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Aethlon Medical Announces Contracting with PPD to Advance Hemopurifier Clinical Programs

SAN DIEGO, Sept. 30, 2021 /PRNewswire/ -- Aethlon Medical, Inc. (Nasdaq: AEMD), a company developing medical technology to treat cancer and life-threatening infectious disease, today announced that it has entered into an agreement with [PPD, Inc.](#) (Nasdaq: PPD), a leading global contract research organization (CRO), for PPD to oversee the company's clinical studies investigating the Hemopurifier, Aethlon's therapeutic blood filtration system, for infectious disease indications.

Pursuant to the agreement, PPD will manage Aethlon's ongoing study of the Hemopurifier for patients who are critically ill with COVID-19 ([NCT04595903](#)). PPD and Aethlon also can agree to include additional studies under their agreement.

"Aethlon is committed to progressing the clinical development of the Hemopurifier," said Charles J. Fisher, M.D., Chief Executive Officer of Aethlon Medical. "PPD is a world class organization with significant experience operating clinical studies. Aethlon plans to move quickly to leverage this experience to advance our studies of the Hemopurifier in COVID-19 patients."

About Aethlon and the Hemopurifier®

Aethlon Medical is a biotechnology company developing the Hemopurifier, a therapeutic blood filtration system indicated for infectious diseases and cancer, as its lead technology. 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 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.

About PPD

PPD is a leading global contract research organization providing comprehensive, integrated drug development, laboratory and lifecycle management services. Our customers and partners include pharmaceutical, biotechnology, medical device, academic and government organizations. With more than 30,000 professionals worldwide, PPD has conducted clinical trials in more than 100 countries to help customers deliver life-changing therapies to improve health. We apply innovative technologies, therapeutic expertise and a firm commitment to quality to bend the cost and time curve of drug development and optimize value. For more information, visit www.ppd.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 dependence upon PPD to manage its clinical trials under the Master Services Agreement between the parties, the Company's ability to enroll patients in and successfully complete 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, 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, 2021, 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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