

IMMUNOMEDICS INC  
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SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of  
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**Immunomedics, Inc.**

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## **Immunomedics Announces New Data for IMMU-132 at Investor R&D Day**

### **IMMU-132 Provides Opportunity for Significant Near-Term Value Creation**

### **Submission for Accelerated Approval Application to FDA for Patients with Metastatic TNBC Remains on Track for mid-2017**

### **Company Advancing IMMU-132 in Three Additional Indications**

MORRIS PLAINS, N.J., Jan. 18, 2017 (GLOBE NEWSWIRE) -- **Immunomedics, Inc.** (NASDAQ:IMMU) (“Immunomedics” or “the Company”) today announced new data for sacituzumab govitecan (**IMMU-132**) during the Company’s Investor R&D Day. The entire presentation is available on the Company’s website, [www.immunomedics.com](http://www.immunomedics.com).

**IMMU-132** is Immunomedics’ proprietary solid tumor therapy candidate that is advancing through development in four indications: metastatic triple-negative breast cancer (TNBC), the lead indication and for which the Food and Drug Administration (FDA) has awarded Breakthrough Therapy Designation; urothelial cancer (UC); small-cell lung cancer (SCLC); and non-small-cell lung cancer (NSCLC). Immunomedics expects to submit a Biological License Application (BLA) to the FDA for accelerated approval of **IMMU-132** in TNBC patients in mid-2017.

Cynthia L. Sullivan, President and Chief Executive Officer, said, “The data to support our BLA filing for accelerated approval for **IMMU-132** in TNBC continues to improve as more confirmed results become available for the patients enrolled into our TNBC clinical trial. Additionally, with the assistance of our outside financial and strategic advisor, Greenhill & Co., LLC, we are making significant progress with multiple partnership and strategic opportunities for **IMMU-132**, and we are very encouraged with the interest thus far. We believe there is a limited and diminishing number of compelling oncology assets available, and we are focused on bringing **IMMU-132** to late-stage cancer patients as expeditiously as possible. Furthermore, now is the right time to deliver on the potential value of **IMMU-132** on behalf of our stockholders.”

### **New IMMU-132 Results Highlight Progress Toward Potential Accelerated Approval**

Ms. Sullivan reported that **IMMU-132** has been studied in over 410 diverse cancer patients, with the dose of 10 mg/kg given on days 1 and 8 of repeated 21-day cycles being the established dose regimen. According to Ms. Sullivan, some patients have been treated for more than a year.

The Company has engaged an independent third-party to review pertinent radiological scan results from the TNBC and its NSCLC indications, in a blinded fashion, as per FDA requirements.

Immunomedics disclosed results in 85 assessable TNBC patients. These results will be part of the BLA submission for the accelerated approval of **IMMU-132**. The Company announced last month that it had achieved the goal of enrolling 100 TNBC patients, as requested by FDA for this BLA filing. The Company reported that the objective response rate and median progression-free survival (PFS, intention-to-treat, or ITT, basis) have been maintained with these additional patient results, while the median overall survival (OS also on ITT basis) has been extended to almost 19 months. These patients experienced two complete and 23 partial responses, while an additional three patients with initial partial responses are awaiting confirmation. Overall, 81% of patients treated with **IMMU-132** showed tumor shrinkage from baseline measurements. The clinical benefit rate (complete and partial remissions, and patients with stable disease) at six months or later computed to 44%. The median duration of response for those with objective responses was almost 11 months. It was emphasized that these are interim results, since 20 patients are continuing treatment; a final outcome must await analysis of all patients enrolled.

The major toxicity (grade  $\geq 3$ ) has been neutropenia (39%) in this and most cancer patient cohorts, which has been manageable by dose reduction, dose delays, or giving a hematopoietic cytokine. Diarrhea, which is the major side effect with irinotecan, the parent drug from which SN-38 is derived, has been much less, such as a grade  $\geq 3$  of 13%.

