PUBLISHED RESULTS FROM CLINICAL TRIALS DEMONSTRATE THERAPEUTIC POTENTIAL FOR IMMUNOMEDICS’ SACITUZUMAB GOVITECAN (IMMU-132) IN THE TREATMENT OF METASTATIC SOLID CANCERS

- Results in Advanced Small-cell Lung Cancer (SCLC) Patients Appear in Advanced Online Publication of the American Association of Cancer Research Journal, *Clinical Cancer Research*
- Results in Advanced Non-small-cell Lung Cancer (NSCLC) Patients Appeared in May 26, 2017 Advanced Online Publication of the American Society of Clinical Oncology Journal, *Journal of Clinical Oncology*

Morris Plains, N.J., July 10, 2017 --- Immunomedics, Inc. (NASDAQ: IMMU) (“Immunomedics” or the “Company”) today reported the publication in two prominent cancer journals of phase II clinical trial results with sacituzumab govitecan (IMMU-132) in a total of 104 patients with lung cancer, including advanced small-cell lung cancer (SCLC) and non-small-cell lung cancer (NSCLC) patients who relapsed after, or were refractory to, prior treatment with standard chemotherapy or immune checkpoint inhibitors.

In the SCLC study published online in *Clinical Cancer Research*, the authors evaluated the novel antibody-drug conjugate (ADC), sacituzumab govitecan, composed of an antibody targeting Trop-2 and carrying the active metabolite of irinotecan, SN-38. The study included 50 SCLC patients with metastatic (stage IV) disease who had a median of 2 prior therapies. Notable findings from the study include:

- Ninety-two percent of the patients evaluated for expression of the target for sacituzumab govitecan, Trop-2, had elevated levels in their archived tumor specimens.
- Patients given repeated treatment cycles had manageable toxicity, mostly Grade >3 neutropenia (34%), and 60% of those patients experienced tumor shrinkage from baseline CT measurements.
- The objective response rate was 17% at the optimal dose schedule; the median duration of response and overall survival were 5.7 and 7.5 months, respectively.
- Activity was observed in patients who were chemosensitive or chemoresistant to frontline chemotherapy, in patients who failed second-line topotecan, and in a subset who relapsed after immune checkpoint inhibitor therapy.

The article’s first author, Jhanelle Gray, M.D., of the Moffitt Cancer Center, Tampa, FL, remarked, “Topotecan, another topoisomerase-I inhibitor, is the only drug approved in the USA for SCLC patients who are responsive to frontline therapy with a platinum-containing chemotherapy. In contrast, sacituzumab govitecan showed activity in patients who were either responsive or refractive to frontline therapy, and also to those who relapsed to topotecan. A randomized, controlled trial comparing these two agents in second-line therapy, as well as sacituzumab in the frontline setting, should be undertaken.”
Dr. David M. Goldenberg, Immunomedics’ founder, commented that, “Sacituzumab govitecan represents a promising new therapeutic candidate for advanced mSCLC, a very lethal cancer with a five-year survival rate of only 6 percent.” Goldenberg continued, “Importantly, this candidate potentially could be the first new therapeutic approved for the treatment of metastatic (stage IV) small-cell lung cancer (mSCLC) in twenty years.”

In the second article published online on May 26, 2017, in the Journal of Clinical Oncology, the authors reported the results of the phase II, multicenter trial of 54 heavily-pretreated patients with metastatic NSCLC who received either 8 or 10 mg/kg sacituzumab govitecan on days 1 and 8 of 21-day cycles. The primary endpoints were safety and objective response rate (ORR). Progression-free survival (PFS) and overall survival (OS) were secondary endpoints. Notable findings from the study include:

- In the response-assessable study population (N = 47), which had a median of 3 prior therapies (range, 2-7), 67% of patients showed a shrinkage from baseline CT measurements.
- The confirmed objective response rate was 19.1%, the median response duration 6.0 months (95% CI, 4.8, 8.3), and the clinical benefit rate (CR+PR+SD>4 months) was 43%. Responses occurred with a median onset of 3.8 months, including patients who had relapsed or progressed after immune checkpoint inhibitor therapy.
- Median intention-to-treat (ITT) PFS was 5.2 months (95% CI, 3.2, 7.1), and median ITT OS was 9.5 months (95% CI, 5.9, 16.7).
- Grade 3 or higher adverse events included neutropenia (28%), diarrhea (7%), nausea (7%), fatigue (6%), and febrile neutropenia (4%).
- Over 90% of 26 assessable archival tumor specimens were highly positive for Trop-2 by immunohistochemistry.

Dr. D. Ross Camidge, Director of Thoracic Oncology at the University of Colorado Cancer Center and senior author of this study, commented, “In a heavily pretreated population like this, the results with sacituzumab govitecan are quite encouraging, suggesting further trials both alone and in combination with other drugs, potentially including immunotherapy, should be strongly considered.” Camidge continued, “Non-small-cell lung cancer patients will always benefit from additional therapeutic choices, and while immunotherapy and oncogene targeted therapy have certainly revolutionized the treatment for subsets of the disease, the use of ‘smarter’ chemotherapy in the form of an effective antibody-drug conjugate such as sacituzumab govitecan may well be the next major advance we see.”

