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Aethlon Medical's Hemopurifier® shows Changes in Extracellular Vesicles, Extracellular MicroRNAs, and T Cell Numbers in Australian Oncology Clinical Trial

SAN DIEGO, Oct. 7, 2025 /PRNewswire/ -- Aethlon Medical, Inc. ("Aethlon" or the "Company") (Nasdaq: AEMD) today provided observations on the preliminary changes in extracellular vesicle (EV), microRNA and lymphocyte counts in the first patient cohort in its ongoing oncology clinical trial in Australia. The study is a safety, feasibility, and dose-finding trial evaluating the company's Hemopurifier (HP) in patients with cancer not responding to anti-PD-1 therapy.

"As we promised during our last earnings call, we are sharing early observations from our ongoing safety, feasibility, and dose-finding clinical trial of the Aethlon Hemopurifier, which is currently being evaluated in cancer patients in Australia," said James (Jim) Frakes, CEO and CFO of Aethlon Medical. In the initial three patients, there were encouraging changes in extracellular vesicles (EVs), microRNAs, and lymphocytes, following a single Hemopurifier treatment.

We observed interesting directional changes in EV numbers, microRNAs and lymphocytes following a single Hemopurifier treatment in the three participants in the first cohort. Additional data from the subsequent two cohorts will help determine whether these observations are reproducible, and whether there is a dose response with additional Hemopurifier treatments in terms of the magnitude and duration of the changes.

Additional details of these early observations are provided below:

- **EVs**: Two of the three participants in the trial showed decreases in large EVs also known as microvesicles. EVs are nanoparticles that are involved in cell-to-cell communication and are implicated in the spread of cancer (metastasis), growth of new blood vessels to the tumor, (angiogenesis), cell death (apoptosis), and inhibition of the body's T cells, which are important for killing tumor cells.
    - **Platelet Derived EVs:** Decreases were observed in large and small platelet-derived EVs in two of the three patients.
    - **EV PD-L1**: Decreases in the subset of large EVs carrying PD-L1 were observed in all three participants during the Hemopurifier treatment. Persistently elevated counts of EVs with PD-L1 have been associated with lack of response to anti-PD-1 agents.

- **MicroRNAs**: Following a single 4-hour HP treatment, decreases were observed in seven out of ten miRNAs examined in two of the three participants. MicroRNAs are one component of the cargo of extracellular vesicles, previously reported to promote cancer growth and metastasis.

  The EV and microRNA levels typically returned to pre-Hemopurifier treatment levels between 1 - 3 weeks.

- **Lymphocyte Counts:**
  - **Laboratory Ratios**: After a single 4-hour-treament, improvements in laboratory ratios associated with responses to immunotherapy including Neutrophil, Lymphocyte, Monocyte, Lymphocyte, Lymphocyte, Albumin and Systemic Immune-Inflammation were observed in at least two participants.

- **T cells and T cell subsets:** Increases were noted in total T cell numbers, CD8 and CD4 T cell subsets, and tumor specific T cells (CD137 +ve) in participants following Hemopurifier treatment without a consistent pattern in terms of timing of improvement.

Important Caveats:

- We are making these observations on three patients with one participant withdrawing from the study after 1 week due to cancer progression and thus supplying only limited follow-up data.
- The small number of participants allows for only "directional" descriptive statistics and not formal statistical analyses.
- These participants received only a single Hemopurifier treatment and thus we cannot make any statements about "dose response" i.e., will changes be greater or more long lasting with more treatments.
- There is heterogeneity within the data in terms of a) the number of Hemopurifier treated patients who experienced changes in the variables of interest, b) the magnitude of the changes observed, and (c) the timing and duration of the laboratory changes observed.

We cannot make any correlation between the changes observed above and the clinical efficacy of the Hemopurifier in cancer. These observations are from an early feasibility study and should not be interpreted as evidence of clinical benefit or safety beyond the study parameters. Determinations of the presence or absence of clinical efficacy can only be determined in a larger premarket approval or PMA trial specifically designed with this as the primary endpoint.

About the Hemopurifier®

The Aethlon Hemopurifier® is an investigational medical device designed to remove enveloped viruses, fragments of 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 viral proteins. EVs released by solid tumors are believed to play a role in metastasis and the resistance to immunotherapies and chemotherapy. Removal of enveloped viruses, fragments of viruses, and EVs has been demonstrated in both *in vitro* studies and in human patients.

The Hemopurifier® holds a U.S. Food and Drug Breakthrough Device Designation 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.

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. Forward-looking statements in this release include, among others, statements regarding: the potential safety, utility, or effectiveness of the Hemopurifier®; the Company's ability to enroll and complete clinical trials, including in Australia; the timing, scope, and outcomes of those studies; the Company's ability to obtain and maintain necessary regulatory approvals; manufacturing capacity for clinical and future commercial use; the availability of sufficient capital; and the Company's ability to advance research in cancer, infectious diseases, and other extracellular-vesicle-associated conditions. 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 and safety of the Hemopurifier in cancer and infectious diseases, COVID-19 and in the transplant setting; the Company's ability to achieve and realize the anticipated benefits from operational and financial milestones; the Company's ability to maintain its listing on Nasdaq, 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 trial in Australia, including on the timeline expected by the Company; 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; unforeseen changes in regulatory requirements; the Company's collaborative research with UCSF Long Covid Clinic; and the Company's ability to further research potential applications of the Hemopurifier in other EV-associated diseases, the ability of the Company to maintain its current Patents 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, 2025, 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. Because the Hemopurifier® is an investigational device, its safety and effectiveness have not been established, and no conclusions should be drawn regarding clinical benefit. These observations are from an early feasibility study and should not be interpreted as evidence of

clinical benefit or safety beyond the study parameters.

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