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Aethlon Medical Announces U.S. FDA Approval of Hemopurifier COVID-19 Study Protocol Amendment

Approval eliminates the requirement for previous dialysis treatment, potentially enabling accelerated enrollment in the ongoing clinical study

SAN DIEGO, July 11, 2022 /PRNewswire/ -- Aethlon Medical, Inc. (Nasdaq: AEMD), a medical therapeutic company focused on developing products to diagnose and treat cancer and life threatening infectious diseases, today announced that the U.S. Food and Drug Administration (FDA) has approved an amendment to the protocol of its ongoing clinical trial investigating the Aethlon Hemopurifier® for patients with severe COVID-19. The newly approved protocol amendment eliminates the inclusion criteria that patients must have a dialysis catheter in place and have tolerated dialysis at the time of screening.

"We are pleased that the FDA has approved our protocol amendment for the COVID-19 trial," said Charles J. Fisher, Jr., M.D., Chief Executive Officer of Aethlon Medical. "We anticipate that this protocol amendment will enable us to enroll patients at an increased rate now that dialysis treatment is no longer a study requirement. We look forward to providing access to this potentially life-saving therapy to patients in need."

The Aethlon Hemopurifier is a therapeutic blood filtration system that can bind and remove life-threatening viruses and harmful exosomes from blood. Aethlon is currently evaluating the safety and feasibility of the Hemopurifier in an active Early Feasibility Study (EFS), analogous to a Phase 1 clinical trial for a drug or biologic, which is designed to enroll up to 40 severe COVID-19 patients [NCT04595903]. Aethlon recently announced that the first patient has completed Hemopurifier treatment in the trial and that there are nine hospitals actively screening patients.

"We have learned from our study sites during screening, from data presentations and from thought leaders in the field that the incidence of COVID-19-induced kidney injury, resulting in the need for kidney replacement therapy (KRT), has decreased dramatically during the course of the pandemic," said Steven LaRosa, M.D., Chief Medical Officer of Aethlon Medical. "As such, we worked closely with the FDA to construct updated wording in the protocol and informed consent that allows patients to participate in the study who do not already require KRT yet still protects patient safety."

"This protocol amendment will need to be submitted by the investigative teams and approved by the IRB at each clinical site; a process that can take several months. It also remains to be seen if the prevailing COVID-19 variant BA.5 will result in increased ICU admissions; a requirement of the clinical study," continued Dr. LaRosa.

Aethlon is working with PPD, Inc., an established contract research organization (CRO), to advance this clinical study.

About Aethlon and the Hemopurifier®

Aethlon Medical is a medical technology company developing the Hemopurifier, a therapeutic blood filtration system indicated for infectious diseases and cancer. In human studies, the Hemopurifier has demonstrated the removal of life-threatening viruses and harmful exosomes from blood utilizing a 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. Under an Investigational Device Exemption (IDE) application, the FDA approved a single site, open-label Early Feasibility Study (EFS) to evaluate the Hemopurifier for reducing cancer-associated exosomes prior to the administration of standard-of-care pembrolizumab (KEYTRUDA®) in patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck. The EFS is being conducted at the University of Pittsburgh Medical Center Hillman Cancer Center.

The Hemopurifier also holds an FDA Breakthrough Device designation and an open IDE application related to the treatment of life-threatening viruses that are not addressed with approved therapies. A recent amendment to the IDE enabled Aethlon to implement a new EFS protocol to treat up to 40 COVID-19 patients at up to 20 clinical sites in the U.S. In two case studies of patients treated under Emergency Use (EU), the Hemopurifier demonstrated binding of SARS-CoV-2 spike protein and removal of SARS-CoV-2 virus from the circulation of a human patient.

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 enroll additional patients as a result of this protocol amendment, the Company's ability to enroll additional sites for its clinical trials, the Company's ability to enroll patients in and successfully complete its trials in COVID-19 patients and in its head and neck cancer trials, the Company's ability to successfully treat patients under any Emergency Use pathway, the Company's ability to

successfully complete development of its Hemopurifier, the Company's ability to raise additional funds, the Company's ability to expand its clinical trials into other areas of cancer, 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, 2022, 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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