

## **IMMUNOMEDICS ANNOUNCES ORPHAN DRUG DESIGNATION FOR IMMU-132 FOR PANCREATIC CANCER THERAPY**

**Morris Plains, NJ, June 9, 2014 --- Immunomedics, Inc., (Nasdaq: IMMU)** today announced that IMMU-132, the Company's antibody-drug conjugate (ADC) for solid cancer therapy, has received orphan drug status from the Office of Orphan Products Development of the U.S. Food and Drug Administration (FDA) for the treatment of pancreatic cancer.

"This is the second orphan designation from FDA for IMMU-132, which has demonstrated activity in patients with advanced pancreatic cancer, as well as partial responses in 5 other types of solid cancer," commented Cynthia L. Sullivan, President and Chief Executive Officer.

As recently reported by the Company at the American Association for Cancer Research Special Conference on Pancreatic Cancer: Innovations in Research and Treatment, 13 pancreatic cancer patients who had failed 1-5 prior therapies showed a median time-to-progression of 12.7 weeks (range 4.3-21.4 weeks) after receiving repeated doses of IMMU-132. This compared favorably with the median 8.0 weeks (range 4-36 weeks) estimated from the patients' last prior therapy.

IMMU-132 has also been designated an orphan drug by FDA for the treatment of patients with small-cell lung cancer. In an ongoing Phase I/II clinical study, IMMU-132 has resulted in partial responses in patients with colorectal cancer, esophageal cancer, triple negative breast cancer, and small-cell and non-small-cell lung cancers.

Orphan drug status is granted by FDA to a drug or biological product to treat a rare disease or condition upon request of a sponsor. Orphan drug designation qualifies the Company for various development incentives, including tax credits for qualified clinical testing, a waiver from FDA's application User Fee for marketing application, and a seven-year period of marketing exclusivity in the United States for IMMU-132, if it is approved by FDA for the treatment of patients with pancreatic or small-cell lung cancer.

The granting of an orphan designation request does not alter the standard regulatory requirements and process for obtaining marketing approval. Safety and effectiveness of a drug must be established through adequate and well-controlled studies.

### **About IMMU-132**

IMMU-132 is composed of hRS7, a humanized antibody that binds to the trophoblast cell-surface antigen (TROP-2), also known as the epithelial glycoprotein-1 antigen (EGP-1). TROP-2 is expressed by many human tumors, such as cancers of the breast, cervix, colon and rectum, kidney, liver, lung, ovary, pancreas, and prostate, but with only limited expression in normal human tissues. The antibody, hRS7, internalizes into cancer cells following binding to TROP-2, making it a suitable candidate for the delivery of cytotoxic drugs.

SN-38 is the active metabolite of irinotecan, which is a standard therapy for patients with metastatic colorectal cancer, but has major gastrointestinal and hematologic toxicity. By attaching SN-38 to tumor-targeting antibodies, delivery of SN-38 to the tumor may be increased

several-fold while mitigating systemic toxicity. Preclinical studies have indicated that IMMU-132 delivers 120-times the amount of SN-38 to a human pancreatic tumor xenograft than when irinotecan is given. In various animal models of human cancers, IMMU-132 significantly improved survival and tumor regression.

### **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 has an ongoing collaboration with UCB, S.A. (UCB), who has worldwide rights in non-cancer indications to Immunomedics' Phase III product candidate, epratuzumab. UCB expects Phase III data in systemic lupus erythematosus (SLE) in the first quarter of 2015. Immunomedics is exploring epratuzumab in oncology in collaboration with outside cancer study groups. Immunomedics' most advanced wholly owned candidate is <sup>90</sup>Y-clivatuzumab tetraxetan, which is in an ongoing Phase III registration trial in patients with pancreatic cancer. Immunomedics' portfolio of wholly owned product candidates also includes antibody-drug conjugates (ADCs) that are designed to deliver a specific payload of a chemotherapeutic directly to the tumor while reducing overall toxicity effects that typically occur when these chemotherapeutic agents are dosed alone. Immunomedics' most advanced ADCs are IMMU-132 and IMMU-130, which are in Phase I/II trials for a number of solid tumors and metastatic colorectal cancer (mCRC), respectively. 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 pre-clinical development. These include bispecific antibodies which have application as T-cell redirecting immunotherapies targeting cancers and infectious diseases as well as next-generation therapies in cancer and autoimmune disease. Immunomedics creates these bispecific antibodies using its patented DOCK-AND-LOCK™ (DNL™) protein conjugation technology. The Company believes that its portfolio of intellectual property, which includes approximately 248 active patents in the United States and more than 400 foreign patents, protects its product candidates and technologies. Immunomedics' 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 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), our dependence on UCB for the further development of epratuzumab for non-cancer indications, risks associated with the outcome of pending litigation, 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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