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Aethlon Receives Clearance From Drug Controller General of India For Potential Phase 1 Trial of its Hemopurifier® in Oncology

SAN DIEGO, Oct. 10, 2023 /PRNewswire/ -- Aethlon Medical, Inc. (Nasdaq: AEMD), a medical therapeutic company focused on developing products to treat cancer and life threatening viral infections and for use in organ transplantation, today announced that it has received clearance from the Drug Controller General of India (DCGI), the central drug authority in India, to conduct a phase 1 safety, feasibility and dose-finding trial of the company's Hemopurifier® in patients with solid tumors who have stable or progressive disease during anti-PD-1 monotherapy treatment, such as Keytruda® or Opdivo®. The trial is expected to begin following completion of an internal in vitro binding study of relevant targets, and subsequent approval by the respective Ethics Boards of interested sites in India.

"Receipt of clearance from the DCGI to conduct this early feasibility study is another important step in the progression of our plan to evaluate use of our Hemopurifier as a treatment option in multiple tumor types, where cancer associated extracellular vesicles may promote immune suppression and resistance to anti-PD-1 antibodies," stated Charles J. Fisher, Jr., M.D., Chief Executive Officer of Aethlon Medical. "We expect to begin patient recruitment once we have completed an internal in vitro binding study to confirm that relevant targets are bound by the Hemopurifier, and after we receive subsequent approval by the Ethics Boards of the interested sites for the trial in India. The planned oncology trial in India is designed to be a safety study in nine to 18 patients to examine three cohorts of Hemopurifier treatments in patients receiving pembrolizumab (Keytruda) or nivolumab (Opdivo) therapy as standard of care for their malignancy. The trial is designed to include multiple tumor types, as well as Hemopurifier dosing intervals, to help direct further development of the Hemopurifier for use in oncology.

The trial's primary endpoint will be to assess the safety and feasibility of the Hemopurifier-treated patients at different treatment intervals in patients with solid tumors with stable or progressive disease after 60 days of pembrolizumab or nivolumab monotherapy. Additionally, the effects of Hemopurifier treatment on the immune response to cancer will be assessed.

"Additionally, we continue to work with our contract research organization, North American Science Associates, LLC (NAMSA), to initiate a similar oncology clinical trial in Australia; specifically, a safety, feasibility and dose finding trial in solid tumors in patients failing treatment with anti-PD-1 antibodies. We believe these planned trials will help inform future oncology efficacy trials with our Hemopurifier," concluded Dr. Fisher.

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. In human studies, the Hemopurifier has demonstrated the removal of life-threatening viruses and harmful exosomes from blood 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 cancer and infectious diseases, the Company's ability to complete the internal binding study of relevant extracellular vesicles, the Company's ability to obtain the approval by the respective Ethics Boards of interested clinical trial sites in India and in Australia; the Company's ability to 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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