

June 18, 2024



# Aethlon Medical Receives Ethics Committee Approval for Hemopurifier® Cancer Trial

*Aethlon Medical Granted Full Ethics Approval From the Human Research Ethics Committee at Central Adelaide Local Health Network for a Safety, Feasibility, and Dose Finding Study of its Hemopurifier® in Cancer Patients with Solid Tumors Not Responding to Anti-PD-1 Antibodies*

SAN DIEGO, June 18, 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 that, on June 13, 2024, the Human Research Ethics Committee (HREC) of the Central Adelaide Local Health Network (CALHN) granted full ethics approval for Aethlon's safety, feasibility and dose-finding clinical trial of the Hemopurifier® in cancer 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 approval is valid for three years, until June 13, 2027. The trial will be conducted by Prof. Michael Brown and his staff at the Cancer Clinical Trials Unit, CALHN, Royal Adelaide Hospital, located in Adelaide, Australia.

Currently, only approximately 30% of patients who receive pembrolizumab or nivolumab will have lasting clinical responses to these agents. Extracellular vesicles (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 approval from the Human Research Ethics Committee at Central Adelaide Local Health Network marks a significant milestone for Aethlon, as they deemed that our clinical study meets the requirements of the Australia's National Statement on Ethical Conduct in Human Research," stated Steven LaRosa, MD, Chief Medical Officer of Aethlon Medical. "We look forward to working closely with Prof. Brown and his staff, and with our Contract Research Organizations, NAMSA and ReSQ Clinical Research. The next steps include submission to the Therapeutic Goods Administration, the national health regulatory agency of Australia, obtaining approval from the CALHN Research Governance Committee, and conducting a site initiation visit to facilitate patient enrollment. Following this Ethics Board approval, we plan to submit to the Ethics Committees at two additional sites in Australia and one in India."

The primary endpoint of the approximate 18-patient, safety, feasibility and dose-finding trial is safety. The trial will monitor any adverse events and clinically significant changes in 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](http://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 successfully complete development of the Hemopurifier and to successfully demonstrate the utility of the Hemopurifier in patients with solid tumors in our planned oncology clinical trials, the Company's ability work with the requisite personnel and complete the next steps to facilitate patient enrollment, the Company's ability to submit additional studies and obtain the approval by the additional respective Ethics Boards of interested clinical trial sites in India and in Australia, the Company's ability to recruit patients for and manage 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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