

September 19, 2024



Aethlon Receives Ethics Committee Approval for Hemopurifier® Cancer Trial in India

Aethlon Medical Granted Full Ethics Approval from the Medanta Institutional Ethics Committee 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, Sept. 19, 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 September 9, 2024, the Medanta Institutional Ethics Committee (MIEC) 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 one year, followed by annual reviews. This trial has previously been reviewed by the Institutional Review Board at Medanta. Additionally, the company previously received a No Objection Certificate (NOC) from DCGI (the Indian Regulatory Authority) for the proposed oncology trial. The trial will be conducted by Dr. Ashok K. Vaid and his staff at the Department of Medical Oncology and Hematology at Medanta Medicity Hospital in Gurugram, India. The Hemopurifier treatments will be performed by Dr. Puneet Sodhi from the Department of Nephrology, who has conducted more Hemopurifier treatments than anyone else in the world.

"The approval from the MIEC, coming closely on the heels of our two ethics committee approvals in Australia, to conduct this early feasibility study, is another important step in our plan to evaluate use of the Hemopurifier as a treatment option in multiple tumor types, where cancer associated exosomes may promote immune suppression and metastasis," stated Steven LaRosa, MD, Chief Medical Officer of Aethlon Medical. "We are very pleased that the MIEC accepted our study protocol and look forward to working, again, with Medanta Hospital with the expectation of recruiting patients in the fourth calendar quarter of this year. We believe that the planned safety, feasibility and dose finding trial, taking place in both India and Australia, in solid tumors in patients failing treatment with anti-PD-1 antibodies, will help inform future oncology efficacy trails."

At present, only approximately 30% of cancer patients who receive pembrolizumab or nivolumab treatment for solid tumors will have lasting clinical responses to these agents. Extracellular vesicles (EVs) produced by tumors have been implicated in resistance to anti-PD-1 therapies as well as the spread of cancers. 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 EVs in cancer patient plasma samples.

The primary endpoint of the approximately nine to 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 PD-1 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 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 to recruit patients for and manage its clinical trials and studies; the results of the safety, feasibility and dose finding study; unforeseen changes in regulatory requirements; 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, 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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