T-DM1 Significantly Improved Progression-Free Survival Compared to Standard of Care for Previously Untreated HER2-Positive Metastatic Breast Cancer

- Notable results from Genentech/Roche Phase II trial are featured in conference's official press program
- T-DM1 utilizes ImmunoGen's Targeted Antibody Payload (TAP) technology with the HER2-targeting trastuzumab (Herceptin(R)) antibody

WALTHAM, Mass., Sept. 24, 2011 (GLOBE NEWSWIRE) -- ImmunoGen, Inc. (Nasdaq:IMGN), a biotechnology company that develops targeted anticancer products using its TAP technology, today announced findings from the first randomized clinical trial conducted with trastuzumab emtansine (also known as T-DM1). Trastuzumab emtansine consists of ImmunoGen's DM1 cancer cell-killing agent attached to the HER2-targeting antibody, trastuzumab, developed by Genentech, a member of the Roche Group, and is in global development by Roche. The study findings are being presented (abstract #5001; presentation at 9:10 am CET on Sept. 25) at the 2011 European Multidisciplinary Cancer Congress taking place in Stockholm, Sweden.

The results are from a 137-patient, randomized Phase II trial conducted by Roche comparing trastuzumab emtansine, used as a single agent, against Herceptin[®] (trastuzumab) plus chemotherapy (docetaxel) for first-line treatment of HER2-positive metastatic breast cancer. Herceptin plus chemotherapy is standard of care for this cancer. The primary endpoints of the study were progression-free survival (PFS) and assessment of safety.

The study results are being featured in the conference's official press program and include:

- Median PFS was significantly greater for patients receiving trastuzumab emtansine compared to those receiving Herceptin plus chemotherapy (median PFS of 14.2 months vs. 9.2 months, respectively; p = 0.035). The hazard ratio was 0.59, which means that treatment with trastuzumab emtansine reduced the probability of disease progression or death by 41 percent compared to treatment with Herceptin plus chemotherapy.
- Patients receiving trastuzumab emtansine had significantly fewer common side effects and fewer severe adverse events (Grade 3 or greater) than patients receiving Herceptin plus chemotherapy. In fact, patients receiving trastuzumab emtansine had approximately half the incidence of severe adverse events as those receiving the standard first-line regimen (46.4 percent vs. 89.4 percent). Treatment discontinuations due to adverse events were markedly lower in the trastuzumab emtansine treatment arm than in the Herceptin plus chemotherapy arm (7.2 percent vs. 28.8 percent).

The most frequent severe adverse events in the trastuzumab emtansine treatment arm were low platelet count (8.7 percent) and increased levels of two different liver enzymes (ALT, 8.7 percent; AST, 8.7 percent). The most frequent severe adverse events in the Herceptin plus chemotherapy arm were neutropenia (60.6 percent), leucopenia (25.8 percent), and febrile neutropenia (13.6 percent).

Single agent therapy with trastuzumab emtansine achieved a 64.2 percent objective response rate, compared with 58.0 percent for the combination of Herceptin plus chemotherapy. Overall survival data were not mature and thus not reported. The trial design allows patients in the Herceptin plus chemotherapy treatment arm with disease progression to subsequently receive trastuzumab emtansine.

"It is noteworthy that single-agent therapy with trastuzumab emtansine demonstrated both efficacy and tolerability advantages over Herceptin given with separate chemotherapy," commented Daniel Junius, President and CEO. "These findings further demonstrate the power of our TAP technology. We expect the body of impressive clinical results to grow substantially as the number of later-stage trials underway with TAP compounds continues to increase."

Trastuzumab emtansine is in Phase III testing for first-, second-, and third-line treatment of HER2-positive metastatic breast cancer (the MARIANNE, EMILIA, and TH3RESA trials, respectively) and in Phase II testing for adjuvant/neoadjuvant use for earlier-stage disease. Roche expects to report results from the second-line, EMILIA trial in 2012 and to use these results to support a global regulatory submission for trastuzumab emtansine in 2012. Three other compounds utilizing ImmunoGen's TAP technology -- IMGN901, SAR3419, and BT-062 -- are expected to be in Phase II clinical testing by mid-2012, with as many as seven other TAP compounds in early stage clinical testing.

About ImmunoGen, Inc.

ImmunoGen, Inc. develops targeted anticancer therapeutics using the Company's expertise in tumor biology, monoclonal antibodies, potent cancer-cell killing agents and engineered linkers. 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 now numerous TAP compounds in clinical development and a wealth of clinical data reported. ImmunoGen's collaborative partners include Amgen, Bayer HealthCare Pharmaceuticals, Biotest, Novartis, Roche, and Sanofi. The most advanced compound using ImmunoGen's TAP technology, trastuzumab emtansine (T-DM1), is in Phase III testing through the Company's collaboration with Genentech, a member of the Roche Group. More information about ImmunoGen can be found at www.immunogen.com.

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 by ImmunoGen and the Company's collaborators, including trastuzumab emtansine, including risks related to clinical studies, 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, 2011 and other reports filed with the Securities and Exchange Commission.

Herceptin® is a registered trademark of Genentech, a member of the Roche Group.

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