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Aethlon Medical Announces The Conclusion Of Hemopurifier Clinical Study

The Technology is a Candidate to Treat Emerging Bioterror and Pandemic Threats

SAN DIEGO, March 13, 2017 /PRNewswire/ -- Aethlon Medical, Inc. (Nasdaq: AEMD), a therapeutic technology company focused on unmet needs in global health and biodefense, announced today that the company has concluded an FDA-approved feasibility study designed to assess the safety of the Aethlon Hemopurifier® in health-compromised individuals. The single-site study was conducted at DaVita Med Center Dialysis in Houston, Texas.

The Hemopurifier is a first-in-class medical device that reduces the presence of circulating viruses in infected individuals. The technology is a first-line candidate defense against a broad-spectrum of viruses that are not addressed with antiviral drug therapies, including natural occurring pandemic threats and agents of bioterrorism. Additionally, the device provides a strategy to augment the benefit of proven antiviral drug regimens.

The Hemopurifier had previously been administered to individuals infected with Hepatitis C virus (HCV), HIV and the Ebola virus, for which it was approved by the FDA under Emergency-Use Authorization.

In the feasibility study, the Hemopurifier was observed to be well tolerated in End-Stage Renal Disease (ESRD) volunteers who were also infected with Hepatitis C virus (HCV). The inclusion of HCV-infected ESRD subjects served as a model to demonstrate virus reduction. No device-related adverse events were observed in enrolled subjects who met the study inclusion/exclusion criteria.

The study originally was estimated to enroll ten subjects, but was concluded after the treatment of eight subjects based on the Hemopurifier being well-tolerated in the study, the breadth of previous human treatment experiences and the absence of qualified HCV-infected ESRD candidates at the study location.

"We achieved our primary study objective, which was to demonstrate that our Hemopurifier can be safely administered to very health-compromised individuals," stated Jim Joyce, Chairman and CEO of Aethlon Medical. "We will now proceed to submit a final report and look forward to collaborating with our FDA review team to establish market clearance pathways to treat viral threats that are not well addressed with traditional drug therapies."

In preclinical studies, the Hemopurifier has been demonstrated to capture a wide-range of bioterror and pandemic threats that are not addressed with antiviral drug therapies.

Aethlon believes the device can fulfill the broad-spectrum medical countermeasure objective of the U.S. Department of Health and Human Services (HHS) Public Health Emergency Medical Countermeasure Enterprise (PHEMCE). This initiative is directed toward bioterror, pandemic threats and other pathogens that are not well addressed with drug or vaccine therapies.

The Company also seeks to advance the Hemopurifier under the provisions of the 21st Century Cures Act, which was signed into law in December 2016. The Act establishes new rules that direct the FDA to approve drugs and devices with greater urgency. Specific to medical devices, the Act requires the FDA to establish a priority review program for "breakthrough" devices, or for devices that target diseases for which no FDA-cleared or approved alternatives are available.

About The Study Protocol

The study was a single-arm, sequential, controlled feasibility/safety study in which each enrolled subject served as his/her own control. The control period was the week immediately preceding the administration of Hemopurifier therapy, during which eligible subjects were monitored during three standard intermittent hemodialysis sessions, which are required to maintain the life of ESRD patients. Collected data points included vital signs, blood chemistries, hematology and liver function. On weeks two and three, enrolled subjects received the administration of Hemopurifier® therapy three times per week (6-Hemopurifier treatments in total) coincident with their ongoing standard intermittent hemodialysis treatments. During these two weeks, subjects were assessed for the same clinical parameters as during the control period. The collected data will be included in a final report to be provided to FDA. The final report will also include observations of viral load reduction during treatment, as well as a quantitative post-treatment assessment of total viruses captured within the Hemopurifier.

About Aethlon Medical, Inc.

Aethlon Medical develops immunotherapeutic technologies to combat infectious disease and cancer. To augment the body's natural immune defenses, the Aethlon Hemopurifier® reduces the presence of circulating viruses in infected individuals. The technology provides a first-line candidate defense against viruses that are not addressed with proven drug therapies, including naturally occurring pandemic threats and agents of bioterrorism. The Hemopurifier® can also be deployed as a strategy to improve the benefit of approved antiviral drug regimens. At present, the Hemopurifier® is being advanced in the United States under an FDA approved clinical study. Aethlon Medical is also investigating the potential use of the Hemopurifier® to reduce the presence of tumor-derived exosomes, which contribute to immune-suppression and the spread of metastasis in cancer patients. Aethlon Medical is also the majority owner of Exosome Sciences, Inc. (ESI), which is focused on the discovery of exosomal biomarkers to diagnose and monitor cancer and neurological disorders, including Alzheimer's disease (AD) and Chronic Traumatic Encephalopathy (CTE). ESI's TauSome™ biomarker is being clinically evaluated as the basis for a blood-based test to identify CTE in living individuals. Additional information can be found online at www.AethlonMedical.com and www.ExosomeSciences.com. You can also connect with us on Twitter, LinkedIn, Facebook and Google+.

This press release contains forward-looking statements within the meaning of Section 27A

of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 that involve risks and uncertainties. Statements containing words such as "may," "believe," "anticipate," "expect," "intend," "plan," "project," "will," "projections," "estimate," or similar expressions constitute forward-looking statements. Such forward-looking statements are subject to significant risks and uncertainties and actual results may differ materially from the results anticipated in the forward-looking statements. Factors that may contribute to such differences include, without limitation, the Company's ability to maintain its listing on the Nasdaq Capital Market, or any other national securities exchange, that the Company or its subsidiary will not be able to commercialize its products, including any CTE-related products, that the FDA will not approve the initiation or continuation of the Company's clinical programs or provide market clearance of the Company's products, including clearance through the 21st Century Cures Act, 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, the impact of government regulations, patent protection on the Company's proprietary technology, the ability of the Company to meet the milestones contemplated in its contract with DARPA, product liability exposure, uncertainty of market acceptance, competition, technological change, and other risk factors. The foregoing list of risks and uncertainties is illustrative, but is not exhaustive. Additional factors that could cause results to differ materially from those anticipated in forward-looking statements can be found under the caption "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended March 31, 2016, and in the Company's other filings with the Securities and Exchange Commission. Except as may be required by law, the Company does not intend, nor does it undertake any duty, to update this information to reflect future events or circumstances.

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To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/aethlon-medical-announces-the-conclusion-of-hemopurifier-clinical-study-300422200.html>

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