# Aethlon Medical Discloses Submission of Hepatitis C Virus (HCV) IDE to FDA

The Associated Press

Aethlon Medical, Inc. (OTCBB: AEMD), the pioneer in developing selective therapeutic filtration devices to address infectious disease, cancer and other life-threatening conditions, disclosed today that it has submitted an Investigational Device Exemption (IDE) to the U.S. Food and Drug Administration (FDA) that requests permission to initiate a clinical feasibility study of Hepatitis-C (HCV) infected individuals enrolled to receive Hemopurifier@ therapy. Upon approval by FDA, an IDE allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application.

(Photo: http://photos.prnewswire.com/prnh/20090325/LA88762LOGO-b [1]) The Aethlon Hemopurifier@ is a first-in-class medical device that targets the rapid clearance of HCV from the entire circulatory system.

The goal of therapy is to improve the benefit of interferon-based or all-antiviral HCV drug regimens. Aethlon's IDE submission included clinical data from Hemopurifier@ studies of HCV-infected individuals conducted at the Apollo Hospital, Fortis Hospital, and the Medanta Medicity Institute, all located in India. As requested by FDA during a Pre-IDE meeting, Aethlon also provided data that quantified the capture of HCV within the Hemopurifier@ during treatment. The proposed feasibility study would enroll 10 patients with End Stage Renal Disease (ESRD) and concomitant HCV infection. The study would be conducted by the Renal Research Institute (RRI), which was established in 1997 as a partnership between Fresenius Medical Care (FMC) and Beth Israel Medical Center, New York City.

About Aethlon Medical Aethlon Medical creates innovative medical devices that address unmet medical needs in cancer, infectious disease, and other life-threatening conditions. Our Aethlon ADAPTT System is a revenue-stage technology platform that provides the basis for a new class of devices the rapid, yet selective removal of disease promoting particles from the entire circulatory system. At present, The Aethlon ADAPTT product pipeline includes the Aethlon Hemopurifier@ to address infectious disease and cancer, and a medical device being developed under a 5-year contract with Defense Advanced Research Projects Agency (DARPA) to reduce the incidence of sepsis in combat-injured soldiers.

For more information, please visit www.aethlonmedical.com [2].

About The Aethlon Hemopurifier@ The Aethlon Hemopurifier@ is a first-in-class medical device that selectively targets the rapid clearance of infectious viral pathogens and immunosuppressive proteins from the entire circulatory system. In the treatment of Hepatitis C virus (HCV), human studies have demonstrated that

Hemopurifier@ therapy may improve immediate, rapid and sustained virologic response rates when administered in the first few days of standard-of-care drug therapy. In addition to accelerating viral load depletion, post-treatment analysis of the Hemopurifier@ has documented the capture of up to 300 billion HCV copies of HCV during a single six-hour treatment. Access to Hemopurifier@ therapy is available on a compassionate-use basis through the Medanta Medicity Institute (Medicity), a leading center for medical tourism in India.

The Medicity is offering treatment access to infected individuals who previously failed or subsequently relapsed standard-of-care drug regimens. The Hemopurifier@ is also being offered as a salvage therapy to infected individuals who suffer a viral breakthrough during standard-of-care therapy. U.S. studies of the Hemopurifier@ are currently pending approval of an IDE submitted to FDA.

The Aethlon Hemopurifier@ and Cancer In addition to the opportunity to address a broad-spectrum of infectious viral pathogens, the Hemopurifier@ has been discovered to capture tumor-derived exosomes underlying several forms of cancer. Tumor-derived exosomes have recently emerged to be a vital therapeutic target in cancer care. These microvesicular particles suppress the immune response in cancer patients through apoptosis of immune cells and their quantity in circulation correlates directly with disease progression. Beyond possessing immunosuppressive properties, tumor-derived exosomes facilitate tumor growth, metastasis, and the development of drug resistance. By addressing this unmet medical need, the Hemopurifier@ is positioned as an adjunct to improve established cancer treatment regimens.

Certain statements herein may be forward-looking and involve risks and uncertainties.  Such forward-looking statements involve assumptions, known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Aethlon Medical, Inc. to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. Such potential risks and uncertainties include, without limitation, that the FDA will not approve the initiation of the Company's clinical programs or provide market clearance of the company's products, future human studies whether revenue or non-revenue generating from either compassionate use or non-compassionate use of the Aethlon ADAPTT system or the Aethlon Hemopurifier@ as an adjunct therapy to improve patient responsiveness to established cancer or hepatitis C therapies or as a standalone cancer or hepatitis C therapy, the Company's ability to raise capital when needed, the Company's ability to complete the development of its planned products, the Company's ability to manufacture its products either internally or through outside companies and provide its services, the impact of government regulations, patent protection on the Company's proprietary technology, product liability exposure, uncertainty of market acceptance, competition, technological change, and other risk factors. In such instances, actual results could differ materially as a result of a variety of factors, including the risks associated with the effect of changing economic conditions and other risk factors detailed in the Company's Securities and Exchange Commission filings. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events,

or otherwise.

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