

AIM ImmunoTech Inc

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AIM ImmunoTech is developing immuno-therapeutics to treat multiple types of cancers and fighting coronavirus too

- Lead drug Ampligen in clinical trials to address both chronic fatigue syndrome and to treat multiple cancers
- Clinical trial also widened to include cancer patients suffering from long-term effects of coronavirus
- Positive results from a pancreatic cancer Early Access Program (EAP) evaluating Ampligen in the Netherlands.

What AIM ImmunoTech does:

AIM ImmunoTech Inc. (NYSE:AIM) is an immuno-pharma company headquartered in Ocala, Florida which is focused on the research and development of therapeutics to treat multiple types of cancers, as well as immune-deficiency disorders.

It has established a strong foundation of laboratory, pre-clinical and clinical data with respect to the development of nucleic acids and natural interferon to enhance the natural antiviral defense system of the human body and to aid the development of therapeutic products for the treatment of certain cancers and chronic diseases.

The group's lead drug Ampligen (rintatolimod) is an experimental ribonucleic acid (RNA) that is in clinical trials to address both chronic fatigue syndrome and to treat multiple cancers.

However, a study has also shown that Ampligen can decrease the infectious viral yield of coronavirus (COVID-19) trigger SARS-CoV-2 by 90% (in an vitro model).

In conjunction with the Institute for Antiviral Research at Utah State University, the company tested intranasal Ampligen and found that dramatic reduction in viral yield could be achieved at clinically achievable dosage levels.

The company has recruited patients at Roswell Park cancer center for a trial which will examine Ampligen in combination with interferon alfa-2b in cancer patients with coronavirus (COVID-19). Ampligen has also been shipped to Japan where it will be used in a test as a potential vaccine adjuvant for COVID-19.

How is it doing:

Given the deadly pandemic sweeping the world, it is no surprise that the focus for AIM ImmunoTech recently has been on using Ampligen in the fight against coronavirus (COVID-19).

At the start of October, AIM ImmunoTech revealed that it had received Institutional Review Board (IRB) approval to widen the clinical trial for its drug candidate Ampligen to people suffering from long-term effects of COVID-19.

The group, known as COVID-19 'long haulers' because they continue to show chronic fatigue-like symptoms for months

Price: 2.16

Market Cap: \$85.73 m

1 Year Share Price Graph



Share Information

Code: AIM

Listing: NYSE

52 week High Low
7.05 0.39

Sector: Pharma & Biotech

Website: aimimmuno.com

Company Synopsis:

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action@proactiveinvestors.com

after officially recovering from their initial illness, will be included in the clinical trial for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS).

Up to 20 of the 100 active participants can be long haulers, according to the new trial protocol amendment, Florida-based AIM told investors. The firm is now preparing the IRB-approved protocol for submission to the US Food and Drug Administration (FDA).

At the same time, the company reported progress in Japan, where it is working with Shionogi & Co Ltd and the country's National Institute of Infectious Diseases on potentially using Ampligen as part of a COVID-19 vaccine. The company said The Japan Agency for Medical Research and Development has expressed support for efforts in a recent publication. AIM ImmunoTech has completed two shipments of Ampligen to Japan, which were received by the NIID and Shionogi respectively.

In September, the group had announced that recruitment for the company's Phase 1/2a study of Ampligen in cancer patients with the coronavirus (COVID-19) had begun at the Roswell Park Comprehensive Cancer Center in Buffalo, New York. The study will examine the effectiveness of Ampligen in combination with the protein interferon alpha-2b in treating cancer patients with mild-to-moderate COVID-19.

In June, it filed a provisional utility patent application for Ampligen to be used as a possible treatment for chronic fatigue syndrome (CFS) associated with COVID-19.

Ampligen has already proven to be a powerful drug conferring protective survival in SARS animal experiments. The drug has shown heightened levels of activity in Phase 2 and 3 trials of patients with CFS.

The drug was approved in Argentina for CFS in June, and in August the company said it was preparing to test the drug as a therapy for the fatigue-like illness induced by the coronavirus. AIM ImmunoTech has clearance from Argentinian regulators to import the first shipment of commercial-grade vials of the drug. After a final inspection and release tests, the company hoped to receive approval for commercial sales.

In April, the company also signed a material transfer and research agreement with Chinese vaping device manufacturer Shenzhen Smoore Technology Limited, allowing the company to analyze one of its devices as a possible delivery for AIM's flagship drug Ampligen. The agreement allows AIM ImmunoTech to conduct research in China on the efficacy of the Smoore inhalation device as a delivery method for the drug.

Cancer fight going on too

Away from coronavirus, on the cancer front, at the end of September, AIM ImmunoTech reported positive results from a pancreatic cancer Early Access Program (EAP) evaluating its drug Ampligen in the Netherlands.

The group said Professor Casper van Eijck and his team at Erasmus University Medical Center had found a statistically significantly positive survival benefit when using Ampligen in patients with locally advanced/metastatic pancreatic cancer after systemic chemotherapy.

A detailed clinical report and an article for publication are being prepared by van Eijck and his team, the company said.

AIM ImmunoTech said it will work with its contract research organization, Amarex Clinical Research LLC, to seek FDA fast-track and possibly breakthrough designations and to obtain investigational new drug authorizations to conduct a follow-up pancreatic cancer Phase 2/3 clinical trial. Such a trial would have sites in the Netherlands led by van Eijck, as well as, at major cancer research centers in the US.

The company also plans to file dual orphan drug status applications for use of Ampligen in the treatment of late-stage pancreatic carcinoma with the FDA and the European Medicines Agency (EMA). If granted, this extends a company's exclusivity rights once a drug reaches the market.

The National Cancer Institute has also issued an award of \$14.5 million to Roswell Park to fund five clinical trials in melanoma, colorectal and ovarian cancers. These trials will test chemokine modulation incorporating Ampligen as an immuno-modulator, as part of a strategy to turn "cold" less responsive tumors into "hot" tumors.

Roswell Park and Moffitt Cancer Center have both received 'Breakthrough Awards' from the Department of Defense. Together, these clinical trials are receiving approximately \$15 million in federal funding in part with a significant focus upon Ampligen as a potential synergistic agent in combination with several other immunotherapies, including pembrolizumab (Keytruda) and Intron A.

On the financial front, in a business update on August 17, AIM ImmunoTech revealed that it had cash, cash equivalents and marketable securities of \$40.3 million as of June 30, 2020, nearly 5 times more than the \$8.8 million it had at the end of 2019.

A year ago, the company - which changed its name from Hemispherx Biopharma on September 30, 2019 - revealed that it had raised approximately \$10 million from public markets over the space of a few months to fund the development of Ampligen.

Inflection points:

- News on Roswell Park clinical trials of cancer patients with COVID-19
- Further progress in Japan on COVID-19 testing with Shionogi & Co
- Detailed report from pancreatic cancer Early Access Program (EAP) evaluating Ampligen in the Netherlands.

What the boss says:

In August's business and clinical update, AIM ImmunoTech CEO Thomas Equels said: "AIM is engaged in extremely important and potentially groundbreaking pre-clinical and clinical research in critical unmet medical needs such as COVID-19 and cancer-providing us 'multiple shots on goal' within large addressable markets."

He added: "Given these multiple indications, AIM's strategy to support these trials has been to maximize third-party, non-dilutive funding directly awarded to the clinical sites, which we have accomplished in many of our trials.

"We believe we are extremely well-positioned to execute on our strategy going forward, which, in turn, we expect will drive significant value for stockholders."

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