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Aethlon Medical, Inc. Announces Positive Data Safety Monitoring Board Review and Recommendation to Advance to Next Clinical Trial Cohort

SAN DIEGO, July 15, 2025 /PRNewswire/ -- Aethlon Medical, Inc. (Nasdaq: AEMD), a clinical-stage biotechnology company developing the investigational Aethlon Hemopurifier®, an extracorporeal device for Oncology and other indications, today announced that the independent Data Safety Monitoring Board (DSMB) overseeing its ongoing clinical trial AEMD-2022-06 has completed its scheduled safety review and recommended advancing to the next patient cohort without modification.

The trial, titled "Safety, Feasibility, and Dose-Finding Study of Aethlon Hemopurifier in Patients with Solid Tumors Who Have Stable or Progressive Disease While on a Treatment That Includes Pembrolizumab or Nivolumab", is being conducted to assess the Hemopurifier's safety, feasibility, and optimal dosing.

The DSMB- comprising independent medical experts in nephrology and oncology- reviewed data from the initial cohort of three participants, each of whom received a single 4-hour Hemopurifier treatment. Based on their evaluation, the board found no safety concerns and confirmed that the Hemopurifier continues to demonstrate a favorable safety and tolerability profile. To date, no serious adverse events (SAEs) or Dose-Limiting Toxicities (DLTs) related to the Hemopurifier have been reported.

"The DSMB's positive recommendation is encouraging and underscores the favorable safety profile observed to date in patients with cancer," according to Steven LaRosa, M.D, Chief Medical Officer of Aethlon Medical. "This marks a significant step forward in the clinical development program for the Hemopurifier in Oncology and brings the company closer to potentially addressing the significant unmet medical need for the approximately 60-70% of patients with cancer who do not experience a lasting clinical response to anti-PD-1 immunotherapy."

Enrollment for Cohort 2 is now open. In this phase, participants will receive two Hemopurifier treatments over a one-week period at the study's three active clinical sites in Australia. This trial, which aims to enroll approximately 9 to 18-patients, is designed to evaluate the safety, feasibility of administering the Hemopurifier at varying dosing intervals in patients with solid tumors who have stable or progressive disease, while receiving treatment that includes Pembrolizumab (Keytruda®) or Nivolumab (Opdivo®).

The primary endpoint of this trial is the incidence of adverse events and clinically significant changes in safety laboratory tests of Hemopurifier- treated patients. In addition to safety monitoring, 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 findings are expected to inform the design of a future efficacy and safety, Premarket Approval (PMA), study required by regulatory authorities.

Aethlon Medical, Inc. remains committed to advancing the Hemopurifier for use in oncology and will continue to provide updates as the clinical trial progresses.

About the Hemopurifier®

The Aethlon Hemopurifier is an investigational medical device designed to remove enveloped viruses and tumor-derived extracellular vesicles (EVs) from circulation. It is used extracorporeally with a blood pump and combines plasma separation, size exclusion, and affinity binding using a plant lectin resin that targets mannose-rich surfaces found on EVs and viruses. EVs released by solid tumors are believed to play a role in metastasis and the resistance to immunotherapies and chemotherapy. Removal of enveloped viruses and extracellular vesicles has been demonstrated in both vitro studies and human subjects.

The Hemopurifier holds a U.S. Food and Drug Breakthrough Device for:

- The treatment of individuals with advanced or metastatic cancer unresponsive to or intolerant of standard-of-care therapy; and
- The treatment of life-threatening viruses not addressed with approved therapies.

The Hemopurifier is being developed under an open Investigational Device Exemption (IDE) for both indications.

About Aethlon Medical, Inc.

Aethlon Medical, Inc. (Nasdaq: AEMD) is a clinical stage medical device company headquartered in San Diego, California. Aethlon is advancing the Hemopurifier, to address unmet needs in oncology and infectious disease, using a novel platform designed to selectively remove circulation pathogenic targets from biologic fluids. For more information 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; development under IDE for indications; 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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