

# AIM ImmunoTech Inc.

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## AIM ImmunoTech's Ampligen study on brain-metastatic breast cancer funded by DoD's \$6.42M award to Roswell Park

AIM ImmunoTech Inc (NYSE American:AIM) announced Thursday that the US Department of Defense has granted a four-year, \$6.42 million "Breakthrough Award" to the Roswell Park Comprehensive Cancer Center for a clinical study on a combination of therapies, including the company's drug Ampligen, in patients with brain-metastatic breast cancer (BMBC).

About 10-15% of women with stage IV breast cancer develop brain metastases. For most, the breast cancer has already traveled to another part of the body, such as the bones, liver, or lung. However, for about 17% of women in this group, the brain is the only site of metastasis.

### READ: Hemispherx Biopharma changes name to AIM ImmunoTech Inc to reflect flagship drug Ampligen

In a statement, the company said the funding is through the DoD's breast cancer research program, which started the Breakthrough Awards to support research that has the potential to end breast cancer. The Phase II trial, slated to kick off in 2020, will be the first clinical study to assess the effectiveness of a three-pronged strategy combining distinct immunotherapy approaches:

- A new dendritic-cell treatment vaccine developed by Dr Pawel Kalinski and his colleagues in collaboration with Brian Czerniecki, who is the chair of the Breast Oncology Department at Moffitt Cancer Center in Tampa, Florida
- Chemokine modulation using a combination proposed and validated by Dr Kalinski as an optimized adjuvant for dendritic-cell vaccines, incorporating Ampligen and interferon alfa-2b
- Immune checkpoint inhibition

The company said the team will study this approach first in patients with localized BMBC, or breast cancer that has begun to spread to the brain but is not yet widely disseminated.

"A major limitation of cancer immunotherapy is that tumors adapt to naturally occurring effector cells by shutting down production of the relevant chemokines in the tumor microenvironment," said Dr Kalinski, the principal investigator for the project, in a statement.

"Our strategy uses a unique combination of biologic agents to make tumors visible to the immune system by making them look like tissue that's been infected by a virus. We've never tested them all together before in patients, but the findings from earlier clinical and preclinical studies lend strong support for assessing this combination even in the most aggressive and hard-to-treat cancer types," he added.

Ocala, Florida-based AIM ImmunoTech is making steady progress with its flagship drug Ampligen that is in clinical trials to treat multiple cancers.

**Price:** 1.07

**Market Cap:** \$8.84 m

#### 1 Year Share Price Graph



February 2019 August 2019 February 2020

#### Share Information

**Code:** AIM

**Listing:** NYSE

<b>52 week</b>	<b>High</b>	<b>Low</b>
	14.8104	0.39

**Sector:** Pharma & Biotech

**Website:** aimimmuno.com

#### Company Synopsis:

AIM ImmunoTech Inc. is an immunopharma company headquartered in Ocala, Florida and focused on the research and development of therapeutics to treat multiple types of cancers, as well as immune-deficiency disorders.

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### Important milestone

"We believe that this is an important milestone for AIM ImmunoTech, as Ampligen being a part of this Breakthrough Award presents an opportunity for establishing the proposition that these combinational therapies may help to turn 'cold' tumors that don't respond to existing therapies into 'hot' ones that the immune system can be trained to recognize and attack," said AIM ImmunoTech CEO Thomas K Equels.

AIM's flagship products include the Argentina-approved drug rintatolimod, which has the trade names Ampligen or Rintamod and the FDA-approved drug Alferon N Injection. Based on the results of peer-reviewed pre-clinical studies and clinical trials, AIM believes that Ampligen may have broad-spectrum anti-viral and anti-cancer properties.

Clinical trials of Ampligen include studies of cancer patients with renal cell carcinoma, malignant melanoma, colorectal cancer, advanced recurrent ovarian cancer and triple-negative metastatic breast cancer.

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