

November 11, 2024



Aethlon Medical Reaches Key Milestone with Enrollment of the First Patient in (FPI) Its Hemopurifier® Cancer Trial in Australia

Patient Enrolled at the Cancer Clinical Trial Unit, CALHN, Royal Adelaide Hospital

Aethlon's Trial is a Safety, Feasibility, and Dose Finding Study of the Hemopurifier® in Patients with Solid Tumors Not Responding to Anti-PD-1 Antibodies

SAN DIEGO, Nov. 11, 2024 /PRNewswire/ -- [Aethlon Medical, Inc.](#) (Nasdaq: AEMD), a medical therapeutic company focused on developing products to treat cancer and life-threatening infectious diseases, today announced enrollment of the first patient in its Australian safety, feasibility and dose-finding clinical trial of the Hemopurifier® in 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.

The first patient completed screening activities confirming their eligibility on November 8, 2024, and has now entered a two-month run-in period, receiving anti-PD-1 therapy. During this time, concentrations of Extracellular vesicles (EVs) and anti-tumor T cell activity will be measured. If imaging after this two-month run-in period reveals no improvement in the patient's tumor, they will be treated with the Hemopurifier, followed by monitoring to identify decreases in EV concentrations and improvements in T cell anti-tumor activity.

"Enrollment 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 thrilled with the pre-screening activity being done to identify patients at Royal Adelaide, as well as the second site, Pindara Private Hospital in the Gold Coast. We are grateful to the patient for consenting to be part of this study. This trial is our initial step in determining if the Hemopurifier treatment can improve upon the 30-40% response rates to anti-PD-1 therapies such as Opdivo and Keytruda."

Currently, only approximately 30% 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 nine to 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 Aethlon and the Hemopurifier®

Aethlon Medical is a medical therapeutic company focused on developing the Hemopurifier, a clinical stage immunotherapeutic device which is designed to combat cancer and life-threatening viral infections and for use in organ transplantation. In human studies, the Hemopurifier has demonstrated the removal of life-threatening viruses and in pre-clinical studies, the Hemopurifier has demonstrated the removal of harmful exosomes from biological fluids, utilizing its proprietary lectin-based technology. This action has potential applications in cancer, where exosomes may promote immune suppression and metastasis, and in life-threatening infectious diseases. The Hemopurifier is a U.S. Food and Drug Administration (FDA) designated Breakthrough Device indicated for the treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard of care therapy, and with cancer types in which exosomes have been shown to participate in the development or severity of the disease. 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.

Additional information can be found at www.AethlonMedical.com.

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 differences include, without limitation, the Company's ability to raise additional capital on terms favorable to the Company, or at all; the Company's ability to successfully complete development of the Hemopurifier; the Company's ability to successfully demonstrate the utility of the Hemopurifier in patients with solid tumors in our oncology clinical trials; the Company's ability to achieve and realize the anticipated benefits from potential milestones; the Company's ability to obtain approval from the Ethics Committee of its third location in Australia, including on the timeline expected by the Company; the Company's ability to enroll additional patients in its oncology clinical trials in Australia and India, including on the

timeline expected by the Company; whether or not patients that are enrolled in the Company's clinical trials will respond to PD-1 antibody monotherapy; the number of patients that are enrolled in the Company's clinical trials that will ultimately be treated with the Company's Hemopurifier; the Company's ability to manage and successfully complete its clinical trials; the Company's ability to successfully manufacture the Hemopurifier in sufficient quantities for its clinical trials; and other potential risks. 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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