



## IMMUNOMEDICS REPORTS RESULTS FROM THREE PHASE I TRIALS WITH IMMU-130 IN METASTATIC COLORECTAL CANCER

**San Diego, CA, April 7, 2014 --- Immunomedics, Inc. (Nasdaq: IMMU)**, a biopharmaceutical company primarily focused on the development of monoclonal antibody-based products for the targeted treatment of cancer, autoimmune and other serious diseases, today reported the results from 3 Phase I trials with IMMU-130, the Company's investigational anti-CEACAM5 antibody conjugated to the irinotecan-metabolite, SN-38. The antibody-drug conjugate (ADC) was therapeutically active in all 3 trials, but a more frequent dosing schedule, with administrations of IMMU-130 once or twice-weekly for 2 weeks followed by a week off, was more active in patients with metastatic colorectal cancer (mCRC) than when administered every other week.

Results from these Phase I studies were presented at the 2014 Annual Meeting of the American Association for Cancer Research in San Diego, CA, by a group of clinical investigators, with the first author being Dr. Neil H. Segal from Memorial Sloan-Kettering Cancer Center, New York, NY.

Patients with advanced mCRC who relapsed after at least one irinotecan-containing treatment were enrolled in these multicenter trials. Six patients completed at least 1 cycle of once-weekly therapy in this ongoing trial, with 3 out of 4 patients with computer tomography (CT) assessment reporting stable disease as their best response.

For the twice-weekly dosing regimen, 16 patients have been enrolled, with 8 patients having CT-assessments of response. Best responses out of 8 assessable patients included one having a partial response (shrinkage of 66% of target tumors measured by CT, based on RECIST criteria) and 5 patients having stable disease. The patient with the partial response received 40 IMMU-130 injections over 8 months, with disease shrinkage first observed within 2 months from the start of treatment, and with the partial response now continuing for more than 4 months.

In another Phase I study in which IMMU-130 was administered every 14 days, another partial response was reported in a patient whose colorectal cancer had spread to the lungs and liver after multiple prior therapies. This patient tolerated a total of 18 doses at 16 mg/kg and showed a 40.6% decrease in the liver and lung target lesions measured by CT, with disease shrinkage observed over a period of about 9 months.

In all three trials, measurement of SN-38 concentrations in the serum found much higher levels that were sustained longer than is typically found with irinotecan therapy (the parental drug of SN-38). However, most of the SN-38 remains bound to the antibody, keeping it in an inactive form to normal tissues while in circulation, which reduces toxicity, yet allowing for higher concentrations of activated SN-38 to be delivered to the tumor where it is released from the pH-sensitive linker. Neutropenia and manageable diarrhea were the main side effects.

"These results suggest that IMMU-130 may have a high therapeutic index and can be administered in repeated cycles in advanced mCRC patients," commented Cynthia L. Sullivan, President and Chief Executive Officer. "A Phase II trial evaluating once or twice-weekly dosing

for 2 weeks in a 21-day cycle is ongoing in mCRC. Since the target of IMMU-130, CEACAM5, has elevated expression in breast and lung cancers, as well as other tumors, this ADC may be useful in other cancers as well,” Ms. Sullivan added.

### **About Immunomedics**

Immunomedics is a New Jersey-based biopharmaceutical company primarily focused on the development of monoclonal antibody-based products for the targeted treatment of cancer, autoimmune and other serious diseases. We have developed a number of advanced proprietary technologies that allow us to create humanized antibodies that can be used either alone in unlabeled or “naked” form, or conjugated with radioactive isotopes, chemotherapeutics, cytokines or toxins, in each case to create highly targeted agents. Using these technologies, we have built a pipeline of therapeutic product candidates that utilize several different mechanisms of action. Our lead product candidate, epratuzumab, is currently in two Phase III clinical trials in lupus. In oncology, clivatuzumab tetraxetan labeled with a radioisotope is in a Phase III pivotal trial in advanced pancreatic cancer patients. Other solid tumor therapeutics in Phase II clinical development include 2 antibody-drug conjugates, IMMU-132 (anti-TROP-2-SN-38) and IMMU-130 (anti-CEACAM5-SN-38). We also have a majority ownership in IBC Pharmaceuticals, Inc., which is developing a novel DOCK-AND-LOCK™ (DNL™) method with us for making fusion proteins and multifunctional antibodies. DNL™ is being used particularly to make bispecific antibodies targeting cancers and infectious diseases as a T-cell redirecting immunotherapy, as well as bispecific antibodies for next-generation cancer and autoimmune disease therapies. We believe that our portfolio of intellectual property, which includes approximately 245 active patents in the United States and more than 400 foreign patents, protects our product candidates and technologies. Our strength in intellectual property has resulted in the top-4 ranking in the January 2014 Patent Board scorecard in the Biotechnology industry. For additional information on us, please visit our website at [www.immunomedics.com](http://www.immunomedics.com). The information on our website does not, however, form a part of this press release.

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