PRECLINICAL STUDY ON ENHANCING SACITUZUMAB GOVITECAN (IMMU-132) ACTIVITY IN SN-38-RESISTANT CANCER CELLS PUBLISHED

Morris Plains, NJ, August 18, 2016 --- Immunomedics, Inc. (Nasdaq: IMMU) today announced that adding an inhibitor of ATP-binding cassette (ABC) transporters to sacituzumab govitecan, the Company’s lead antibody-drug conjugate (ADC) for solid cancer therapy, increased the median survival of mice bearing a SN-38-resistant human gastric cancer cell line. Results from this preclinical study were published in Molecular Cancer Therapeutics.1

Sacituzumab govitecan 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 hRS7, a humanized antibody that targets the Trop-2 receptor expressed by many solid cancers. This ADC has produced promising therapeutic results in some patients with metastatic solid cancers in an open-label, single arm Phase 2 study. Based on results from this mid-stage trial, the FDA has granted sacituzumab govitecan Breakthrough Therapy designation for the treatment of patients with triple-negative breast cancer who have failed prior therapies for metastatic disease, and the Company is working with the regulatory agency toward a potential accelerated approval in this disease setting.

A common cause of treatment failure in cancer therapy is multidrug resistance. In general, the occurrence of drug resistance in cancer cells can be intrinsic or acquired, with each type resulting from a variety of factors, such as decreased uptake of soluble drugs, activation of drug-detoxifying systems, modulation or mutation of drug targets, defective apoptosis pathways, and, above all, overexpression of the ABC transporters, which act by expelling drugs from the cell, thereby lowering the amount of drugs inside the cancer cells.

The objective of this preclinical study was to explore the use of known inhibitors of ABC transporters for improving the therapeutic efficacy of sacituzumab govitecan by overcoming SN-38-resistance. Human breast and gastric cancer cell lines were first made resistant to SN-38 by continuously exposing them to increased concentrations of SN-38 over a period of approximately 2 years. The two SN-38-resistant cell lines were shown to be 50-fold less responsive to SN-38 than their parental cells.

Treatment of both SN-38-resistant human cancer cell lines with known inhibitors of ABC transporters restored toxicity of SN-38. More importantly, when sacituzumab govitecan was combined with YHO-13351, an inhibitor of ABC transporter, in mice bearing SN-38-resistant human gastric cancer cell line, a statistically significant 64% improvement in median survival was achieved in comparison with untreated animals (P = 0.0278). Sacituzumab govitecan alone had a 29% improvement in median survival, while YHO-13351 showed no effect on its own. Although irinotecan plus YHO-13551 improved the survival of the mice, it did not reach significance (P = 0.0852).

Commenting on these preclinical results, Cynthia L. Sullivan, President and Chief Executive Officer stated, "These in vivo results suggest that suitable inhibitors that are tolerated well by the host animals can overcome ABC resistance and that the resistant tumor lines can become
Ms. Sullivan added, ÒWe are pursuing further work to address the feasibility of preclinical testing for such drug resistance as a predictive bioassay to select patients who should receive ABC-blocking therapy with IMMÚ-132, in order to enhance the potency of IMMÚ-132 in cancer cells that are intrinsically or become resistant to SN-38.Ó

References

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 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 288 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), 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.

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