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Aethlon Medical Announces Receipt of IRB Approval to Initiate Hemopurifier® Clinical Studies

SAN DIEGO, Sept. 2, 2014 /PRNewswire/ -- Aethlon Medical, Inc. (NASDAQ:OTCQB: AEMD), the pioneer in developing targeted therapeutic devices to address infectious disease, cancer and other life-threatening conditions, announced today that it has received independent internal review board (IRB) approval to initiate human clinical studies of Hemopurifier® therapy at DaVita MedCenter Dialysis located in Houston, Texas.

Aethlon previously disclosed that the United States Food and Drug Administration (FDA) had approved an Investigational Device Exemption (IDE) that would allow for the initiation of Hemopurifier® feasibility studies in the United States. As a result of the independent IRB approval, the Company is now permitted to initiate the IDE approved study. Enrollment of patients who meet the study inclusion/exclusion criteria is expected to begin in the coming weeks. The Hemopurifier® is a first-in-class therapeutic device that targets the rapid elimination of circulating viruses and tumor-secreted exosomes that suppress the immune system of cancer patients.

Upon receipt of IDE approval from FDA, Aethlon initiated discussions with various clinical partner candidates. On February 26, 2014, the Company disclosed that it had reached an agreement in principle with DaVita Clinical Research® (DCR) and subsequently disclosed that it had completed a definitive agreement with DCR on May 20, 2014. DCR is a specialty contract research organization (CRO) with experience in conducting more than 300 early phase clinical trials. As a subsidiary of DaVita Healthcare Partners Inc, DCR has access to one third of the total U.S. ESRD patient population and maintains a network that exceeds 150 investigative physicians' practices at more than 250 clinical sites.

Aethlon further disclosed that Dr. Stephen Z. Fadem had been named Principal Investigator of the IDE approved study. Dr. Fadem is Chief Medical Officer at Kidney Associates, PLLC and the Medical Director for the Houston Kidney Center Integrated Service Network at DaVita Kidney Care, a division of DaVita HealthCare Partners Inc.

Under the feasibility study protocol, Aethlon will enroll ten end-stage renal disease (ESRD) patients who are infected with the Hepatitis C virus (HCV) to demonstrate the safety of Hemopurifier® therapy in an infectious disease model. Upon successful completion of the feasibility study, Aethlon plans to conduct pivotal efficacy studies required for market clearance to treat HCV and other chronic viral indications. Previous clinical studies of Hemopurifier® therapy have been conducted in HIV and HCV-infected individuals at the Apollo Hospital, Fortis Hospital, Sigma New Life Hospital, and the Medanta Medicity Institute, all located in India.

Aethlon's feasibility study will also contribute safety data to advance the Hemopurifier® as a broad-spectrum countermeasure against high-risk bioterror and pandemic threats, which are so lethal they do not allow for the administration of clinical efficacy studies. In this regard, the Company is pursuing Emergency Use Authorization (EUA) approvals based on previous human treatment outcomes and pre-clinical validations against a broad-spectrum of viral pathogens.

Previously, *in vitro* studies of bioterror and pandemic threats have verified Hemopurifier® capture of ebola hemorrhagic virus, dengue hemorrhagic virus, lassa hemorrhagic virus, H5N1 avian influenza (bird flu), the reconstructed 1918 influenza virus (r1918), 2009 H1N1 influenza virus (swine flu), West Nile virus, and monkeypox, which serves as a model for human smallpox infection. These studies were conducted with leading government and non-government research organizations, including The U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), The Centers for Disease Control and Prevention (CDC), The National Institute of Virology (NIV), The Battelle Biomedical Research Center (BBRC) and The Southwest Foundation for Biomedical Research (SFBR).

Aethlon also disclosed that it may pursue investigate Humanitarian Use Device (HUD) pathways for orphan indications that affect fewer than 4,000 individuals in the U.S. each year.

About Aethlon Medical
Aethlon Medical creates medical devices that target unmet therapeutic needs in infectious disease and cancer. The company's lead product is the Aethlon Hemopurifier®, a first-in-class device that selectively targets the rapid elimination of circulating viruses and tumor-secreted exosomes that promote cancer progression. Exosome Sciences, Inc. is a majority owned subsidiary that is advancing exosome-based products to diagnose and monitor cancer, infectious disease and neurological disorders. Additional information can be found online at www.AethlonMedical.com or www.ExosomeSciences.com.

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 ESI will not be able to commercialize its

future products, 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 of the Aethlon ADAPT™ 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 or as a broad spectrum defense against viral pathogens, 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, the ability of the Company to meet the milestones contemplated in the DARPA contract, 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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