

IMMUNOMEDICS INC
Form DEFA14A
February 17, 2017

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of
the Securities Exchange Act of 1934 (Amendment No.)

Filed by the Registrant

Filed by a Party other than the Registrant

Check the appropriate box:

Preliminary Proxy Statement

Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))

Definitive Proxy Statement

Definitive Additional Materials

Soliciting Material under §240.14a-12

Immunomedics, Inc.
(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

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No fee required.

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IMMUNOMEDICS PRESENTS UPDATED RESULTS WITH SACITUZUMAB GOVITECAN (IMMU-132) IN HEAVILY-PRETREATED PATIENTS WITH METASTATIC UROTHELIAL CANCER

Phase 2 Results Reported at 2017 Genitourinary (GU) Cancers Symposium

Objective Response Rate (ORR) of 31%, One Confirmed Complete Response (CR) and Ten Confirmed Partial Responses (PRs)

Median Progression-Free Survival (PFS) of 7.2 Months

Median Overall Survival (OS) of 15.5 Months

Orlando, FL, February 17, 2017 --- Immunomedics, Inc., (NASDAQ: IMMU) (“Immunomedics” or “the Company”) today announced that sacituzumab govitecan (IMMU-132) is active in patients with metastatic urothelial cancer (UC) and has the potential to become a second line or later treatment to platinum-based or immuno-oncology therapy for these patients.

“With larger numbers than the initial report, I remain impressed with the safety and efficacy results produced by sacituzumab govitecan in a difficult-to-treat patient population that had a median of two prior therapies and had extensive metastatic disease,” commented Dr. Scott T. Tagawa, the Richard A. Stratton Associate Professor in Hematology and Oncology, and an Associate Professor of Clinical Medicine and of Clinical Urology at Weill Cornell Medicine and an oncologist at NewYork-Presbyterian, who presented the results at the GU conference.

“While patients with metastatic UC usually respond well to initial therapy with a platinum-containing regimen, few options are available after they become refractive. Second-line immune checkpoint-inhibitor (IO) therapy was recently approved by the FDA, such as atezolizumab and nivolumab, with expected approval of pembrolizumab as well. Although responders to the new IO therapy may do well for a prolonged period of time, about three-fourths do

not respond and overall median PFS is less than 2.5 months and median OS less than 13 months have been reported,” added Dr. Tagawa, who has served as a consultant to Immunomedics.

In the ongoing Phase 2 study with sacituzumab govitecan in metastatic UC, the ORR among 36 assessable patients was 31% (11/36), including one confirmed CR and ten confirmed PRs. The median duration of response for these ten patients was 7.5 months (95% confidence interval [CI], 4.4 to 12.9 months), with one patient having a PR for more than 18 months and continuing therapy. Overall, 69% of patients showed tumor shrinkage from baseline with sacituzumab govitecan therapy, and 14 patients are still under therapy.

For the 41 intention-to-treat patients, median PFS was 7.2 months (95% CI, 6.7 to 11.7 months) and median OS was 15.5 months (95% CI, 8.9 to 17.2 months). Of the twelve patients with progression after prior IO therapy and chemotherapy, there were one unconfirmed PR and six patients with stable disease following sacituzumab govitecan treatment.

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The Company announced on February 10, 2017 that an exclusive global licensing agreement was entered into with Seattle Genetics (NASDAQ: SGEN), providing Seattle Genetics worldwide rights to develop, manufacture and commercialize sacituzumab govitecan in multiple indications, including UC.

“We are pleased with these promising results, especially the long-term control of advanced disease in patients who failed multiple prior therapies, and look forward to working closely with Seattle Genetics to bring this important investigational product to cancer patients expeditiously,” stated Cynthia L. Sullivan, President and Chief Executive Officer of Immunomedics. Ms. Sullivan added, “We remain on target to commence our Phase 3 randomized trial in patients with advanced triple-negative breast cancer in March, and are working diligently to complete the submission of our Biologics License Application to FDA for Accelerated Approval of this indication.”

In addition to Dr. Tagawa, other clinical investigators participating in this study include Drs. Allyson J. Ocean, Bishoy Faltas, and Ana Molina, his colleagues at NewYork-Presbyterian and Weill Cornell Medicine, New York, NY; Dr. Elaine Lam, University of Colorado Cancer Center, Aurora, CO; Drs. Philip Saylor and Aditya Bardia, Massachusetts General Hospital Cancer Center, Harvard Medical School, Boston, MA; Dr. Julio J. Hajdenberg, UF Health Cancer Center-Orlando Health, Orlando, FL; Dr. Alicia K. Morgans, Vanderbilt-Ingram Cancer Center, Nashville, TN; Drs. Kevin Kalinsky and Emerson Lim, NewYork-Presbyterian/Columbia University Medical Center-Herbert Irving Comprehensive Cancer Center, New York, NY; and Dr. Matthew D. Galsky, Icahn School of Medicine Mount Sinai, Tisch Cancer Institute, New York, NY.

A total of 44 patients with metastatic UC had been enrolled into this open-label multicenter study. Sites of metastases included liver (N=9; 25%), lymph nodes (N=14; 39%), lungs (N=14; 39%), pelvis (N=9, 25%), and bone (N=4; 11%). Patients received a median of six doses (range, 1-50) of sacituzumab govitecan, which was administered at 8 or 10 mg/kg on days 1 and 8 of 3-week cycles. Despite repeated dosing, grade 3 or higher adverse events were limited to neutropenia (30%), febrile neutropenia (11%), fatigue (11%), and diarrhea (3%).

