August 27, 2012

ImmunoGen, Inc. Announces Trastuzumab Emtansine (T-DM1) Significantly Improved Survival in the EMILIA Phase III Trial

- Trastuzumab emtansine significantly improved overall survival (OS) as well as progression-free survival (PFS) in its lead Phase III trial, EMILIA.
- Separately, the marketing application for trastuzumab emtansine has been submitted to the US FDA, and one is to be submitted shortly to the European Medicines Agency (EMA).

WALTHAM, Mass.--(BUSINESS WIRE)-- ImmunoGen, Inc. (Nasdaq: IMGN), a biotechnology company that develops anticancer products using its Targeted Antibody Payload (TAP) technology and antibody expertise, today announced that Roche has reported that updated results from its EMILIA Phase III trial show that patients treated with trastuzumab emtansine had a significant improvement in OS compared to those randomized to standard-of-care therapy. Trastuzumab emtansine utilizes ImmunoGen's TAP technology with the trastuzumab antibody and is in global development by Roche under an agreement between ImmunoGen and Genentech, a member of the Roche Group.

Also reported today was that Genentech has submitted a Biologics License Application (BLA) for trastuzumab emtansine to the US FDA, and that Roche expects to soon submit a Marketing Authorization Application (MAA) to the EMA.

EMILIA was designed to evaluate trastuzumab emtansine for the treatment of patients with metastatic HER2-positive breast cancer who have previously received trastuzumab (Herceptin®) and a taxane. Patients enrolled were randomized to treatment with trastuzumab emtansine — used alone — or with lapatinib (Tykerb®) plus capecitabine (Xeloda®), standard-of-care in this setting.

The first EMILIA results were reported at the American Society of Clinical Oncology (ASCO) annual meeting in June 2012, and included that trastuzumab emtansine significantly improved PFS compared to standard-of-care therapy and that fewer of the trastuzumab emtansine-treated patients experienced Grade 3 or higher (severe) adverse events.[1] A previous interim analysis of OS demonstrated a trend towards improved OS in the trastuzumab emtansine-treated patients. The updated results reported today will be presented at an upcoming medical meeting.

"It's impressive that the overall survival endpoint has already been met — this had been expected to occur well after the submission of the BLA and MAA to the regulatory authorities," commented Daniel Junius, President and CEO. "We developed our TAP technology to achieve more effective, better tolerated anticancer therapies, and are delighted that people treated with trastuzumab emtansine survived significantly longer than those who received a standard therapy."

Roche has Phase III trials underway evaluating trastuzumab emtansine both for newly diagnosed and for previously treated metastatic HER2-positive breast cancer. Additionally, it plans to initiate registration trials beginning in 2013 to evaluate the compound for three settings in earlier-stage disease: adjuvant use; neoadjuvant use; and treatment of patients with residual invasive disease following standard neoadjuvant therapy.

About ImmunoGen's TAP Technology

A TAP compound consists of a monoclonal, or manufactured, antibody that binds specifically to a target found on tumor cells with one of the Company's highly potent cancer-killing agents attached as a payload. The antibody serves to target the payload specifically to the cancer cells, and the payload serves to kill the cancer cells. In the case of some compounds that use ImmunoGen's TAP technology (trastuzumab emtansine and ImmunoGen's IMGN529 compound), the antibody component also has meaningful anticancer activity.

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-killing agents specifically to tumor cells. There are now ten TAP compounds in clinical development, of which three are wholly owned by the Company. A marketing application for trastuzumab emtansine (T-DM1), the most advanced compound using ImmunoGen's TAP technology, has been submitted in the US. Roche is developing this compound globally under an agreement between ImmunoGen and 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, including trastuzumab emtansine (T-DM1), including risks related to clinical studies and regulatory submissions, 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.

[1]ASCO June 2012 (abstract #LBA1).

Tykerb® is a registered trademark of GlaxoSmithKline plc. Xeloda® is a registered trademark of Roche. Herceptin® is a registered trademark of Genentech, a member of the Roche Group.

For Investors:
ImmunoGen, Inc.
Carol Hausner, 781-895-0600
Executive Director, Investor Relations and Corporate Communications
info@immunogen.com
or
For Media:
The Yates Network
Barbara Yates, 781-258-6153

Source: ImmunoGen, Inc.

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