ImmunoGen, Inc. Announces Clinical Data for T-DM1 Used in Combination with Pertuzumab for First-Line Treatment of HER2+ Metastatic Breast Cancer

WALTHAM, Mass., Dec 10, 2010 (BUSINESS WIRE) --

ImmunoGen, Inc. (Nasdaq: IMGN), a biopharmaceutical company that develops anticancer therapeutics using its Targeted Antibody Payload (TAP) technology, today announced the presentation of the first clinical data for trastuzumab-DM1 (T-DM1) used in combination with pertuzumab for first-line treatment of HER2+ metastatic breast cancer (mBC). These data were presented at the 33rd Annual San Antonio Breast Cancer Symposium (SABCS).

T-DM1 consists of the HER2-targeting antibody, trastuzumab, with ImmunoGen's cancer cell-killing agent attached using the Company's linker and method of attachment. T-DM1 is in global development by Roche under a licensing agreement between ImmunoGen and Genentech, a member of the Roche Group. Pertuzumab is a HER2 Dimerization Inhibitor in development by Roche.

T-DM1 Plus Pertuzumab for First-Line HER2+ mBC

The data reported today are from a Phase Ib/II clinical trial conducted by Roche to assess T-DM1 used in combination with pertuzumab to treat HER2+ mBC. The study enrolled 21 patients who had not received prior systemic anticancer therapy for metastatic disease. Among these patients, 57.1% had a confirmed objective response to treatment with T-DM1 plus pertuzumab.

All of these patients had received anticancer agents prior to their development of metastatic disease (e.g., as adjuvant therapy). Eighty-six percent (86%) of these patients had received Herceptin® (trastuzumab), 71% had received a taxane, and 62% had received an anthracycline before being diagnosed with metastatic disease.

T-DM1 Used Alone for First-Line HER2+ mBC

In October, preliminary data were reported for T-DM1 used alone as first-line treatment for HER2+ mBC.¹ Those data were from a 137-patient, randomized Phase II trial. At the time of the cut-off date for the data included in that presentation, 47.8% of patients receiving T-DM1 as a single agent had a confirmed objective response, as compared to 41.4% of patients treated with Herceptin used in combination with a taxane. It was noted in the oral presentation that the study groups included patients with unconfirmed responses at the time of the data cut-off. Updated data from this trial are expected in 2Q2011.

“The data that have been reported with T-DM1 for the first-line treatment of HER2+ metastatic breast cancer are highly encouraging, both with T-DM1 as a single agent and used in combination with pertuzumab,” commented Daniel Junius, President and Chief Executive Officer. “Our TAP technology is designed to produce effective anticancer agents that also are well tolerated, supporting their evaluation in earlier stages of disease and/or as part of combination regimens.”

About the Development of T-DM1 for First-Line Use

In addition to the Phase II trial reported, a Phase III trial, MARIANNE, is underway that assesses T-DM1 for first-line treatment of HER2+ mBC. In MARIANNE, T-DM1 given as a single agent and T-DM1 given in combination with pertuzumab are both compared to Herceptin used in combination with a taxane.

About the Trial Reported at SABCS

The Ph 1b/II trial reported at SABCS was designed to assess T-DM1 used in combination with pertuzumab for HER2+ mBC, both as first-line therapy and to treat patients with disease that had recurred after treatment with other anticancer regimens. In addition to the findings reported at SABCS for the first-line setting, data were reported for the 46 patients with relapsed disease which were consistent with those previously reported for a subset of these patients.²

About ImmunoGen’s Targeted Antibody Payload (TAP) Technology

The Company’s TAP technology uses tumor-targeting manufactured antibodies to deliver one of ImmunoGen’s highly potent cancer-cell killing agents (e.g., DM1, DM4) specifically to tumors. These agents are many-fold more potent than standard chemotherapy drugs and were developed by ImmunoGen specifically for targeted delivery to tumors. ImmunoGen also has engineered linker technology that keeps the cancer-cell killing agent attached to the antibody until it reaches the cancer cell
and then controls the release of the agent inside the cell. In addition to T-DM1, six other compounds that make use of ImmunoGen's TAP technology are in clinical testing.

About ImmunoGen, Inc.

ImmunoGen, Inc. develops targeted anticancer therapeutics using the Company's expertise in tumor biology, monoclonal antibodies and potent cancer-cell killing agents. The Company's TAP technology uses monoclonal antibodies to deliver one of ImmunoGen's proprietary cancer-cell killing agents specifically to tumor cells. There are currently seven TAP compounds in the clinic, with a wealth of clinical data reported with the technology. ImmunoGen's collaborative partners include Amgen, Bayer Schering Pharma, Biogen Idec, Biotest, Genentech (a member of the Roche Group), Novartis, and sanofi-aventis. The most advanced compound using ImmunoGen's TAP technology, trastuzumab-DM1 (T-DM1), is in Phase III testing through the Company's collaboration with Genentech. More information about ImmunoGen can be found at www.immunogen.com.


Herceptin® is a registered trademark of Genentech.

This press release includes forward-looking statements. For these statements, ImmunoGen claims the protection of the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. It should be noted that there are risks and uncertainties related to the development of novel anticancer products, including T-DM1, including risks related to uncertainties around clinical trials conducted and their timings and results. A review of these risks can be found in ImmunoGen's Annual Report on Form 10-K for the fiscal year ended June 30, 2010 and other reports filed with the Securities and Exchange Commission.

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