IMMUNOMEDICS REPORTS SACITUZUMAB GOVITECAN (IMMU-132) IS ACTIVE IN PATIENTS WITH METASTATIC SMALL-CELL LUNG CANCER WHO ARE SENSITIVE OR RESISTANT TO FIRST-LINE CHEMOTHERAPY

Washington, D.C., April 5, 2017 --- Immunomedics, Inc., (NASDAQ: IMMU) (the Company) today reported that sacituzumab govitecan (IMMU-132), the Company’s lead antibody-drug conjugate (ADC), has activity and manageable toxicity in patients with advanced and heavily-pretreated metastatic small-cell lung cancer (SCLC).

"Despite recent progress in immunotherapy and the identification of other novel targets for SCLC, this still is a lethal disease, especially in the population that is chemoresistant to first-line therapy," remarked Jhanelle E. Gray, MD, Medical Oncologist and the Director of Clinical Research in the Department of Thoracic Oncology at H. Lee Moffitt Cancer Center and Research Institute in Tampa, Florida, who presented the updated results at the 2017 AACR Annual Meeting.

The relapse of SCLC to frontline chemotherapy continues to be divided into two categories, resistant relapse, occurring within three months of the first platinum-based therapy, and sensitive relapse, which occurs after at least 3 months post treatment. Although there is still some ambiguity regarding the best management of recurrent SCLC, topotecan, a topoisomerase-I inhibitor similar to the SN-38 used in the ADC studied here, is the only product approved for second-line chemosensitive relapse. In the twenty years since the approval of topotecan in the second-line setting, no new agent has been licensed for metastatic SCLC therapy in second-line or later therapy.

It is in this setting that the results reported at the AACR conference with sacituzumab govitecan in advanced-disease patients (stage IV) are promising. A total of 53 patients with metastatic SCLC were enrolled into the open-label Phase 2 study after receiving a median of 2 prior lines of therapy (range, 1 to 7). All patients had previously received cisplatin or carboplatin plus etoposide, and were considered chemosensitive (N=27, 51%) or chemoresistant (N=26, 49%) to their platinum-containing frontline therapy, based on a duration of response of more than 3 months or less than 3 months, respectively. Treatments with sacituzumab govitecan were administered at a dose of either 8 or 10 mg/kg on days 1 and 8 of 21-day cycles. The primary endpoints were safety and objective response rate (ORR), with duration of response, progression-free survival (PFS), and overall survival (OS) as secondary endpoints.

Sixty percent of patients showed tumor shrinkage from baseline measurements using computed tomography (CT). On an intention-to-treat (ITT) basis (N= 50), the ORR was 14% (17% for the 10 mg/kg group) and the median response duration was 5.7 months (95% confidence interval [CI], 3.6 to 19.9 months). Clinical benefit rate (CBR) at 4 months was 34%, with median PFS and median OS at 3.7 months (95% CI, 2.1 to 4.3 months) and 7.5 months (95% CI, 6.2 to 8.8 months), respectively. There was no statistical difference in ORR, PFS or OS between those patients who were chemosensitive or chemoresistant to first-line chemotherapy, but the CBR was
50% and 26%, respectively. There was a statistically significant higher OS in those patients who received prior topotecan versus no topotecan therapy.

The current results of sacituzumab govitecan in heavily-pretreated patients with advanced, relapsed, stage IV, SCLC, despite the limitations of a one-arm trial, suggest that this investigational ADC may gain a role in the therapy of both chemosensitive and chemoresistant SCLC patients, both before or after topotecan treatment, and thus needs to be studied further in such settings, commented Cynthia L. Sullivan, President and Chief Executive Officer of Immunomedics.

Grade 3 or higher adverse events included neutropenia (34%), fatigue (13%), diarrhea (9%), and anemia (6%). Trop-2 tumor staining was not required for patient selection, due to 92% (23/25) positivity. No antibodies to the drug conjugate or its components were detected on serial blood collections, despite more than 60 doses being given.

In addition to Dr. Gray, other clinical investigators who participated in this multicenter study included Drs. Rebecca S. Heist and Leena Gandhi, Massachusetts General Hospital Cancer Center, Harvard Medical School, Boston, MA; Drs. Alexander N. Starodub and Ebenezer Kio, Indiana University Health Center for Cancer Care, Goshen, IN (Dr. Starodub's current address is Parkview Cancer Institute, Fort Wayne, IN); Drs. D. Ross Camidge, W. Thomas Purcell and Wells A. Messersmith, University of Colorado Cancer Center, Aurora, CO; Drs. Gregory Masters, Michael J. Guarino, Jamal Misleh and Charles J. Schneider, Helen F Graham Cancer Center, Newark, DE; Drs. Bryan J. Schneider, Allyson J. Ocean and Ronald J. Scheff, Weill Cornell Medicine, New York, NY; Dr. Tirrell Johnson, UF Health Cancer Center, Orlando, FL; and Dr. Kevin Kalinsky, Columbia University-Herbert Irving Comprehensive Cancer Center, New York, NY.

About Small-Cell Lung Cancer (SCLC)
SCLC comprises approximately 15% of all lung cancers, yet has one of the lowest 5-year survival rates at 6%. 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 metastatic SCLC 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 less than 10 months with platinum-based chemotherapy. Responses to second-line therapy have been poorer, such as less than 10%, and with a median survival of only 4 to 5 months following second- or third-line chemotherapy. Since 1998, the only approved drug in this second-line setting is topotecan, indicated for recurrent patients who were sensitive (duration of response exceeding 3 months). Unfortunately, those patients with platinum-resistant metastatic SCLC (i.e., response duration of less than 3 months) fare even worse.

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 toxicities 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 310 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.

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.
For More Information:
Dr. Chau Cheng
Senior Director, Investor Relations & Corporate Secretary
(973) 605-8200, extension 123
cccheng@immunomedics.com