January 30, 2025

Zacks Small-Cap Research (NOTE)

Sponsored – Impartial - Comprehensive

M. Marin
312-265-9211
mmarin@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Aethlon Medical (AEMD-NASDAQ)

AEMD Treats First Patient in Australian Safety, Feasibility & Dose-Finding Clinical Trial of Hemopurifier

Research Note

Aethlon Medical (NASDAQ: AEMD) announced that the first patient in its Australian safety, feasibility and dose-finding clinical trial has been treated with the Hemopurifier. The trial is designed for patients with solid tumors who have stable or progressive disease during anti-PD-1 monotherapy treatment. In other words, the trial is evaluating the Hemopurifier in patients who do not appear to have benefitted from treatment with standard therapies alone. Therapies such as Keytruda® are used to treat a broad range of cancer tumor types.

Unfortunately, currently only about 30% to 40% of cancer patients who receive these treatments for solid tumors have lasting clinical responses. Oncology patients who do not respond to such therapy will be eligible to enroll in the Hemopurifier study, in which sequential cohorts will receive 1, 2, or 3 Hemopurifier treatments during a one-week period.



Source: Aethlon Medical

© Copyright 2025, Zacks Investment Research. All Rights Reserved.

If the Hemopurifier, in conjunction with these treatments, can improve outcomes for a higher percentage of patients, the benefits would be substantial, in our view, as would the expected commercial prospects of the Hemopurifier. The company's goal is to build its database to help with the development of the Hemopurifier as an oncology treatment.

Each patient will be its own control, as a patient's extracellular vesicle (EV) level pre- and post Hemopurifier treatment will be monitored. If there is a quantifiable decrease in EV levels, the Hemopurifier treatment is expected to improve their T-cell's ability to fight the cancer.

The first patient treated in the study was enrolled in the trial on October 29, 2024 at the Cancer Clinical Trials Unit, CALHN, Royal Adelaide Hospital in Australia. After a two-month run in period of treatment with the anti-PD-1 drug Nivolumab during which serial measurements of EVs and anti-tumor T cell activity were taken, it was determined that the disease had progressed. The patient was then treated with the Hemopurifer on January 29, 2025.

Hemopurifier treatment was tolerated without complications

Hemopurifier treatment was for four hours on a single day. The patient **tolerated the procedure without complications**. AEMD anticipates that data from the first treatment cohort will provide insight into the Hemopurifier's potential ability to reduce tumor-derived EVs and enhance T cell activity against tumors. Follow-up safety visits, EV and T cell measurements as well as imaging for clinical response, are planned as part of the clinical study.

EVs that are produced by tumors are associated with the spread of cancers and the resistance to anti-PD-1 therapies. The Hemopurifier is designed to bind and remove EVs from the bloodstream and In preclinical studies has demonstrated the ability to reduce the number of exosomes from the plasma of cancer patient samples. AEMD's thesis is that this capability might improve therapeutic response rates to anti-PD-1 antibodies.

The study is designed to include roughly 18-patients. The primary endpoint is the incidence of adverse events (AEs) and clinically significant changes in safety lab tests of Hemopurifier treated patients at different treatment intervals following a two-month run-in period of PD-1 antibody, Keytruda® or Opdivo® monotherapy. In addition to monitoring safety, the study is designed to examine the number of Hemopurifier treatments needed to decrease the concentration of EVs and if these changes in EV concentrations improve the body's own natural ability to attack tumor cells.

Treatment of the first patient in this trial is an important step forward, we believe, as the company continues to advance research and clinical development activities for the Hemopurifier. Depending on the read out of the data from this study, the analyses are expected to inform the design of a subsequent efficacy and safety, Premarket Approval (PMA), study that would be needed for AEMD to move the Hemopurifier forward toward potential regulatory approval.

AEMD's clinical activities are being conducted in Australia, as well as in India. There are multiple advantages associated with this strategy. Clinical development costs generally are lower in both markets. In addition, assessing participants in both markets will also enable the company to determine the Hemopurifier impact on diverse patient populations.

Risks include that there might be delays in the company's clinical and subsequent commercialization timelines, the clinical trials might not produce the results that management anticipates, regulatory approval might take longer than expected or might not come at all, AEMD might need to raise additional capital earlier than expected and / or the company might not be able to advance the Hemopurifier in various programs, among other risks.

DISCLOSURE

SUBSCRIBE TO ZACKS SMALL CAP RESEARCH to receive our articles and reports emailed directly to you each morning. Please visit our website for additional information on Zacks SCR.

DISCLOSURE: Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm, engaged by the issuer, for providing research coverage for a period of no less than one year. Research articles, as seen here, are part of the service Zacks provides and Zacks receives quarterly payments totaling a maximum fee of $40,000 annually for these services. Full Disclaimer HERE.