Dr. Linda T. Vahdat, Professor of Medicine at Weill Cornell Medical College, and Co-Leader of the Breast Cancer Program at Meyer Cancer Center, New York, who is one of the senior investigators in the **IMMU-132** trial and presenter of these results, said: “These are excellent results in this very advanced and heavily-pretreated group of patients who have exhausted virtually all therapeutic options, and come with a relatively good safety profile. As the first investigator to recognize the potential role of **IMMU-132** in TNBC, I am delighted with this outcome and look forward to its future use in these critical patients.”

“Further, with encouraging preclinical results of the combination of **IMMU-132** with PARP inhibitors in TNBC models, we are interested in the prospect of this combination in an earlier therapy setting for these patients,” Dr. Vahdat added.

In addition to TNBC, Immunomedics is making progress with **IMMU-132** across the other three advanced indications. In patients with urothelial cancer, especially metastatic urinary bladder cancer, Dr. Scott T. Tagawa, Associate Professor of Medicine and Urology, Weill Cornell Medical College, and Attending Physician, New York-Presbyterian Hospital, New York, reported on 27 assessable patients from more than 40 patients enrolled. The objective response rate was 33%, including one complete and eight partial remissions. The duration of objective response was a median of 7.5 months, with one patient with a partial response approaching 17 months. The clinical benefit rate at six months or later was 59%, but 10 patients are still under therapy. Overall, 70% of the patients

showed tumor shrinkage from baseline with **IMMU**-132 therapy. The median PFS and OS on an ITT basis were seven and almost 16 months, respectively. The safety profile was similar to the findings in patients with TNBC.

“These patients had a median of two prior therapies and had extensive metastatic disease. While patients with metastatic urothelial cancer respond well to initial therapy with a platinum-containing regimen, few options are available after they become refractive. The recent approval of an immune checkpoint inhibitor has been an important advance, but only a fraction of patients respond. In our trial, we had two such patients who were unresponsive to this therapy but showed tumor shrinkage with **IMMU**-132,” Dr. Tagawa said: “I am impressed with the results we have seen in this difficult-to-treat population and we continue to enroll these advanced patients in order to better position this new agent in the management of this disease, either as a second line therapy or perhaps someday in combination with chemotherapy or an immune checkpoint inhibitor.”

Interim results in patients with lung cancers also were presented. Dr. Ronald J. Scheff, Assistant Professor of Clinical Medicine at Weill Cornell Medical College, New York, reported on over 50 patients with metastatic NSCLC being enrolled, showing about one-fifth of evaluable patients had a partial response. Overall, 64% of patients had tumor shrinkage from baseline measurements when given **IMMU-132**. These patients had a median of three prior therapies. Importantly, patients with either nonsquamous or squamous pathology responded, as well as patients who failed a prior immune checkpoint inhibitor treatment. The clinical benefit rate at four months or later was 43%. The median duration of response was eight months, but two patients remain under therapy and responsive for over 20 months. Median PFS and OS on an ITT basis were five and over nine months, respectively.

In patients with metastatic SCLC who had a median of two prior therapies, 16% experienced a confirmed partial response, with an additional nine patients showing tumor shrinkage >20%. Overall, 60% of patients showed tumor shrinkage from baseline. The clinical benefit rate at 4 months or later was 40%. The median duration of partial responses and stable disease was about five months (two patients extending out to 21 months), while the median PFS and OS on an ITT basis were almost four months and seven months, respectively.

“These results in advanced metastatic NSCLC and SCLC patients are very impressive. Durable responses were seen even in patients refractory to multiple prior therapeutic regimens, including immune checkpoint inhibitors,” Dr. Scheff said. “NSCLC is the most common cause of cancer death in the Western World, with very poor 5-year survival statistics. The demonstration of a median survival of over 9 months after patients had already progressed after a range of one to seven prior therapies represents a significant advance.”

Dr. Scheff added, “Although advanced metastatic SCLC commonly responds favorably to first-line chemotherapy, the disease typically subsequently recurs and is associated with a poor prognosis. An agent such as **IMMU-132** that can control disease in some patients for up to almost two years is most encouraging.”