Dr. Behzad Aghazadeh, Chairman of the Board of Immunomedics, stated, “These promising results in two lung cancer indications, comprising the major cancer killers, attest to the breadth of the therapeutic potential for IMMU-132 in the treatment of metastatic solid cancers. Our principal focus is to seek accelerated approval for this ADC in patients with advanced, heavily-pretreated triple-negative breast cancer (TNBC), for which there is no approved therapy and significant patient unmet need.” Aghazadeh continued, “We have also reported that sacituzumab govitecan, in addition to TNBC, SCLC, and NSCLC, is active in patients with metastatic urothelial cancers, where we hope to update results at a future medical meeting, so we now know it is active in at least four different major solid cancers.”
References

About Lung Cancer
Lung cancer is the most prevalent cancer worldwide; 1.8 million patients were diagnosed in 2012. It is also the leading cause of cancer deaths, taking 1.6 million lives annually. The vast majority of lung cancer cases (85%) comprise the NSCLC type, which has had a median life expectancy of 10 months when standard chemotherapy is used. With the introduction of immune checkpoint inhibitors, median survival has increased to almost 15 months when at least 50% of cells were positive for PD-L1. In fact, pembrolizumab was reported to be more effective than chemotherapy in the frontline setting of patients with metastatic NSCLC at high levels of PD-L1 positivity (progression-free survival 10.3 months vs. 6.0 months for those given platinum-based chemotherapy), but this population only constituted about one-quarter of metastatic NSCLC patients. In pretreated patients with metastatic NSCLC, the objective response rates for the immune checkpoint inhibitors generally range from 14% to 20%.

SCLC comprises approximately 15% of all lung cancers, and has the worst prognosis. This is because of its highly aggressive nature, with about two-thirds of patients already having metastatic disease at diagnosis. While palliative first-line therapy of stage IV SCLC (mSCLC) has a high initial response rate of 60% to 75%, the outcome is poor, with a median progression-free survival of only 5.5 months and a median overall survival of <10 months with platinum-based chemotherapy. Responses to second-line therapy have been poorer, such as <10%, with a median survival of only 4 to 5 months following second- or third-line chemotherapy. Unfortunately, those patients with platinum-resistant mSCLC (i.e., response duration <3 months) fare even worse. In the USA, the only approved drug in this second-line setting of chemosensitive patients (duration of response exceeding 3 months), since 1998, is topotecan, indicated for recurrent patients who were sensitive to frontline chemotherapy with platinum-containing regimens. Still, irinotecan, taxanes, vinorelbine, gemcitabine, and pemetrexed are given frequently to patients with chemosensitive recurrent disease. Even when patients respond to second-line therapies, there is usually no improved survival. Immune checkpoint inhibitors have not gained a role in the management of mSCLC.

About Sacituzumab Govitecan
Sacituzumab govitecan is a second-generation ADC composed of a humanized anti-Trop-2 antibody conjugated at a drug:antibody ratio of 7.6 with SN-38, the active metabolite of the
approved drug, irinotecan. Both irinotecan and SN-38 inhibit the nuclear enzyme, topoisomerase-1, resulting in double-strand DNA breaks and death of the affected cells. SN-38 is about 1,000-fold more potent than its parental prodrug, irinotecan. However, because it is delivered selectively by the anti-Trop-2 antibody, it is believed this toxicity is selective for cancer cells having higher levels of Trop-2 than normal cells. This results in a selective targeting and killing of cancer cells having Trop-2, which includes a large number of cancer types. Because of the way SN-38 is attached to the cancer-targeting antibody, sacituzumab therapy avoids the debilitating diarrhea caused by irinotecan therapy. However, like irinotecan, the major adverse effect is neutropenia, which is manageable either by reducing or delaying therapy, or treating the patient with a drug that stimulates production of neutrophils. To-date, sacituzumab govitecan has been studied by Immunomedics in approximately 500 patients comprising several different advanced solid cancers.

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’ most advanced product candidate is IMMU-132 (sacituzumab govitecan), an antibody-drug conjugate that 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’ primary goal is to bring IMMU-132 to market for the benefit of patients and the creation of shareholder value. 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.

Cautionary note regarding 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, forecasts of future operating results, potential collaborations, and capital raising activities, timing for bringing any product candidate to market, 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.
For More Information:
Dr. Chau Cheng
Senior Director, Investor Relations & Corporate Secretary
(973) 605-8200, extension 123
ccheng@immunomedics.com

Media/Investor Contact:
Dan Zacchei / Jaimee Pavia
Sloane & Company
212-486-9500
Dzacchei@sloanepr.com
Jpavia@sloanepr.com

###