

January 29, 2025



# Aethlon Medical Treats First Patient in Australian Hemopurifier® Cancer Trial

*First Patient enrolled and treated at the Cancer Clinical Trial Unit, CALHN, Royal Adelaide Hospital*

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

SAN DIEGO, Jan. 29, 2025 /PRNewswire/ -- [Aethlon Medical, Inc.](https://www.aethlonmedical.com) (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 first 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 enrolled on October 29, 2024, by Prof. Michael Brown and his staff at the Cancer Clinical Trials Unit, CALHN, Royal Adelaide Hospital in Australia, and treated with the Hemopurifier on January 29, 2025, by Prof. Toby Coates and the dialysis staff.

The patient treated was determined to have progressive disease following a two-month "run-in" period of the anti-PD-1 drug Nivolumab. During this period, serial measurements of extracellular vesicles (EVs) and anti-tumor T cell activity were obtained. The patient was then treated with the Aethlon Hemopurifier for 4 hours on a single day and tolerated the procedure without complications. The patient will have follow-up safety visits, EV and T cell measurements as well as imaging for clinical response.

"Treatment of the first patient represents the achievement of a critical milestone for Aethlon Medical in the clinical development of the Hemopurifier in Oncology," stated Steven LaRosa, MD, Chief Medical Officer of Aethlon Medical. "We are excited to receive the data from this first treatment cohort, anticipating insights into how the Hemopurifier may reduce tumor-derived extracellular vesicles and enhance T cell activity against tumors".

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](http://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; 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. 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, 2023, 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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