

## IMMUNOMEDICS ANNOUNCES ORPHAN DRUG DESIGNATION FOR VELTUZUMAB FOR THE TREATMENT OF PEMPHIGUS

**Morris Plains, NJ, November 21, 2014** --- [Immunomedics, Inc.](#), (Nasdaq: IMMU) today announced that the Office of Orphan Products Development of the U.S. Food and Drug Administration (FDA) has granted orphan status for the use of veltuzumab, the Company's humanized anti-CD20 antibody, for the treatment of pemphigus.

Pemphigus is a debilitating and potentially fatal autoimmune blistering disease of the skin and mucous membranes. In most cases, irregularly-shaped, painful erosions or lesions (ulcerations) initially develop in the mucous membranes lining the inside of the mouth. To maintain disease control typically requires long-term exposure to corticosteroids and other drugs which suppress the immune system and may themselves contribute to osteoporosis, septicemia, and other serious adverse events seen in this population.

In a recently published compassion-use case study report<sup>1</sup>, a patient with pemphigus vulgaris refractory to multiple agents, including rituximab, was successfully treated with veltuzumab administered by subcutaneous injection. Subcutaneous veltuzumab was safe and effective, resulting in complete remission of disease off therapy and no serious adverse events during 35 months of follow-up.

“We are pleased to receive the Orphan Drug designation for veltuzumab in pemphigus from the FDA,” commented Cynthia L. Sullivan, President and Chief Executive Officer. “Obtaining the orphan status is consistent with our strategy to out license this asset,” Ms. Sullivan added.

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 veltuzumab, if it is approved by FDA for the treatment of patients with pemphigus.

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.

### Reference

1. Ellebrecht C.T., Choi E.J., Allman D.M., Tsai D.E., Wegener W.A., Goldenberg D.M. and Payne A.S. Subcutaneous Veltuzumab, a Humanized Anti-CD20 Antibody, in the Treatment of Refractory Pemphigus Vulgaris. *JAMA Dermatol.* 2014 Aug 13. doi: 10.1001/jamadermatol.2014.1939. Epub ahead of print

### 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

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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), to whom the Company licensed epratuzumab for the treatment of all non-cancer indications worldwide. UCB expects Phase 3 data in systemic lupus erythematosus in the first half of 2015. Immunomedics is exploring epratuzumab in oncology in collaboration with independent cancer study groups. Immunomedics' most advanced candidate to which it retains worldwide rights for all indications is <sup>90</sup>Y-clivatuzumab tetraxetan. The Company initiated a Phase 3 registration trial in January 2014 in patients with advanced pancreatic cancer and expects topline data in mid-2016. 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 toxic effects that are usually found with conventional administration of these chemotherapeutic agents. Immunomedics' most advanced ADCs are IMMU-132 and IMMU-130, which are in Phase 2 trials for a number of solid tumors and metastatic colorectal cancer, 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 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<sup>®</sup> protein conjugation technology. The Company believes that its portfolio of intellectual property, which includes approximately 259 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 a top-8 ranking in the Biotechnology industry by the Patent Board for the 2014 fiscal year. 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, availability of required financing and other sources of funds on acceptable terms, if at all, 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 and competitive risks to marketed products, 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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