, I welcome Dr. Pitkin to our team and very much look towards capitalizing on her special expertise with regulatory and quality affairs vital to HepaLife's core business," concluded Mr. Menzler.

Dr. Pitkin will assist with HepaLife's global product development efforts and play an important role in developing the regulatory strategy and quality systems for the Company's portfolio of cell-based technologies, including: the first-of-its kind artificial liver device, in-vitro toxicology testing platforms, and a novel vaccine production system.

### **Zorina Pitkin, PhD, RAC:**

Dr. Zorina Pitkin has over 18 years of experience in the field of biotechnology and is Regulatory Affairs Certified. Dr. Pitkin's experience includes the development and implementation of delivery and quality system programs and regulatory strategies for cellular therapies and biologic/device combination products, including FDA-approved Phase II/III clinical trials, and Xenotransplantation.

Dr. Pitkin has been elected to serve a 2006 – 2008 term on the Board of Directors of the Regulatory Affairs Professional Society (RAPS), the leading worldwide member organization devoted to the health product regulatory profession with more than 12,000 individual members from industry, government, research, clinical and academic organizations in over 50 countries.

Dr. Pitkin also serves as a Consultant for Tolerx, Inc., a biopharmaceutical company focused on the discovery, development, and commercialization of novel immunotherapies. She previously served as Senior Vice President of Regulatory Affairs and Quality Systems at RenaMed Biologics, a company developing a cell-based bioartificial kidney device.

Prior to RenaMed, Dr. Pitkin co-founded Circe Biomedical, Inc., credited with pioneering the first cell-based device for acute liver failure of its time. While regulatory approvals were not realized for the company's product, its founding technology remains widely-respected as the first cell-based artificial liver to successfully enter Phase II/III clinical trials. Under her guidance as Vice President of Regulatory Affairs and Quality at Circe, Dr. Pitkin successfully obtained orphan drug designation and fast-track status for the company's early bioartificial liver device technology from the FDA.

Dr. Pitkin previously served in several managerial, quality, and research positions at Cellcor, Inc., developers of living cell-based therapy for the treatment of metastatic renal cell carcinoma (cancer of the kidneys), and chronic Hepatitis B infection. While at Cellcor, Dr. Pitkin helped establish a successful, comprehensive, quality control program in compliance with 'Current Good Manufacturing Practice' (cGMP) guidelines.

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Dr. Zorina Pitkin earned a PhD in Biological Sciences from the Research Institute of Influenza, Russian Academy of Medical Sciences, and a MS degree in Chemical Technology of Bio-active Compounds from the Academy of Chemistry and Pharmacy in St. Petersburg, Russia.

## **ABOUT HEPALIFE TECHNOLOGIES, INC.**

Based in Boston, Massachusetts, HepaLife Technologies, Inc. (OTCBB: HPLF) (FWB: HL1) (WKN: 500625) is a developer of cell-based medical technologies addressing prevalent human health concerns.

Current cell-based technologies under development by HepaLife include 1) the first-of-its-kind artificial liver device, 2) proprietary in-vitro toxicology and pre-clinical drug testing platforms, and 3) novel cell-culture based vaccine production methods for the manufacture of vaccines against H5N1 avian influenza and other viruses.

For additional information, please visit [www.hepalife.com](http://www.hepalife.com).

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