IMMUNOMEDICS ANNOUNCES PUBLICATION OF PHASE 2 RESULTS WITH LABETUZUMAB GOVITECAN (IMMU-130) THAT DEMONSTRATE PROMISING EFFICACY AS A SINGLE AGENT IN PATIENTS WITH METASTATIC COLORECTAL CANCER

Results Appeared in Advanced Online Publication of the American Society of Clinical Oncology Journal, Journal of Clinical Oncology

Morris Plains, N.J., August 21, 2017 --- Immunomedics, Inc. (NASDAQ: IMMU) (“Immunomedics” or the “Company”) today announced that labetuzumab govitecan (IMMU-130), the second agent from its first-in-class antibody-drug conjugate (ADC) program, produced encouraging survival results in a multicenter, open-label Phase 2 study in heavily-pretreated patients with metastatic colorectal cancer (mCRC).

“As a single agent, IMMU-130 has demonstrated promising efficacy in late-stage mCRC and warrants further study,” remarked Jordan D. Berlin, MD, Professor of Medicine, Co-Leader of the Gastrointestinal Cancer Research Program and Director of Phase I Research at the Vanderbilt-Ingram Cancer Center, Nashville, TN, and the senior author of the article published online in the Journal of Clinical Oncology. “I believe it has potential to be studied in a combination therapy in a frontline setting.”

Interim median progression-free survival (PFS) and overall survival (OS) for patients who received once-weekly labetuzumab govitecan at the 8 or 10 mg/kg dose level are summarized below.

<table>
<thead>
<tr>
<th>Labetuzumab Govitecan Dose</th>
<th>8 mg/kg once-weekly</th>
<th>10 mg/kg once-weekly</th>
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</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>21</td>
<td>22</td>
</tr>
<tr>
<td>Median PFS* (months)</td>
<td>4.6 (3.9 – 6.1)</td>
<td>3.6 (2.1 – 6.0)</td>
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<tr>
<td>Median OS (months)</td>
<td>7.5 (5.7 – 16.1)</td>
<td>6.4 (5.0 – 11.2)</td>
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* Treatment response was evaluated in accordance with the rules set by the Response Evaluation Criteria in Solid Tumors (RECIST 1.1) using computed tomography as the imaging tool for tumor size measurements.

All of these patients had received prior irinotecan therapy. Interestingly, 23 patients had prior treatment with regorafenib, which was approved in the U.S. for the treatment of patients with previously-treated mCRC based on a median PFS of 2.0 months and a median OS of 6.4 months. In this subset of the patients, the median PFS and OS with labetuzumab govitecan were 4.0 and 6.7 months, respectively.

Labetuzumab govitecan is an ADC that incorporates a moderately-toxic drug, SN-38, with an antibody against CEACAM5, the same CEA measured in plasma and having a high expression in many solid cancers, particularly CRC. It is the second ADC, after the lead sacituzumab govitecan (IMMU-132) product candidate, to be studied clinically and to show promising activity in very advanced cancer patients. IMMU-132 has FDA Breakthrough Therapy...
Designation and is being prepared for submission to the FDA for accelerated approval as a therapeutic for patients with relapsed/refractive, metastatic triple-negative breast cancer.

The goals of the expanded Phase 2 study with labetuzumab govitecan were to evaluate dosing schedules, safety and any evidence of efficacy. A total of 86 patients with progressive disease who had received prior therapy with an irinotecan-containing regimen, half of whom had completed 5 prior lines of therapy, were enrolled to receive labetuzumab govitecan either once-weekly at 8 and 10 mg/kg, or twice-weekly at 4 and 6 mg/kg, on weeks 1 and 2 of 3-week repeated cycles. The two once-a-week dose schedules, showing comparable toxicity and efficacy, were chosen for further study.

David M. Goldenberg, ScD, MD, founder and chief scientific officer of the Company, stated: “We developed labetuzumab many years ago for targeting a therapeutic radionuclide for the therapy of colorectal cancer as well as other CEACAM5-expressing cancers, where it showed very encouraging activity in patients with liver metastases of colorectal cancer, as published recently in Cancer. In the current use as an ADC, it was unexpected that this relatively slow-internalizing antibody would show anticancer activity, which suggests to us that both internalization and release of the drug, SN-38, at the cancer cell surface, and in the tumor environment, are important. Studies of labetuzumab govitecan in other cancer types known to express carcinoembryonic antigen are indicated.”

Labetuzumab govitecan was well-tolerated, with a manageable toxicity profile. Major toxicities (Grade >3) among all cohorts were neutropenia (16%), leukopenia (11%), anemia (9%), and diarrhea (7%). Anti-drug or anti-antibody antibodies were not detected.

References

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’ most advanced product candidate is IMMU-132 (sacituzumab govitecan), an antibody-drug conjugate that has received Breakthrough Therapy Designation from the FDA for the treatment of patients with triple-negative breast cancer who have failed at least two prior therapies for metastatic disease. Immunomedics’ primary goal is to bring IMMU-132 to market for the benefit of patients and the creation of stockholder value. For additional information on the Company, please visit its website at www.immunomedics.com. The information on its website does not, however, form a part of this press release.
Cautionary note regarding forward-looking statements
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, anticipated patient enrollment, trial outcomes, timing or associated costs), regulatory applications and related timelines, out-licensing arrangements, forecasts of future operating results, potential collaborations, and capital raising activities, timing for bringing any product candidate to market, 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, the Company’s dependence on business collaborations or availability of required financing from capital markets, or other sources on acceptable terms, if at all, in order to further develop our products and finance our operations, new product development (including clinical trials outcome and regulatory requirements/actions), the risk that we or any of our collaborators may be unable to secure regulatory approval of and market our drug candidates, risks associated with the outcome of pending litigation and competitive risks to marketed products, and the Company’s ability to repay its outstanding indebtedness, if and when required, 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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