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# Aethlon Medical Publishes Case Studies of Two Critically Ill COVID-19 Patients Treated with the Hemopurifier®

**-- Case studies demonstrate the successful removal of viral-associated exosomes in first patient and a 58% decrease of plasma SARS-CoV-2 viral load in the second patient.**

SAN DIEGO, June 3, 2021 /PRNewswire/ -- Aethlon Medical, Inc. (Nasdaq: AEMD), a medical device technology company focused on unmet needs in global health, today announced the publication of a pre-print manuscript highlighting two case studies of critically ill COVID-19 patients treated with the Aethlon Hemopurifier®. Both patients were given access to Hemopurifier® treatment through Emergency Use. The manuscript is titled ["Removal of COVID-19 Spike Protein, Whole Virus, Exosomes and Exosomal microRNAs by the Hemopurifier® Lectin-Affinity Cartridge in Critically Ill Patients with COVID-19 Infection"](#) and was published in *Research Square*.

The Hemopurifier® is a cartridge that is designed to filter viruses and exosomes from the blood. The manuscript describes the use of the Hemopurifier® for a total of nine sessions in two critically ill COVID-19 patients. Each of these two case studies is notable for unique reasons. The first is notable for the improvement in COVID-19 associated coagulopathy (CAC), lung injury, inflammation, and tissue injury despite the absence of demonstrable COVID-19 viremia (having demonstrated strong viremia earlier in the patient's disease cycle), indicating that the removal of exosomes contributed to the patient's recovery. This patient received eight Hemopurifier treatments without complications and eventually was weaned from a ventilator and was discharged from the hospital.

The second patient is notable for the first-ever demonstration of *in vivo* removal of SARS-CoV-2 virus from the blood stream of an infected patient. The patient completed a six hour Hemopurifier® treatment without complications and subsequently was placed on Continuous Renal Replacement Therapy (CRRT). The patient ultimately expired three hours after being placed on CRRT because of the advanced stage of the disease.

"The COVID-19 pandemic has affected the world over, prompting the need for innovative treatment approaches. We believe that the Hemopurifier® is such an innovation, as it is the only known device that can filter out exosomes, which are thought to play a role in the severity of infectious diseases like COVID-19," said Charles J. Fisher, Jr., CEO of Aethlon Medical and an author of the manuscript. "Given the success of the Hemopurifier® as a treatment for Ebola patients, we remain optimistic about our ongoing work in the treatment of COVID-19 patients. These two case studies indicate that the Hemopurifier® was successfully able to clear SARS-CoV-2 virus and associated exosomes from the blood

stream, resulting in a potential benefit for one of the critical COVID-19 patients that were treated."

In addition to the two case studies, the safety and feasibility of the Aethlon Hemopurifier® is being evaluated in an active Early Feasibility Study, analogous to a Phase 1 clinical trial for a drug or biologic, that will enroll up to 40 COVID-19 ICU patients [NCT04595903]. The pre-print manuscript is being submitted to peer reviewed journals, and Aethlon expects it to be published in the near future.

### **About Aethlon and the Hemopurifier®**

Aethlon is focused on addressing unmet needs in global health. The Aethlon Hemopurifier is a clinical-stage immunotherapeutic device designed to combat cancer and life-threatening viral infections. In cancer, the Hemopurifier is designed to deplete the presence of circulating tumor-derived exosomes that promote immune suppression.

The Hemopurifier® is an FDA designated "Breakthrough Device" related to 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, in October 2019, the FDA approved an Early Feasibility Study (EFS), which is the device equivalent of a Phase 1 clinical trial for a drug or biologic, in a single center, open label trial in 10 to 12 subjects. The study is evaluating the HEMOPURIFIER® for reducing cancer-associated exosomes prior to the administration of standard-of-care pembrolizumab (KEYTRUDA®), which is a first-line therapy for 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 a Breakthrough Device designation related to life-threatening viruses that are not addressed with approved therapies. In June 2020, the FDA approved an amendment to the Company's existing open IDE for the Hemopurifier in life threatening viral infections, to allow for the treatment of patients with SARS-CoV-2/COVID-19 infection. This will allow for up to 40 of these patients to be treated under a new Early Feasibility Study protocol at up to 20 clinical sites in the U.S.

Aethlon also owns 80% of Exosome Sciences, Inc., which is focused on the discovery of exosomal biomarkers to diagnose and monitor cancer and neurological disease progression. Additional information can be found online at [www.AethlonMedical.com](http://www.AethlonMedical.com) and [www.ExosomeSciences.com](http://www.ExosomeSciences.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 patients in and successfully complete the COVID-19 trial, 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, 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, 2020, 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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