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Aethlon Medical Announces Approval of Ebola Treatment Protocol

SAN DIEGO, Jan. 2, 2015 /PRNewswire/ -- Aethlon Medical, Inc. ([AEMD](#)), the pioneer in developing targeted therapeutic devices to address infectious diseases and cancer, today announced that the United States Food and Drug Administration (FDA) has approved a clinical protocol to treat Ebola-infected individuals in the U.S. with the Aethlon Hemopurifier®. In the treatment of viral pathogens, the Hemopurifier® is a first-in-class bio-filtration device designed for the single-use removal of viruses and shed glycoproteins from the circulatory system of infected individuals. The device targets antiviral drug resistance and serves as a first-line countermeasure against Ebola and other viruses that are not addressed with proven drug therapies.



The approved Ebola treatment protocol allows for an investigational study to be conducted at up to 10 U.S. clinical sites, and up to 20 U.S. subjects may be enrolled to receive the treatment protocol. Patients who meet the enrollment criteria will receive a daily six to eight hour administration of Hemopurifier® therapy until the point that Ebola viral load drops below 1000 copies/ml. The goal of the study is to standardize and evaluate the use of the Hemopurifier® as supportive care in the treatment of Ebola virus disease.

The Ebola treatment protocol resulted from the submission of a supplement to an Investigation Device Exemption (IDE) previously approved by FDA. The supplement was entitled, "Treatment of Ebola Virus Disease (EVD) in Humans with the Aethlon Hemopurifier® Lectin Affinity Plasmapheresis Device." Based on the previously approved IDE protocol, Aethlon is conducting a clinical feasibility study of Hemopurifier® therapy in individuals infected with Hepatitis C virus (HCV) who are also receiving chronic dialysis therapy. A detailed description of the HCV study, including treatment protocol and patient

inclusion/exclusion criteria can be accessed online at www.clinicaltrials.gov.

As the approved Ebola treatment protocol is a deviation from the HCV protocol, Aethlon is required to clearly distinguish data collected in the supplemental Ebola protocol study from data derived from the Company's HCV trials. The Company may not combine data from the two studies. Aethlon must also comply with specified patient protection procedures established by the applicable institution including its institutional review board approval prior to treating a patient under the supplement protocol. The Company must also report any unanticipated adverse events resulting from the supplement protocol to the FDA within 10 working days of the use of the device. There is no assurance that any Ebola-infected patients will be treated under the protocol.

Aethlon previously reported that Hemopurifier® therapy was successfully administered to a critically-ill Ebola patient at Frankfurt University Hospital in Germany. On November 14, 2014, the resulting Hemopurifier® treatment data was presented at the [American Society of Nephrology \(ASN\) Annual Meeting](#) by Helmut Geiger, M.D., Chief of Nephrology at Goethe University, Frankfurt University Hospital. Dr. Geiger reported that 242 million Ebola viruses were captured within the Hemopurifier® during treatment, a number verified by a post-treatment elution protocol. The elution protocol has since be repeated, which resulted in second measurement of 253 million copies of Ebola virus captured within the Hemopurifier®.

Dr. Geiger also reported that the patient's viral load prior to the administration of a single 6.5-hour Hemopurifier® treatment was measured at 400,000 virus copies per milliliter of blood (copies/ml). A post-treatment viral load measurement was reported to be 1,000 copies/ml. The treatment was well tolerated with no adverse events reported. At the time of treatment, the Ebola patient was unconscious and suffering from multiple organ failure, which required mechanical ventilation, continuous dialysis and the administration of vasopressor medications. The patient has since made a full recovery and returned home to his family.

Time Magazine recently named the Aethlon Hemopurifier® to be one of the 25 best inventions of 2014. The magazine also included the Hemopurifier® as one of the 11 most remarkable advances in healthcare in 2014.

About Aethlon Medical, Inc.

Aethlon Medical creates targeted therapeutic devices to address infectious disease, cancer and neurodegenerative disorders. 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. For more information, please visit <http://www.aethlonmedical.com/> and connect with the Company on [Twitter](#), [LinkedIn](#), [Facebook](#) and [Google+](#).

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, including Ebola, 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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