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Aethlon Medical Treats Second Patient in Australian Hemopurifier® Cancer Trial

Second Patient in first cohort enrolled and treated at the Royal North Shore Hospital/University of Sydney

Aethlon Advances Hemopurifier® Study in Solid Tumors Not Responding to Anti-PD-1 Antibodies

SAN DIEGO, June 18, 2025 /PRNewswire/ -- Aethlon Medical, Inc. (Nasdaq: AEMD), a medical therapeutic company focused on developing products to treat cancer and life-threatening infectious diseases, today announced a significant milestone: the treatment of the second patient with the Hemopurifier in its Australian safety, feasibility and dose-finding clinical trial of the Hemopurifier. This trial is designed for patients with solid tumors who have stable or progressive disease during anti-PD-1 monotherapy treatment, such as Keytruda® (pembrolizumab) or Opdivo® (nivolumab) (AEMD-2022-06 Hemopurifier Study). The patient was treated with the Hemopurifier June 11, 2025 by Genesis Care and Royal North Shore Hospital/University of Sydney. Professor Stephen Clarke, Medical Oncologist, is the Principal Investigator for the study and the Hemopurifier session was supervised by Dr. Emma O'Lone.

Ongoing progress has been made in our Australian Oncology trial of the Hemopurifier in participants with solid tumors not responding to anti-PD-1 agents. We have now completed Hemopurifier treatments in 2 participants in the first cohort. Our first participant completed the Hemopurifier treatment at Royal Adelaide Hospital on January 29, 2025. Participant # 2 was treated with the Hemopurifier at Royal North Shore/University of Sydney on June 2, 2025. Both participants completed the 4-hour Hemopurifier treatment without device deficiencies or immediate complications. As of June 10, 2025, both patients have completed the pre-specified 7-day safety follow-up period that will be presented to an independent Data Safety Monitoring Board (DSMB) following the treatment of a third patient in the cohort.

The DSMB will review safety data on this first cohort and provide a recommendation to Aethlon Medical Senior Leadership about advancing to the second treatment cohort where 3 participants will receive 2 Hemopurifier treatments during a one-week period. We would expect data on extracellular removal by the Hemopurifier and effects on anti-tumor T cell activity on participants in the first cohort in approximately three months following enrollment of the third patient.

"We are pleased that both patients treated with the Hemopurifier thus far have tolerated the 4-hour treatment without immediate complications. We look forward to enrolling the third participant to trigger a safety review of the first cohort by the DSMB," stated Steven LaRosa, MD, Chief Medical Officer of Aethlon Medical.

Currently, only approximately 30-40% of patients who receive pembrolizumab or nivolumab will have lasting clinical responses to these agents. EVs produced by tumors have been implicated in the spread of cancers as well as the resistance to anti-PD-1 therapies. The Aethlon Hemopurifier has been designed to bind and remove these EVs from the bloodstream, which may improve therapeutic response rates to anti-PD-1 antibodies. In preclinical studies, the Hemopurifier has been shown to reduce the number of exosomes from the plasma of cancer patient samples.

The primary endpoint of the approximately 18-patient, safety, feasibility, and dose-finding trial is the incidence of adverse events and clinically significant changes in safety lab tests of Hemopurifier treated patients with solid tumors with stable or progressive disease at different treatment intervals, after a two-month run-in period of PD-1 antibody, Keytruda® or Opdivo® monotherapy. Patients who do not respond to the therapy will be eligible to enter the Hemopurifier period of the study where sequential cohorts will receive 1, 2, or 3 Hemopurifier treatments during a one-week period. In addition to monitoring safety, the study is designed to examine the number of Hemopurifier treatments needed to decrease the concentration of EVs and if these changes in EV concentrations improve the body's own natural ability to attack tumor cells. These exploratory central laboratory analyses are expected to inform the design of a subsequent efficacy and safety, Premarket Approval (PMA), study required by regulatory agencies**.**

About the Hemopurifier®

The Aethlon Hemopurifier is an investigational medical device designed to remove enveloped viruses and tumor-derived extracellular vesicles from circulation. The Hemopurifier is an extracorporeal device that is used in concert with a blood pump. The device incorporates plasma separation, size exclusion, and affinity binding to an affinity resin containing a plant lectin. Mannose on the surface of enveloped viruses and extracellular vesicles binds to the plant lectin within the device. Extracellular vesicles released from solid tumors have been implicated in the spread of cancers known as metastasis as well as in the resistance to immunotherapy and chemotherapeutic agents. Removal of enveloped viruses and extracellular vesicles has been observed in in vitro studies and in human subjects. The Hemopurifier holds a U.S. Food and Drug Breakthrough Device for the treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard-of-care therapy. The Hemopurifier also holds an FDA Breakthrough Device designation and an open Investigational Device Exemption (IDE) application related to the treatment of life-threatening viruses that are not addressed with approved therapies.

About Aethlon Medical, Inc.

Aethlon Medical, Inc. is a publicly traded medical device company based in San Diego, California. The company aims to leverage its therapeutic device, The Hemopurifier, to remove enveloped viruses and extracellular vesicles from biologic fluids. Aethlon Medical's innovative platform is enabling the development of new options for cancer and life-threatening infectious diseases. For more information on Aethlon Medical, Inc. and its clinical development program, visit www.AethlonMedical.com and follow the company on LinkedIn.

Forward Looking Statements

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," "potentially" 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. These forward-looking statements are based upon Aethlon's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Factors that may contribute to such include, without limitation, the number of patients who receive pembrolizumab or nivolumab that will have lasting clinical responses to these agents; device deficiencies or immediate complications; the possibility of novel treatment strategies; how the Hemopurifier may reduce tumor-derived extracellular vesicles and enhance T cell activity against tumors; the efficacy of continued clinical trials; and/or the number of patients enrolled in each cohort. 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, 2024, and in the Company's other filings with the Securities and Exchange Commission, including its quarterly Reports on Form 10-Q. All forward-looking statements contained in this press release speak only as of the date on which they were made. 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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