ImmunoGen, Inc. Announces FDA Has Granted Priority Review Status to the Trastuzumab Emtansine (T-DM1) Marketing Application

WALTHAM, Mass.--(BUSINESS WIRE)-- ImmunoGen, Inc. (Nasdaq: IMGN), a biopharmaceutical company that develops anticancer products using its Targeted Antibody Payload (TAP) technology and antibody expertise, today announced that Genentech, a member of the Roche Group, has disclosed that the U.S. Food and Drug Administration (FDA) has officially accepted the Biologics License Application (BLA) for trastuzumab emtansine and granted it Priority Review. The proposed indication is for the treatment of people with HER2-positive, unresectable locally advanced or metastatic breast cancer who have received prior treatment with Herceptin® (trastuzumab) and a taxane chemotherapy. It also disclosed that Roche's Marketing Authorization Application for trastuzumab emtansine for people with HER2-positive metastatic breast cancer has been accepted for review by the European Medicines Agency.

"We're very pleased that the FDA has granted Priority Review to the trastuzumab emtansine BLA," commented Daniel Junius, President and CEO. "This decision underscores the urgent need to have new and more effective treatment options available for patients with this cancer."

The FDA grants Priority Review designation to drugs that may offer major advances in treatment or provide a treatment where no adequate therapy exists. For applications granted Priority Review, the FDA's goal is to complete the review and deliver a decision on marketing approval within six months. The FDA has assigned this BLA a Prescription Drug User Fee Act (PDUFA) goal date of February 26, 2013.

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. Marketing applications for trastuzumab emtansine (T-DM1), the most advanced compound using ImmunoGen's TAP technology, are under review in the US and Europe. 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.

Herceptin® is a registered trademark of Genentech.

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