



IMMUNOMEDICS REPORTS SACITUZUMAB GOVITECAN (IMMU-132) DELIVERS HIGH LEVELS OF SN-38 THAT OVERCOME CHEMORESISTANT TUMORS WITH MODERATE TO STRONG TROP-2 EXPRESSION

Preclinical Study Presented at 2017 AACR Annual Meeting

*Pharmacokinetics of Sacituzumab Govitecan in Patients with Diverse Solid Tumors also
Presented*

Washington, D.C., April 4, 2017 --- [Immunomedics, Inc.](#), (NASDAQ: IMMU) (the Company or we) today announced that its lead antibody-drug conjugate (ADC), sacituzumab govitecan (IMMU-132), with a proprietary SN-38-delivery platform, has the potential to provide clinical benefit both to chemosensitive solid tumors with low Trop-2 expression, as well as to chemoresistant tumors with high Trop-2 expression.

This preclinical study demonstrated that using IMMU-132 to deliver SN-38 to tumor cells is a unique way to accrete enough SN-38 within the tumor to cause significant DNA damage and overpower the DNA-repair systems within the targeted cells, remarked Cynthia L. Sullivan, President and Chief Executive Officer.

The Company had previously reported that exposure to sacituzumab govitecan may induce an increase in several different proteins involved in the repair of DNA double strand breaks resulting in resistance to therapy.¹ Given that sacituzumab govitecan mediated different antitumor responses in different tumor types, despite the fact that some tumor lines expressed similar low levels of Trop-2, DNA repair by some tumor cells may play an important role in determining sensitivity to therapy with sacituzumab govitecan. Furthermore, resistance to chemotherapy (e.g., irinotecan) may also be due in part to increased expression of proteins used to rescue the cell from ensuing DNA damage.

However, we postulated that if enough drug, such as SN-38, enters the cell, significant DNA damage will occur that will overwhelm any repair mechanisms resulting in apoptosis and cell death. We conducted a preclinical study to investigate if sacituzumab govitecan, through its targeting of Trop-2 in solid tumors, would be superior to irinotecan in overcoming the repair of DNA breaks in triple-negative breast cancer (TNBC) cells with moderate to high Trop-2 expression.

A TNBC cell line with very active DNA repair pathways, and low Trop-2 expression, was genetically modified to yield two new tumor lines with moderate and high Trop-2 expression. Mice bearing these three different tumor types (low, moderate and high Trop-2) were randomized into various treatment groups. In all three tumor types, irinotecan, at its maximum tolerated dose (>35-fold more SN-38 than sacituzumab govitecan dose), provided a modest survival benefit relative to the control group, with no significant difference between tumor types. However, in mice bearing tumors with moderate or high Trop-2 expression, sacituzumab govitecan therapy mediated significant antitumor effects compared to all other treatments,

including irinotecan and control ADC therapy. This greatly improved antitumor activity of sacituzumab govitecan over irinotecan is likely due to increased targeting and uptake of SN-38 in these tumors by sacituzumab govitecan at levels capable of overcoming induced DNA repair.

If our hypothesis is correct, these preclinical results may offer an explanation for our clinical observation that moderate to strong Trop-2 expression measured by immunohistochemistry in most cancers might not be useful in predicting a patient's response to sacituzumab govitecan treatment, one of the key findings in our second poster presentation at this year's AACR conference, which focused on the pharmacokinetics of this investigational ADC in patients with diverse solid tumors," added Ms. Sullivan.

The pharmacokinetics study, entitled "Pharmacokinetics of Sacituzumab Govitecan (IMMU-132), an Antibody-drug Conjugate (ADC), Targeting Trop-2, in Patients with Diverse Solid Tumors," was presented by Dr. Robert M. Sharkey, a consultant of the Company. Other co-authors are Dr. Allyson J. Ocean, Weill Cornell Medicine, New York, NY; Dr. Alexander N. Starodub, Indiana University Health Center for Cancer Care, Goshen, IN (current address, Parkview Cancer Institute, Fort Wayne, IN); Dr. Aditya Bardia, Massachusetts General Hospital Cancer Center, Harvard Medical School, Boston, MA; Dr. Michael Guarino, Helen F Graham Cancer Center, Newark, DE; Dr. Wells A. Messersmith, University of Colorado Cancer Center, Aurora, CO; Dr. Jordan D. Berlin, Vanderbilt-Ingram Cancer Center, Nashville, TN; Dr. Vincent J. Picozzi, Virginia Mason Cancer Center, Seattle, WA; Dr. Rebecca Moroosse, UF Health Cancer Center, Orlando, FL; and Immunomedics employees, Drs. William A. Wegener, Pius Maliakal, Serengulam V. Govindan and David M. Goldenberg.

Sacituzumab govitecan cleared in a predictable manner based on *in-vitro* serum stability studies, with no difference between the 8 and 10 mg/kg dose groups studied clinically. While there was a gradual release of SN-38, more than 90% of the SN-38 in the serum at any given time stayed bound to the antibody. Glucuronidated SN-38 concentrations were lower than SN-38, a possible reason for the lower incidence of severe diarrhea as compared to irinotecan. In addition, neither neutropenia nor diarrhea was found to correlate with free SN-38 levels in serum. With no difference in safety and pharmacokinetics, but improved objective response rate and clinical benefit ratio favoring the 10 mg/kg group in TNBC, small-cell and non-small-cell lung cancer indications, 10 mg/kg is selected as the starting dose for future clinical studies in treating patients with multiple cancer indications.

Reference

1. Cardillo TM, Sharkey RM, Rossi DL, et al. Synthetic lethality exploitation by an anti-Trop-2-SN-38 antibody-drug conjugate, IMMU-132, plus PARP-inhibitors in BRCA1/2-wild-type triple-negative breast cancer. *Clin Cancer Res*. Epub ahead of print. Jan 9, 2017.

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 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 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.

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