Ms. Sullivan concluded, “These updated data on our lead indications continue to be impressive, particularly because the results from the additional patients enrolled in these trials did not adversely affect the efficacy and safety outcomes. As a monotherapy in late-stage patients with these solid tumor types, it is very rewarding to have developed a product candidate that could make a positive impact and fill the high unmet medical need of such patients. Our trials continue to evaluate **IMMU-132** in other cancer types, such as other metastatic breast cancers, as well as metastatic endometrial and prostate cancers. The positive results we have achieved thus far are a testament to the strength of our clinical investigators and our talented team, and we remain confident in the near-and long-term potential of **IMMU-132**, which could drive significant value for our stockholders.”

In his concluding remarks, Dr. Goldenberg said that the Company's scientists are conducting studies to enhance the good clinical results with **IMMU-132** even further, such as overcoming drug resistance and devising more effective drug combinations. In addition, he emphasized that clinical trials are now expanding in patients with other forms of metastatic breast cancer, as well as metastatic endometrial and prostate cancers, since they have high expression of Trop-2.

### **Value Realization Process for IMMU-132**

In addition to the new clinical data, Immunomedics announced a series of updates related to other aspects of the IMMU-132 program.

#### ***Commercial***

Immunomedics unveiled a summary of the commercial assessment conducted by Health Advances LLC, an independent third-party consulting firm focused exclusively on the healthcare industry, retained to conduct a full commercial assessment of the U.S. and European market opportunities for IMMU-132. The Health Advances study determined that if the current IMMU-132 clinical data are supported by confirmatory/pivotal studies, the U.S. and European market opportunity for IMMU-132 as a third-line monotherapy in TNBC, UC, NSCLC, and SCLC could exceed **\$3 billion** by 2025. Combination and early-line approaches may increase the opportunity to over **\$7 billion**. “IMMU-132’s initial clinical data are very exciting to top oncology key opinion leaders, who see it as a compelling agent with significant potential to address major unmet needs,” said Andrew Funderburk, Partner, Health Advances.

#### ***Regulatory***

Regulatory developments for the IMMU-132 program in TNBC also were presented. The development timeline includes commencement of the Phase 3 confirmatory trial having a Special Protocol Assessment (SPA) in with FDA, in the next few months. Immunomedics plans to file the results with the 100-patient study required by FDA in the accelerated approval application in mid-2017.

#### ***Chemistry, Manufacturing, and Controls (CMC)***

The Company has added significant value to the IMMU-132 program in preparation of the BLA filing for accelerated approval in TNBC, including the scaled-up manufacturing of the ADC for Phase 3/commercial launch materials, extensive comparability testing of Phase 2 vs. Phase 3/commercial product, stability assessments of Phase 3/commercial lots, and full characterization and other analyses required in the CMC portion of the BLA. Additionally, an independent audit of commercial manufacturing facilities, processes, and other relevant CMC matters is underway, all in preparation for the timely BLA filing.

#### ***Intellectual Property***

IMMU-132 has an exceptionally strong patent portfolio. Including the proprietary linker and the use of this ADC in patient therapy, IMMU-132 has been patented in the United States and abroad. IMMU-132, as a biotechnology product, could gain regulatory exclusivity in the United States for 12 years and for 10 years in Europe. Currently, 32 patents on IMMU-132 have been issued in the United States alone, with a patent life extending to 2033; 16 foreign patents also exist.

Vinson & Elkins L.L.P. and DLA Piper LLP (US) are serving as legal advisors, and Greenhill & Co., LLC, is serving as financial advisor to Immunomedics.

### **About Immunomedics**

Immunomedics 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 IntraALL 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](http://www.immunomedics.com). The information on its website does not, however, form a part of this press release.

### **Important Additional Information**

Immunomedics, Inc. (the "Company"), its directors and certain of its executive officers are 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 the 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](http://www.sec.gov). Copies will also be available at no charge at the Company's website at [www.immunomedics.com](http://www.immunomedics.com), by writing to Immunomedics, Inc. at 300 The American Road, Morris Plains, New Jersey 07950, 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), 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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