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Aethlon Medical's Cancer Therapy Receives "Breakthrough Device" Designation from the U.S. Food and Drug Administration

SAN DIEGO, Nov. 27, 2018 /PRNewswire/ -- Aethlon Medical, Inc. (Nasdaq: AEMD), a therapeutic technology company focused on unmet needs in global health, announced today that it has received a "Breakthrough Device" designation from the U.S. Food and Drug Administration (FDA) to support the advancement of the Aethlon Hemopurifier® for the treatment of cancer. The Aethlon Hemopurifier is a first-in-class technology designed for the rapid depletion of cancer-promoting exosomes and life-threatening viruses.

FDA's Breakthrough Device program was established under the 21st Century Cures Act to facilitate more rapid patient access to breakthrough technologies with the potential to address life threatening disease conditions for which no approved or cleared treatment alternatives exist.

"We are honored to receive this breakthrough designation in oncology as it establishes an opportunity to expand the market for our Hemopurifier and advance our vision for addressing a significant unmet need in cancer care," stated Aethlon Medical founder and CEO, Jim Joyce. "By reducing the presence of tumor-derived exosomes from the circulatory system of cancer patients, we believe our Hemopurifier can improve the benefit of existing cancer treatment regimens and emerging immuno-oncology drugs. Thus providing a rationale for potential partnering opportunities."

Cancer is the second leading cause of death globally and is estimated to account for 9.6 million deaths in 2018 (Source: World Health Organization). Tumor-derived exosomes, which are not addressed with an approved therapy, have been discovered to promote immune suppression, seed the spread of metastasis and inhibit the benefit of many leading cancer therapies. Aethlon has recently demonstrated the ability of the Hemopurifier to capture exosomes underlying several forms of cancer, including breast, ovarian and metastatic melanoma. To learn more about the Hemopurifier in cancer, click here: https://tinyurl.com/Aethlon-White-Paper.

The proposed indications for use (IFU) under the Breakthrough Device designation includes, "The Hemopurifier is a single-use 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. Therapy with the Hemopurifier device should be an adjunct to standard of care for cancer."

Aethlon is also advancing the Hemopurifier as a candidate to treat life-threatening viruses. In this regard, the Hemopurifier was designated as a Breakthrough Device indicated for the treatment of life-threatening highly glycosylated viruses that are not addressed with an approved treatment.

About Aethlon Medical, Inc.

Aethlon Medical 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 depletes the presence of circulating tumor-derived exosomes that promote immune suppression, seed the spread of metastasis and inhibit the benefit of leading cancer therapies. The Hemopurifier is also an FDA designated "Breakthrough Device" related to the treatment of life-threatening viruses that are not addressed with approved therapies. Additionally, Aethlon 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. You can also connect with us on Twitter, LinkedIn and Facebook.

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," 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, the Company's ability to maintain its listing on the Nasdaq Capital Market, or any other national securities exchange, that the Company or its subsidiary will not be able to commercialize its products, that the FDA will not approve the initiation or continuation of the Company's clinical programs or provide market clearance of the Company's products, the Company's ability to raise capital when needed, the Company's ability to complete the development of its planned products, the Company's ability to manufacture its products either internally or through outside companies, the impact of government regulations, patent protection on the Company's proprietary technology, product liability exposure, uncertainty of market acceptance, competition, technological change, and other risk factors. 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, 2018, and in the Company's other filings with the Securities and Exchange Commission. 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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