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Aethlon Medical Announces First Patient Treated in First-in-Human Clinical Trial of HEMOPURIFIER® in Head and Neck Cancer

Study is evaluating the HEMOPURIFIER® for reducing cancer-associated exosomes prior to the administration of standard-of-care KEYTRUDA®

The HEMOPURIFIER® is an FDA designated "Breakthrough Device" for depleting circulating exosomes

SAN DIEGO, Dec. 16, 2020 /PRNewswire/ -- Aethlon Medical, Inc. (Nasdaq: AEMD), a therapeutic medical device and technology company focused on unmet needs in viral diseases, oncology and inflammation, announced today that the first patient has been treated in the Company's first-in-human Early Feasibility Study (EFS) evaluating the HEMOPURIFIER® in patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck. The study is enrolling patients at UPMC Hillman Cancer Center in Pittsburgh, PA. ([Hemopurifier Plus Pembrolizumab in Head and Neck Cancer - Full Text View - ClinicalTrials.gov](#)).

The EFS, which is the device equivalent of a Phase 1 clinical trial for a drug or biologic, is 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 primary endpoint for the study is safety of the HEMOPURIFIER® in a clinical setting. Secondary endpoints include efficacy based on response rates, progression-free and overall survival, and changes in exosome concentration after HEMOPURIFIER® treatment.

In cancer, exosomes have been shown to participate in the development and advancement of disease. Exosomes derived from tumor cells may promote immune suppression and seed the spread of metastasis. These tumor derived exosomes may also inhibit the activity of immuno-oncology drugs such as KEYTRUDA®. Tumor derived exosomes are not currently addressed with any approved therapy.

Dan Zandberg, M.D., Medical Oncologist and Hematologist at UPMC Hillman Cancer Center, Associate Professor of Medicine at the University of Pittsburgh School of Medicine and Principal Investigator of the study, stated, "We are excited to have treated the first head and neck cancer patient with the HEMOPURIFIER®. While KEYTRUDA® can markedly

improve outcome in some head and neck cancer patients, the majority of patients still do not respond. If clearance of exosomes with the HEMOPURIFIER® prior to treatment with KEYTRUDA® can increase the number of patients who are able to respond to KEYTRUDA®, it could represent an important advance in the treatment of this disease. This trial represents the first step in this evaluation."

Charles J. Fisher, Jr., M.D., Chief Executive Officer of Aethlon, stated, "We are delighted to be working with Dr. Zandberg and his colleagues at the University of Pittsburgh and UPMC Hillman to treat the first head and neck cancer patient with the HEMOPURIFIER®. By reducing the presence of immune suppressive exosomes from the circulatory system of head and neck cancer patients prior to treatment with KEYTRUDA®, we believe the HEMOPURIFIER® could have the potential to improve patient outcomes in this disease. The initiation of this first-in-human study addressing cancer-associated exosomes is a significant step towards evaluating the HEMOPURIFIER® for potentially improving the efficacy of KEYTRUDA® in head and neck cancer."

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 cancer. The Hemopurifier also holds a Breakthrough Device designation related to life-threatening viruses that are not addressed with approved therapies. Under the Investigational Device Exemption (IDE) application approved by FDA in October 2019 the FDA has also approved an amendment to the Company's 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 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 and 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," "appear" 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. Factors that may contribute to such differences include, without limitation, Aethlon Medical, Inc.'s (the Company) ability to enroll additional patients in the Early Feasibility Study, the Company's

ability to successfully complete the Early Feasibility Study and achieve the endpoints for the study, or any future studies with its Hemopurifier or to successfully develop and commercialize the Hemopurifier. 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. 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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