June 24, 2024

Zacks Small-Cap Research (NOTE)

Sponsored – Impartial - Comprehensive

M. Marin
312-265-3240
mmarin@zacks.com

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

Aethlon Medical (AEMD-NASDAQ)

Ethics Committee Approval for Safety, Feasibility, Dose-Finding Trial Important Step in Advancing the Hemopurifier

Research Note

Takeaways from recent updates:

- CALHN has granted full ethics approval for Hemopurifier® safety, feasibility & dose-finding clinical trial
- Study will assess the Hemopurifier in cancer patients receiving anti-PD-1 monotherapy treatment
- Unfortunately, only ~ 30% of patients receiving anti-PD-1 monotherapy treatment have lasting responses
- Combined Hemopurifier / immunotherapy treatment might improve outcomes for a higher percent of patients
- Next steps: submission to the Australian regulatory agency & to ethics committees at additional sites
- We believe the 3 Australian sites share same ethics committee, which could facilitate approval process
- Patient enrollment could begin sometime in 2H calendar '24, perhaps as early as August
- Clinical R&D expenses are lower in Australia and India
- Separately, AEMD plans to release FY 2024 results on June 27, 2024

Moving oncology clinical studies forward

Last week Aethlon Medical (NASDAQ: AEMD) announced that the ethics committee of the Central Adelaide Local Health Network (CALHN) has granted full ethics approval for Aethlon's safety, feasibility and dose-finding clinical trial of the Hemopurifier® in cancer patients with solid tumors who have stable or progressive disease during anti-PD-1 monotherapy treatment. PD-1 (Programmed cell death protein 1), is a protein found on the cell surface that plays a role in inhibiting immune responses. This is an important step forward as the company continues to advance research and clinical development activities for the Hemopurifier.

Immunotherapy helps many, but not most

The study will assess the Hemopurifier in cancer patients receiving anti-PD-1 monotherapy treatment such as Keytruda® (pembrolizumab) or Opdivo® (nivolumab). Immunotherapy treatment such as Keytruda and Opdivo helps to block the PD-1 pathway to prevent cancer cells from hiding and, in turn, help the immune system work. However, with certain tumor types, such treatment does not work on the majority of cancer patients. Unfortunately, only about 30% of patients who receive pembrolizumab or nivolumab currently will have lasting clinical responses to these agents, according to AEMD data.

This data is consistent with NIH: "Pembrolizumab (Keytruda® is the brand name) has provided a new first-line option for patients with advanced NSCLC (Non-Small Cell Lung Cancer) and patients can achieve sustained remission once they respond to it, but less than 30% of patients will respond to pembrolizumab."

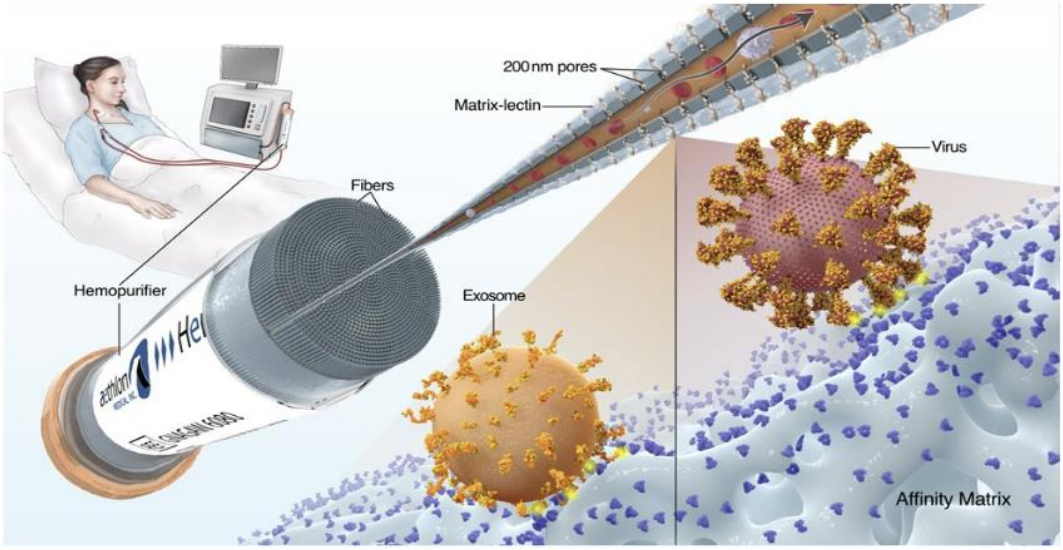
That means that the majority of patients do not respond to checkpoint inhibitors. Aethlon's hypothesis is that using the Hemopurifier in conjunction with treatment of checkpoint inhibitors can increase the percent of patients who can benefit from combined treatment. AEMD hypothesis is that combined Hemopurifier / Immunotherapy treatment can improve outcomes for a higher percent of patients. The company expects the Hemopurifier, in conjunction with an inhibitor, can help improve overall patient outcomes and demonstrate proof of concept about the device's benefits in treating solid tumors associated with a range of cancers.

