

AIM ImmunoTech Issues Stockholder Update and Details Its Expectations for 2020

Ocala, Fla., December 4, 2019 — AIM ImmunoTech (NYSE American:AIM), an immuno-pharma company focused on the research and development of therapeutics to treat multiple types of cancers and immune-deficiency diseases — such as severe chronic fatigue syndrome (CFS) — today provided its stockholders with an update on the first three quarters of 2019 and detailed expected upcoming milestones in clinical studies using its drug Ampligen. For more detailed information on the most recent quarter, please see the company's 10-Q filed on 11/14/19. The below letter is also available on the company's website.

To our valued stockholders,

This has been a transformational year for AIM ImmunoTech. Our flagship drug, Ampligen, is now being studied in six immuno-oncology clinical trials. We are focusing on highly lethal malignancies where there are unmet medical needs. These trials are underway at highly respected National Cancer Institute (NCI)-Designated Cancer Centers. Several more clinical trials are slated for 2020. Our principal obligation is to supply Ampligen, while the substantial costs in all of these clinical trials are funded by third-party grants from government or industry. We believe this significant third-party support validates the potential of Ampligen for use in combinational “synergy” therapies to fight cancer.

Most notably, two grants by the U.S. Department of Defense (DOD) were issued for Ampligen immuno-oncology research. These DOD “Breakthrough Awards” total approximately \$15 million to Roswell Park Comprehensive Cancer Center and Moffitt Cancer Center to study Ampligen in combination with other immunotherapies — including pembrolizumab ([KEYTRUDA®](#)) and [Intron A](#) — in the treatment of brain metastatic breast cancer. We expect both these DOD-funded trials to commence in 2020.

At the same time, we're nearing completion of manufacturing in a plan to ensure sufficient supplies of Ampligen for future clinical trials and the Argentina commercial launch. Once manufacturing is completed, we anticipate a corresponding reduction in our expenses, which should ensure adequate resources as we await data from the ongoing clinical trials and begin preparations for upcoming trials.

Looking ahead, we anticipate several important clinical trial milestones in 2020, some of which we believe will have breakthrough potential:

- Publication of data from a Phase 1/2 study of intraperitoneal chemo-immunotherapy in **advanced recurrent ovarian cancer** at University of Pittsburgh Medical Center. The Phase 1 portion of the study showed the intraperitoneal safety profile of Ampligen with positive survival data. <https://clinicaltrials.gov/ct2/show/NCT02432378>
- Interim data from a follow-up Phase 2 study of **advanced recurrent ovarian cancer** using cisplatin, pembrolizumab, plus Ampligen at University of Pittsburgh Medical Center. Enrollment has commenced and several patients have begun treatment, with up to 45 patients to be enrolled. <https://clinicaltrials.gov/ct2/show/NCT03734692>
- Interim data from a Phase 2 study of **metastatic triple-negative breast cancer** using chemokine modulation therapy, including Ampligen and pembrolizumab, at Roswell Park Comprehensive Cancer Center. A number of the planned 6 patients are in treatment. This is an important study because prevalence of this lethal malignancy is approximately 350,000 in the U.S. alone, and a previous clinical study determined that pembrolizumab as a monotherapy was successful on only 5% of patients who had previously undergone chemotherapy. <https://clinicaltrials.gov/ct2/show/NCT03599453>

- Interim data in a Phase 2a study of Ampligen as a component of a chemokine modulatory regimen (celecoxib) on **Stage 4 colorectal cancer** metastatic to liver at Roswell Park Comprehensive Cancer Center. A number of the 12 planned patients are in treatment.
<https://clinicaltrials.gov/ct2/show/NCT03403634>
- First enrollment and the subsequent commencement of treatment of patients in a Phase 2 study investigating the effectiveness and safety of aspirin and Ampligen with or without interferon-alpha 2b (Intron A) compared to no drug treatments in a randomized three-arm study of patients with **prostate cancer** before undergoing radical prostatectomy (Roswell Park Comprehensive Cancer Center, Dr. G. Chatta, PI). IRB and FDA approval to proceed has been received.
<https://clinicaltrials.gov/ct2/show/NCT03899987>
- First enrollment and subsequent commencement of treatment in a Phase 1 study of chemokine modulation plus neoadjuvant chemotherapy in patients with **early-stage triple negative breast cancer**, which has received FDA authorization. The objective of this study is to evaluate the safety and tolerability of a combination of Ampligen, celecoxib with or without Intron A, when given along with chemotherapy in the early stages of this lethal malignancy.

Once we receive adequate data from the above clinical trials, our plan is to seek Breakthrough / Fast Track designations in certain oncology indications from the FDA. If received, this would make Ampligen eligible for many distinct benefits, including Accelerated Approval, Priority Review and Rolling Review. Such designation would be invaluable, as we continue to work to bring Ampligen to market—especially in these lethal malignancies where a current unmet medical need exists. At the same time, we remain focused on aggressively expanding our patent estate.

Overall, we have had an extremely productive year at AIM and we are focused on achieving these important milestones in order to ensure the future success of Ampligen. In addition to significant non-dilutive, third-party funding support paying for the major expenses in all the ongoing immuno-oncology clinical studies, we successfully raised \$10 million over the past several months. This significantly enhances our balance sheet and provides us a substantial runway to support our ongoing activities as we await results in multiple ongoing immuno-oncology clinical trials.

I would like to thank our stockholders for their continued support. We are engaged in very important research which, if successful, has the potential to save tens of thousands of lives, as well as create long-term value for you, our stockholders. The risks are high, but the potential rewards are great. I look forward to keeping you apprised of developments as they unfold.

Sincerely,

Thomas K. Equels, CEO

About AIM ImmunoTech

AIM ImmunoTech Inc. is an immuno-pharma company focused on the research and development of therapeutics to treat multiple types of cancers. AIM's flagship products include the Argentina-approved drug rintatolimod (trade names Ampligen® or Rintamod®) and the FDA-approved drug Alferon N Injection®. Based on results of published, 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. These and

other potential uses will require additional clinical trials to confirm the safety and effectiveness data necessary to support regulatory approval and additional funding. Rintatolimod is a double-stranded RNA being developed for globally important debilitating diseases and disorders of the immune system.

Cautionary Statement

Some of the statements included in this press release may be forward-looking statements that involve a number of risks and uncertainties. For example, no assurance can be given as to whether the current or planned trials will be successful or yield favorable data and the 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. In addition, initiation of planned clinical trials may not occur secondary to many factors including lack of regulatory approval(s) or lack of study drug. Even if these clinical trials are initiated, we cannot assure that the clinical studies will be successful, or yield any useful data or require additional funding. Among other things, for forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. This press release and prior releases are available at www.aimimmuno.com. The information found on our website is not incorporated by reference into this press release and is included for reference purposes only.

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