Treatment response was assessed by computed tomography (CT) every 8 weeks. Patients with more than 30% tumor shrinkage required confirmation within 4 to 6 weeks after the initial response in accordance with by RECIST 1.1 for single-arm studies.

About Immunomedics

Immunomedics (the “Company”) is a clinical-stage biopharmaceutical company developing monoclonal antibody-based products for the targeted treatment of cancer, autoimmune disorders and other serious diseases. Immunomedics’ advanced proprietary technologies allow the Company to create humanized antibodies that can be used either alone in unlabeled or “naked” form, or conjugated with radioactive isotopes, chemotherapeutics, cytokines or toxins. Using these technologies, Immunomedics has built a pipeline of eight clinical-stage product candidates. Immunomedics’ portfolio of investigational products includes antibody-drug conjugates (ADCs) that are designed to

deliver a specific payload of a chemotherapeutic directly to the tumor while reducing overall toxic effects that are usually found with conventional administration of these chemotherapeutic agents. Immunomedics' most advanced ADCs are sacituzumab govitecan (IMMU-132) and labetuzumab govitecan (IMMU-130), which are in Phase 2 trials for a number of solid tumors and metastatic colorectal cancer, respectively. IMMU-132 has received Breakthrough Therapy Designation from the FDA for the treatment of patients with triple-negative breast cancer who have failed at least two prior therapies for metastatic disease. Immunomedics has a research collaboration with Bayer to study epratuzumab as a thorium-227-labeled antibody. Immunomedics has other ongoing collaborations in oncology with independent cancer study groups. The IntreALL Inter-European study group is conducting a large, randomized Phase 3 trial combining epratuzumab with chemotherapy in children with relapsed acute lymphoblastic leukemia at clinical sites in Australia, Europe, and Israel. Immunomedics also has a number of other product candidates that target solid tumors and hematologic malignancies, as well as other diseases, in various stages of clinical and preclinical development. These include combination therapies involving its antibody-drug conjugates, bispecific antibodies targeting cancers and infectious diseases as T-cell redirecting immunotherapies, as well as bispecific antibodies for next-generation cancer and autoimmune disease therapies, created using its patented DOCK-AND-LOCK® protein conjugation technology. The Company believes that its portfolio of intellectual property, which includes approximately 306 active patents in the United States and more than 400 foreign patents, protects its product candidates and technologies. For additional information on the Company, please visit its website at www.immunomedics.com. The information on its website does not, however, form a part of this press release.

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Important Additional Information

Immunomedics, Inc. (the “Company”), its directors and certain of its executive officers will be deemed to be participants in the solicitation of proxies from Company stockholders in connection with the matters to be considered at the Company’s 2016 Annual Meeting. The Company has filed a definitive proxy statement and form of WHITE proxy card with the U.S. Securities and Exchange Commission (the “SEC”) in connection with any such solicitation of proxies from Company stockholders. **COMPANY STOCKHOLDERS ARE STRONGLY ENCOURAGED TO READ THE DEFINITIVE PROXY STATEMENT (INCLUDING ANY AMENDMENTS AND SUPPLEMENTS), THE ACCOMPANYING WHITE PROXY CARD AND ANY OTHER RELEVANT DOCUMENTS THAT THE COMPANY FILES WITH THE SEC WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION.** Information regarding the identity of participants, and their direct or indirect interests, by security holdings or otherwise, is set forth in the proxy statement and other materials filed by the Company with the SEC. Stockholders will be able to obtain the proxy statement, any amendments or supplements to the proxy statement and other documents filed by the Company with the SEC for no charge at the SEC’s website at www.sec.gov. Copies will also be available at no charge at the Company’s website at www.immunomedics.com, by writing to Immunomedics, Inc. at 300 The American Road, Morris Plains, New Jersey 07950, or by calling the Company’s proxy solicitor, MacKenzie Partners, Inc. at (212) 929-5500, or by calling Dr. Chau Cheng, Senior Director, Investor Relations & Corporate Secretary, (973) 605-8200, extension 123.

Forward-Looking Statements

This release, in addition to historical information, may contain forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Such statements, including statements regarding clinical trials (including the funding therefor, anticipated patient enrollment, trial outcomes, timing or associated costs), regulatory applications and related timelines, out-licensing arrangements (including the timing and amount of contingent payments under the licensing and development agreement with Seattle Genetics), forecasts of future operating results, potential collaborations, and capital raising activities, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. Factors that could cause such differences include, but are not limited to, the Company’s dependence on business collaborations or availability of required financing from capital markets, or other sources on acceptable terms, if at all, in order to further develop our products and finance our operations, new product development (including clinical trials outcome and regulatory requirements/actions), the risk that we or any of our collaborators may be unable to secure regulatory approval of and market our drug candidates, risks associated with the outcome of pending litigation and competitive risks to marketed products, and the Company’s ability to repay its outstanding indebtedness, if and when required, as well as the risks discussed in the Company’s filings with the Securities and Exchange Commission. The Company is not under any obligation, and the Company expressly disclaims any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise.

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