© Copyright 2024, Zacks Investment Research. All Rights Reserved.

Hemopurifier has demonstrated the ability to remove EVs in in vitro studies

Extracellular vesicles (EVs) produced by tumors have been implicated in the spread of cancers as well as the resistance to anti-PD-1 therapies. Aethlon's Hemopurifier has been designed to bind and remove these EVs from the bloodstream, which may improve therapeutic response rates to anti-PD-1 antibodies. In preclinical studies, the Hemopurifier has been shown to reduce the number of exosomes from the plasma of cancer patient samples. In advance of the trial, AEMD conducted an *in vitro* binding study of relevant targets to document that the Hemopurifier captures exosomes underlying various types of cancer, in particular against PD-1 proteins. Data from the in vitro study was presented to the ethics board.

The Hemopurifier® Is Designed To Capture Viruses And Extracellular Vesicles From A Patient's Blood Via Extracorporeal Circuit



Potential Therapeutic Applications:

- Cancer
- Life-threatening viral infections
- Organ Transplantation

Source: Company presentation

Given the Hemopurifier's demonstrated ability to remove exosomes, management believes the device can be used to affect improved outcomes in a number of cancers in conjunction with a checkpoint inhibitor such as Keytruda. Keytruda has been used to treat 25+ different types of cancer. The company's goal is to build its database in oncology to help with the development of the Hemopurifier as an oncology treatment.

Next steps: Submission to the Australian National Health Regulatory Agency

The next steps for AEMD include submission to the TGA (Therapeutic Goods Administration), which is Australia's national health regulatory agency, obtaining approval from the CALHN Research Governance Committee, and conducting a site initiation visit at Royal Adelaide Hospital in Adelaide, Australia to help facilitate patient enrollment. The company also plans to submit to the ethics committees at two additional sites in Australia, which we believe share the same ethics committee with Royal Adelaide, and one in India. We would expect that having the same ethics committee at all three sites in Australia could facilitate the approval process at the other two venues.

The trial at Royal Adelaide Hospital will be led by Prof. Michael Brown. It will be a roughly 18-patient safety, feasibility and dose-finding trial, with a primary endpoint of safety. The trial is also designed to assess how many Hemopurifier treatments are needed to decrease the concentration of EVs and whether the expected changes in EV concentrations improve the body's ability to use its own immune system to fight tumor cells. In success, the results of this study will then be a guideline in designing a subsequent efficacy and safety, Premarket Approval (PMA), study that is required by regulatory agencies.

Given next steps noted above, the company believes that it could see patient enrollment begin sometime in 2H calendar 24, perhaps as early as August. The trial will monitor any adverse events and clinically significant changes in lab tests of Hemopurifier treated patients with solid tumors with stable or progressive disease at different treatment intervals, after a two-month run in PD-1 antibody therapy. Patients who do not respond to Keytruda or Opdivo therapy will be eligible to enter the Hemopurifier period of the study where sequential cohorts will receive one, two or three Hemopurifier treatments during a one-week period.

Basket oncology trial: studying Hemopurifier on variety of cancerous tumors also expected to facilitate patient enrollments…

AEMD goal is to study the impact of the Hemopurifier on a variety of cancerous tumors. The company expects the Hemopurifier, in conjunction with an inhibitor, can help improve overall patient outcomes and demonstrate proof of concept about the device's benefits in treating solid tumors across a broad range of cancers. Given the narrower focus (exclusively on the head & neck cancer) and timing during the pandemic of an earlier planned study, a lack of patient enrollment led to the decision to terminate the trial. By contrast, the company expects patient enrollment to be facilitated by the broader focus of this study as a basket oncology trial designed to study the impact of the Hemopurifier on a variety of cancerous tumors.

The results of such a trial, if positive, could have broad commercial and economic implications for AEMD, in our view. Given the Hemopurifier's demonstrated ability to remove exosomes, management believes the device can be used to affect improved outcomes in a number of cancers in conjunction with a checkpoint inhibitor such as Keytruda. Keytruda has been used to treat 25+ different types of cancer.

R&D spending expected to go further in Australia & India

As we have noted in prior reports, moving ahead with clinical activities in Australia and India initially aligned with the company's cost containment goals, as clinical R&D expenses are substantially lower in these markets. AEMD expects to realize benefits from attractive economic incentives the Australian government provides for clinical development efforts. In India, R&D expenses are substantially lower than in the U.S., according to management. Australia offers an R&D tax incentives rebate program, which enables companies to receive a tax rebate of up to 43.5% on clinical trial related R&D costs and is expected to help it reduce costs, lower risk, and accelerate time to market.

Company to report FY 2024 results on June 27, 2024…

Separately, AEMD plans to release fiscal year 2024 results on Thursday, June 27, 2024 and hold a conference call that day after market close at 4:30 p.m. ET.

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.