



## IMMUNOMEDICS ANNOUNCES INITIATION OF PHASE III CLINICAL TRIAL OF CLIVATUZUMAB TETRAXETAN IN PATIENTS WITH PANCREATIC CANCER

**Morris Plains, NJ, January 9, 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 announced first patient dosing in the Company's Phase III registration study of its pancreatic cancer drug, yttrium-90 (<sup>90</sup>Y)-clivatuzumab tetraxetan.

The PANcreatic Cancer RadioImmunotherapy Trial-1 (PANCRIT-1) is a double-blind, randomized study aimed to evaluate the safety and efficacy of <sup>90</sup>Y-clivatuzumab tetraxetan combined with low-dose gemcitabine and best supportive care in patients with metastatic pancreatic cancer who have received at least two prior therapies, one of which must have been a gemcitabine-containing regimen. The primary endpoint of this study is overall survival (OS).

In a recently completed Phase Ib clinical trial in the same patient population with relapsed pancreatic cancer, the combination of <sup>90</sup>Y-clivatuzumab tetraxetan and low-dose gemcitabine produced a median OS of 4.0 months (6 of 27 subjects were alive 9 months after first dose) with a manageable safety profile. That was statistically significant ( $p = 0.021$ ) compared to the median OS of 2.8 months when patients were treated with <sup>90</sup>Y-clivatuzumab tetraxetan alone. Additionally, there were 2 partial responders in the combination arm. More importantly, the rapid enrollment of the Phase Ib study demonstrated an unmet medical need for treatment options for patients in this late-stage setting.

"This is a major milestone for the Company and for the clinical development of <sup>90</sup>Y-clivatuzumab tetraxetan," remarked Cynthia L. Sullivan, President and Chief Executive Officer. "If the results from the Phase Ib study are confirmed by the PANCRIT-1 trial, clivatuzumab tetraxetan could become the first antibody-directed radiation therapy approved to treat patients with solid tumors. We plan to complete patient accrual in the first half of 2015," Ms. Sullivan added.

### **About PANCRIT-1**

The PANCRIT-1 trial was designed to enroll approximately 440 patients with metastatic pancreatic cancer. A majority of these patients will be recruited at clinical trial sites across the U.S., with additional sites in Canada, Europe and Israel participating. Eligible patients will be randomized 2 to 1 to the treatment arm of 3 doses of <sup>90</sup>Y-clivatuzumab tetraxetan plus 4 doses of gemcitabine at 200 mg/m<sup>2</sup> per cycle or placebo plus low-dose gemcitabine. All patients will receive best supportive care. Treatments are administered during the initial 4 weeks of each 7-week cycle, and may be repeated up to a maximum of 6 cycles.

### **About Clivatuzumab Tetraxetan**

Clivatuzumab tetraxetan contains a humanized, highly specific antibody that targets a mucin antigen found on pancreatic cancer cells, and is conjugated to a linker that facilitates complexing with radiometals. This mucin has been found by tissue staining to be present on about 85% of

pancreatic cancers but is not found on normal pancreas or tissue from patients with pancreatitis. When the antibody-linker complex is radiolabeled with yttrium-90, this enables delivery of high intensity, deep penetrating radiation directly to the pancreatic tumor cells and the addition of gemcitabine acts as a radiosensitizer to increase the anti-tumor activity. <sup>90</sup>Y-clivatuzumab tetraxetan has received Orphan Drug designation in both the U.S. and Europe, and fast track designation in the U.S. for the treatment of patients with pancreatic cancer.

In earlier clinical trials, <sup>90</sup>Y-clivatuzumab tetraxetan has produced encouraging results in combination with gemcitabine in newly-diagnosed pancreatic cancer patients or alone in the relapsed population.<sup>1,2</sup>

### **About Pancreatic Cancer**

According to the American Cancer Society, an estimated 45,220 Americans were diagnosed with pancreatic cancer in 2013, making it the 10th most common cancer diagnosis among men and the 9th most common among women in the U.S. It is, however, the fourth leading cause of cancer death among both men and women nationwide, with approximately 38,460 deaths expected, or about 7% of all cancer deaths.

Currently, only 2 percent of patients diagnosed with pancreatic cancer are alive 5 years later. Gemcitabine alone or in combination with Tarceva or Abraxane are the only FDA-approved front-line treatments for patients with late-stage pancreatic cancer. There are no FDA-approved therapies for patients that relapse and there are few treatment options available.

### **References**

1. Ocean A.J., Pennington K.L., Guarino M.J. et al. Fractionated radioimmunotherapy with <sup>90</sup>Y-clivatuzumab tetraxetan and low-dose gemcitabine is active in advanced pancreatic cancer: A Phase I trial. *Cancer*. 2012 Nov 15;118(22):5497-506. doi: 10.1002/cncr.27592. Epub 2012 May 8.
2. Gulec S.A., Cohen S.J., Pennington K.L. et al. Treatment of advanced pancreatic carcinoma with <sup>90</sup>Y-clivatuzumab tetraxetan: a Phase I single-dose escalation trial. *Clin Cancer Res*. 2011 Jun 15;17(12):4091-100. doi: 10.1158/1078-0432.CCR-10-2579. Epub 2011 Apr 28.

### **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 242 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-10 ranking in the 2012 IEEE Spectrum Patent Power Scorecards in the Biotechnology and Pharmaceuticals category. 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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