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Aethlon Medical® Reports Rapid and Sustained Virologic Response Rates in Hepatitis C (HCV) Treated Patients

SAN DIEGO, Dec. 2, 2014 /PRNewswire/ -- Aethlon Medical, Inc. (OTCQB:AEMD), the pioneer in developing targeted therapeutic devices to address infectious disease and cancer, today reported final clinical outcomes, including rapid virologic response (RVR) and sustained virologic response (SVR) rates, in Hepatitis-C virus (HCV) infected individuals who received Hemopurifier® therapy during a clinical study conducted at the Medanta Medicity Institute in India. Aethlon is now preparing to launch its first human clinical studies in the United States.

The Aethlon Hemopurifier® is a first-in-class bio-filtration device that targets the rapid elimination of viruses and immunosuppressive proteins from the circulatory system of infected individuals. The device is a leading broad-spectrum treatment countermeasure against viral pathogens that are not treatable with drug or vaccine therapies. In HCV care, the device is positioned to address antiviral drug resistance and hard-to-treat patients who are unable to tolerate normally administered doses of antiviral drugs or peginterferon+ribavirin (PR) therapy. It is estimated that approximately 170 million people worldwide are infected with HCV, which leads to chronic liver disease or cirrhosis, and is a leading cause of liver transplantation.

In addition to reporting RVR and SVR rates, Aethlon disclosed that it achieved the following clinical objectives of the HCV study:

- To demonstrate that Hemopurifier® therapy could be administered safely in non-dialysis patients who were infected with HCV.

- To demonstrate the ability to combine Hemopurifier® therapy with an established therapeutic drug regimen.
- To demonstrate that the brief inclusion of Hemopurifier® therapy can improve the normally expected benefit of a therapeutic drug regimen.
- To establish an elution protocol that allows researchers to quantify the number of viruses captured within the Hemopurifier® during a single treatment.

In the study, HCV-infected individuals were enrolled to receive three six-hour Hemopurifier® treatments during the first three days of a 48-week peginterferon+ribavirin (PR) treatment regimen. The study was conducted under the leadership of Dr. Vijay Kher at the Medanta Medicity, a multi-specialty medical institute established to be a premier center for medical tourism in India. Aethlon reported that Hemopurifier® therapy was well tolerated and without device-related adverse events in twelve treated patients. Of these twelve patients, ten completed the Hemopurifier-PR treatment protocol, including eight genotype-1 patients and two genotype-3 patients. Eight of the ten patients (n=8/10) achieved a sustained virologic response (SVR), which is the clinical definition of treatment cure and is defined as undetectable HCV RNA 24-weeks after the completion of the 48-week PR drug regimen. Both genotype-3 patients achieved a SVR (n=2/2), while six of the eight genotype-1 patients achieved a SVR (n=6/8)

Of the ten patients that completed the full treatment protocol, five (n=5/10) also achieved a rapid virologic response (RVR), defined as undetectable HCV RNA at day 30 of therapy. RVR represents the clinical endpoint that best predicts SVR cure rates resulting from PR therapy. As a point of reference, the landmark IDEAL Study of 3,070 HCV genotype-1 patients documented that 10.35% (n=318/3070) of PR treated patients achieved a RVR. Patients that achieved a RVR had SVR rates of 86.2% (n=274/318) versus SVR rates of 32.5% (n=897/2752) in non-RVR patients. Aethlon also disclosed that two of the genotype-1 patients who achieved a RVR also achieved an immediate virologic response (IVR), defined as undetectable HCV RNA seven days after initiation of Hemopurifier-PR treatment protocol. The incidence of IVR was not reported in the IDEAL study.

Data from two patients was not included in the reported Hemopurifier-PR dataset. One of these patients was a genotype-5 patient who discontinued PR therapy at day 180, yet still achieved a SVR. The second patient was a genotype-3 patient who also achieved a SVR, yet was unable to tolerate PR therapy and discontinued therapy at day-90. Overall, ten of the twelve patients (n=10/12) who enrolled in the study achieved a SVR and seven of the twelve (n=7/12) patients achieved an RVR.

Aethlon further disclosed that it established an elution protocol during the study that allowed researchers to quantify the number of viruses captured within the Hemopurifier® during a single treatment. As a result, researchers were able the measure that as many as 300 billion copies of HCV had been captured during a single six-hour treatment.

Aethlon is now preparing to launch the first U.S. clinical Hemopurifier® based on the United States Food and Drug Administration's (FDA)'s approval of an Investigational Device Exemption (IDE). The study, which will be conducted at the DaVita MedCenter Dialysis in Houston, Texas, will contribute safety data to support the advancement of Hemopurifier® therapy as a broad-spectrum countermeasure against bioterror and pandemic threats and chronic viral pathogens such as HIV and HCV. Hemopurifier® therapy is available to treat Ebola patients in the U.S. through FDA expanded access "emergency use" provisions to

address life threatening circumstances for which an alternative therapy is not available. At present, no antiviral therapy or vaccine has proven to be effective against Ebola virus infection in humans.

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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