AIM ImmunoTech Announces Positive Data from Phase 1 Study Evaluating Ampligen® for the Treatment of Stage 4 Metastatic Triple Negative Breast Cancer

Release: 4/11/2022 7:05:00 AM

Phase 1 study of metastatic triple-negative breast cancer using chemokine modulation (CKM) therapy, including Ampligen and pembrolizumab, successfully met primary endpoint

Positive data from this proof-of-concept study demonstrate that short-term systemic CKM followed by pembrolizumab is well-tolerated and selectively enhances local cytotoxic T-lymphocyte (CTL) infiltration in the tumor microenvironment (TME)

Data from clinical research conducted at Roswell Park Comprehensive Cancer Center presented in late-breaking poster session at the AACR 2022 Annual Meeting

OCALA, Fla., April 11, 2022 (GLOBE NEWSWIRE) -- **AIM ImmunoTech Inc. (NYSE: American AIM)** ("AIM" or the "Company"), an immuno-pharma company focused on the research and development of therapeutics to treat multiple types of cancers, immune disorders, and viral diseases, including COVID-19, the disease caused by the SARS-CoV-2 virus, today announced the presentation of positive data from a Phase 1 study at Roswell Park Comprehensive Cancer Center in patients with metastatic triple-negative breast cancer using chemokine modulation therapy, including AIM ImmunoTech Inc.'s drug candidate, Ampligen® (also known as rintatolimod), interferonα-2b, and pembrolizumab at the American Association for Cancer Research (AACR) Annual Meeting 2022, being held April 8-13, 2022, in New Orleans, Louisiana.

The presented research was led by Roswell Park medical oncologist Shipra Gandhi, MD, in collaboration with senior investigator Pawel Kalinski, MD, PhD, Chair of Immunology at Roswell Park.

Title: *Systemic Rintatolimod and Interferonα-2b selectively reprogram local tumor microenvironment in patients with metastatic triple negative breast cancer for enhanced influx of cytotoxic T-lymphocytes but not regulatory T-cells*
Presenter: Shipra Gandhi, MD

"This pilot trial studies the potential of chemokine modulation therapy when given prior to pembrolizumab in participants with triple-negative breast cancer that has spread to other places in the body. Drugs used in chemokine modulation therapy, such as celecoxib, recombinant interferon alfa-2b, and Ampligen appears to work by unleashing or enhancing the body's immune responses against the cancer by either blocking inhibitory immune elements or by activating stimulatory immune elements. Monoclonal antibodies, such as pembrolizumab, may then be better able to interfere with the ability of tumor cells to grow and spread," commented David R. Strayer, MD, Chief Science Officer.

"The data, while from a small number of subjects, is extremely impressive for four out of six Ampligen plus pembrolizumab patients; three demonstrated disease stabilization and one showed a significant and dramatic rapid destruction of the tumor and metastasis. The potential of this signal is completely consistent with the important survival signal shown by Ampligen and pembrolizumab in the advanced recurrent ovarian cancer study conducted at UPMC", commented Thomas K. Equels, Chief Executive Officer.

In the study, six evaluable patients (33-75 years) with mTNBC received 6 doses of Ampligen (200 mg i.v.), IFN-2 (INTRON-A; 20MU/m2 i.v.) and COX-2 inhibitor (celecoxib; 2 x 200 mg, p.o.) over 2 weeks, with tumor biopsies obtained before (within 6 days) and after (within 5 days) CKM. All patients received follow-up pembrolizumab (200 mg, i.v, Q3 weeks).

Summary of Key Findings:

- The pre-determined primary endpoint of efficacy was met (increase in CD8 in TME).
- Uniform increase of immune markers upon treatment was observed: CD8 mRNA (6.1-fold; p-0.034), GZMB mRNA (3.5-fold; p=0.058), ratios of CD8 /FOXP3 and GZMB/FOXP3 (5.7-fold; p=0.036, and 7.6-fold; p=0.024 respectively), thus successfully meeting the pre-determined primary endpoint in the study (increase in CD8 in TME).
- In addition, an increase in CTL attractants CXCL10 (2.6-fold; p=0.104) and CCL5 (3.3-fold; p=0.019) was observed. In contrast, Treg marker FOXP3 or Treg attractants CCL22 or CXCL12 were not enhanced.
- Three patients had stable disease lasting 2.4, 2.5 and 3.8 months, as of data cut off September 1, 2021.
- An additional patient (non-evaluable) had a partial response (breast tumor autoamputation) with massive tumor necrosis in the post-CKM biopsy.

For more information about the study, please visit ClinicalTrials.gov: NCT03599453.

About AIM ImmunoTech Inc.

AIM ImmunoTech Inc. is an immuno-pharma company focused on the research and development of therapeutics to treat multiple types of cancers, immune disorders, and viral diseases, including COVID-19, the disease caused by the SARS-CoV-2 virus.

For more information, please visit www.aimimmuno.com.

Cautionary Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 (the "PSLRA"). Words such as "may," "will," "expect," "plan," "anticipate" and similar expressions (as well as other words or expressions referencing future events or circumstances) are intended to identify forward-looking statements. Many of these forward-looking statements involve a number of risks and uncertainties. Among other things, for those statements, the Company claims the protection of safe harbor for forward-looking statements contained in the PSLRA. The Company does not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. The study discussed above was only proof of concept and will require further studies. Studies and trials are subject to many factors including lack of regulatory approval(s), lack of study drug, or a change in priorities at the institutions sponsoring other trials. Significant additional testing and trials will be required to determine whether Ampligen will be an effective treatment of Stage 4 metastatic triple negative breast cancer or otherwise, and no assurance can be given that this will be the case.

Investor Relations Contact
JTC Team, LLC
Jenene Thomas
833-475-8247
AIM@jtcir.com