

**IMMUNOMEDICS REPORTS CONTINUING POSITIVE RESULTS WITH  
SACITUZUMAB GOVITECAN IN HEAVILY PRE-TREATED  
METASTATIC TRIPLE-NEGATIVE BREAST CANCER PATIENTS**

- Objective Response Rate (ORR) of 31%, 78% Confirmed --**
- Median Progression-Free Survival (PFS) was 6.0 Months, 58% Maturity --**
- Interim Results Presented at 2015 San Antonio Breast Cancer Symposium --**

**San Antonio, TX, December 10, 2015** --- [Immunomedics, Inc.](#) (Nasdaq: IMMU) today announced updated results from a Phase 2 clinical study of sacituzumab govitecan, its lead investigational antibody-drug conjugate (ADC), in patients with metastatic triple-negative breast cancer (mTNBC) who had received a median of 5 (range, 2 ó 12) prior lines of therapy. Despite this late-stage setting, the ADC, as a single agent, produced an interim ORR of 31% by RECIST 1.1 in 58 evaluable patients, with 78% of these responding patients confirmed with a follow-up computed tomography scan, including 2 patients with a complete response.

Among the 60 intent-to-treat patients, the interim median PFS was 6.0 months, with 58% of these patients having experienced a PFS event. Importantly, there is a significant positive correlation between PFS and maximal tumor shrinkage relative to baseline ( $R=0.62$ ,  $P<0.001$ ) for the 31 patients whose cancer had progressed after reporting stable disease, partial or complete response as their best response. Median overall survival data were too early to report, with 83% of patients still alive.

Sacituzumab govitecan has an acceptable interim safety profile in the 60 mTNBC patients reported at the Symposium. The major toxicity was Grade 3 or 4 neutropenia in 15% of patients. Severe diarrhea, commonly reported with irinotecan, was rare with only 5% Grade 3/4 incidents. Moreover, repeated doses can be given over months without evoking interfering anti-sacituzumab govitecan antibodies from patients' own immune system.

“This study provides us with a strong basis for a first pivotal Phase 3 trial in mTNBC, and we will continue the regulatory and manufacturing activities in calendar year 2016,” remarked Cynthia L. Sullivan, President and Chief Executive Officer. “We are fully committed to partnering this important Phase 3 asset, and that partnership will include the full dedication to progress sacituzumab govitecan not only in TNBC, but simultaneously in other indications.”

The Company has filed a multicenter, international, randomized, open-label Phase 3 study of approximately 328 patients with mTNBC who are refractory or relapsing after at least 2 prior chemotherapies that included a taxane for their metastatic disease. In accordance with the Company's Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration, the primary endpoint of the trial will be PFS, which will be measured by an independent centralized and blinded group of radiology experts who will be assessing tumor response using RECIST 1.1 criteria. Overall survival, ORR, duration of response, and time to onset of response will serve as secondary endpoints.

The Phase 2 study was updated by Aditya Bardia, MD, MPH, Assistant Professor of Medicine at Harvard Medical School, Attending Physician at the Massachusetts General Hospital Cancer

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Center in Boston, and an investigator in this trial. Dr. Steven Isakoff, a colleague of Dr. Bardia, also participated in this multicenter study. Other Principal Investigators include Drs. Jennifer R. Diamond and Wells A. Messersmith, University of Colorado Cancer Center, Aurora, CO; Drs. Ingrid A. Mayer and Jordan D. Berlin, Vanderbilt-Ingram Cancer Center, Vanderbilt University, Nashville, TN; Dr. Alexander N. Starodub, Indiana University Health Center for Cancer Care, Goshen, IN; Drs. Rebecca L. Moroose and Sajeve S. Thomas, UF Health Cancer Center, Orlando, FL; Drs. Allyson J. Ocean and Linda T. Vahdat, Weill Cornell Medical College, New York, NY; Dr. Michael J. Guarino, Helen F. Graham Cancer Center & Research Institute, Newark, DE; Dr. Joyce A. O'Shaughnessy, Baylor Sammons Cancer Center, Texas Oncology, Dallas, TX; and Drs. Kevin Kalinsky and Matthew Maurer, Columbia University Medical Center, New York, NY.

### **About Triple-Negative Breast Cancer (TNBC)**

TNBC is a serious disease, with an annual incidence estimated to be about 40,000 people, 20,000 for mTNBC, in the United States. mTNBC is insensitive to most of the available targeted therapies for breast cancer treatment, including HER2-directed therapy (such as trastuzumab), and endocrine therapies (such as tamoxifen or the aromatase inhibitors). The median overall survival is 10-13 months and the median PFS is usually 3-4 months. There is currently no single standard chemotherapy to treat patients with relapsed/refractory mTNBC. Rapid relapse, with visceral and brain metastases are very common.

### **About Sacituzumab Govitecan**

Sacituzumab govitecan, or IMMU-132, is a first-in-class ADC developed by the Company by conjugating the moderately-toxic drug, SN-38, site-specifically and at a high ratio of drug to antibody, to a humanized antibody that targets the TROP-2 receptor expressed by many solid cancers. SN-38 is the active metabolite of irinotecan (Camptosar), which is used to treat certain solid cancers as a part of combination therapies, so its pharmacology and properties are well-known. The ADC has received Fast Track designation from the FDA for the treatment of patients with triple-negative breast cancer, small-cell and non-small-cell lung cancers, and has also been designated an orphan drug for the treatment of patients with small-cell lung or pancreatic cancer in the U.S., and for the treatment of patients with pancreatic cancer in the European Union.

### **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 nine clinical-stage product candidates. Immunomedics' most advanced candidate is <sup>90</sup>Y-clivatuzumab tetraxetan. The radiolabeled antibody is in a Phase 3 registration trial in patients with advanced pancreatic cancer. Immunomedics expects patient enrollment to be completed in calendar year 2016. Immunomedics' portfolio of investigational products also 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. 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 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<sup>®</sup> protein conjugation technology. The Company believes that its portfolio of intellectual property, which includes approximately 277 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.

*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, outcomes, timing or associated costs), 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, new product development (including clinical trials outcome and regulatory requirements/actions), the Company's dependence on business collaborations in order to further develop our products and finance our operations, 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 availability of required financing and other sources of funds on acceptable terms, if at all, 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](mailto:ccheng@immunomedics.com)