



## IMMUNOMEDICS REPORTS FINAL EFFICACY RESULTS OF PHASE Ib TRIAL WITH YTTRIUM-90-LABELED CLIVATUZUMAB TETRAKETAN IN PATIENTS WITH METASTATIC PANCREATIC CANCER

### -- Treatment Responses Improved Significantly with Repeated Cycles in Combination with Gemcitabine --

Chicago, IL, June 1, 2014 --- Immunomedics, Inc., (Nasdaq: IMMU) today reported an overall disease response rate of 41%, including 2 patients (7%) with partial response and 10 patients (34%) with stable disease as best response, in 29 patients with relapsed/refractory, metastatic pancreatic cancer treated with the investigational pancreatic cancer therapeutic, clivatuzumab tetraxetan labeled with yttrium-90 (<sup>90</sup>Y), in combination with low-dose gemcitabine as a radiosensitizer. This was compared to a control group of 29 similar patients who received <sup>90</sup>Y-clivatuzumab tetraxetan without low-dose gemcitabine. Treatment responses were assessed by computed tomography (CT) based on RECIST criteria.

Results from the multicenter Phase Ib study were presented by Vincent J. Picozzi Jr., M.D., Director of the Pancreas Center of Excellence at the Virginia Mason Medical Center’s Digestive Disease Institute, Seattle, WA, at the 2014 Annual Meeting of the American Society of Clinical Oncology (ASCO).

Within the 2 subgroups of patients, adding low-dose gemcitabine extended the median overall survival (OS) for the 29 patients in Arm A to 3.9 months, a statistically significant ( $p=0.017$ ) improvement compared with the 2.8 month median OS for the 29 patients receiving only <sup>90</sup>Y-clivatuzumab tetraxetan in Arm B.

Furthermore, for patients in Arm A, there were 48%, 34%, 21%, and 10% of patients alive at 3, 6, 9, and 12 months, respectively, indicating that the combination of radiolabeled antibody and gemcitabine improved survival throughout the study.

Treatment Arm	Number of Patients Enrolled	Survival Results			
		3 Months	6 Months	9 Months	12 Months
A	29	14 (48%)	10 (34%)	6 (21%)	3 (10%)
B	29	10 (34%)	3 (10%)	1 (3%)	0 (0%)

Patients who received multiple cycles of the combination therapy had the best outcome, with a median OS of 7.9 months. This was statistically significant ( $p=0.004$ ) compared to the median OS of 3.4 months in patients receiving multiple cycles of <sup>90</sup>Y-clivatuzumab tetraxetan only. Additionally, 2 patients in Arm A had a partial response and 2 patients are still alive 13 and 15 months after the start of their combination treatment

NEWS RELEASE

Since patients' response and outcome are expected to deteriorate with each successive round of treatment, these results, obtained from patients who had received at least 2 prior therapies, appear to compare favorably with those from second-line investigational treatment regimens reported at the 2014 ASCO Gastrointestinal Cancers Symposium.<sup>1</sup>

The only clinically significant side effect was reduction in platelets, which was transient and manageable.

“Based on these encouraging results, we have launched the Phase III PANCRIT<sup>®</sup>-1 registration trial, positioning <sup>90</sup>Y-clivatuzumab tetraxetan as a therapy for patients in this late-stage setting,” commented Cynthia L. Sullivan, President and Chief Executive Officer of Immunomedics. “The primary end-point will be overall survival and the protocol allows the independent Data and Safety Monitoring Board one planned interim analysis of data on overall survival to be conducted after a predetermined number of events have occurred. We plan to complete patient accrual by the second half of 2015, with top-line results expected in the first half of 2016,” Ms. Sullivan reiterated.

#### **Reference**

1. Choi M, Saif MW, Kim R. Is there a role for second line therapy in advanced pancreatic cancer? JOP 2014 Mar 10;15(2):106-109. doi: 10.6092/1590-8577/2325.

#### **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<sup>™</sup> (DNL<sup>™</sup>) 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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