# Genentech Receives Refuse to File Letter from FDA for T-DM1

## – New BLA Expected to be Submitted in Mid-2012 –

WALTHAM, Mass.--(BUSINESS WIRE)--ImmunoGen, Inc. (Nasdaq: IMGN), a biotechnology company that develops antibody-based targeted anticancer products, today announced that Genentech, a member of the Roche Group, today announced its receipt of a Refuse to File (RTF) letter from the US Food and Drug Administration (FDA) for the accelerated approval of the Biologic License Application (BLA) for trastuzumab-DM1, or T-DM1, submitted in July 2010. Genentech also stated that as planned, it will continue with its ongoing Phase III registrational T-DM1 trial, known as EMILIA, and that it will continue to work with the FDA and expects to submit a new T-DM1 BLA in mid-2012.

Genentech noted that in its review of the BLA, the FDA stated that the T-DM1 trials did not meet the standard for accelerated approval because all available treatment choices approved for metastatic breast cancer, regardless of HER2 status, had not been exhausted in the study population. Genentech re-affirmed its confidence in T-DM1 as “an important, novel HER2-targeted medicine,” and indicated that it remains fully committed to its ongoing development. In particular, as noted above, it intends to continue the EMILIA study which compares T-DM1 to lapatinib in combination with capecitabine in people with advanced, HER2-positive breast cancer whose disease has worsened after receiving initial treatment.

“It is a significant disappointment that there will be a delay in the opportunity for T-DM1 to be approved for patients with advanced HER2 positive breast cancer,” commented Daniel Junius, President and CEO of ImmunoGen. “In the meantime we continue to focus on the development of our robust and expanding pipeline as well as advancing our technology through new partnerships.”

The BLA submitted for T-DM1 in July 2010 requested accelerated approval for T-DM1 based on the results of a single-arm Phase II study, which showed T-DM1 shrank tumors in one-third of women with advanced HER2-positive breast cancer, who had received on average seven prior medicines, including two HER2-targeted medicines.

T-DM1 consists of ImmunoGen, Inc.’s DM1 cancer-cell killing agent attached to Genentech’s HER2-targeting antibody, trastuzumab, using ImmunoGen’s linker and methods of attachment. T-DM1 is in global development by Roche under a collaboration agreement between Genentech and ImmunoGen.

### Updated Financial Guidance

The Company indicated that the financial guidance provided for its fiscal year 2011 on August 4, 2010, is no longer valid due to the impact of Genentech’s receipt of the RTF letter and that updated guidance is being developed and will be provided at a future date.

### Conference Call

ImmunoGen will host a conference call today, Friday, August 27, 2010 at 8:30 am EDT to discuss the above information. To access the live call by phone, dial 913-312-1429, Passcode 2469462. The call also may be accessed through the Investor Information section of the Company’s website, http://www.immunogen.com. Following the live webcast, a replay of the call will be available at the same location through September 3, 2010.

### About ImmunoGen, Inc.

ImmunoGen, Inc. develops targeted anticancer therapeutics using its expertise in cancer biology, monoclonal antibodies and the creation and attachment of potent cancer-cell killing agents. The Company’s TAP technology uses engineered antibodies to deliver one of ImmunoGen’s proprietary cancer-cell killing agents specifically to tumor targets. In addition to the Company’s product pipeline, compounds are in clinical testing through ImmunoGen’s collaborations with Genentech, sanofi-aventis, Biogen Idec and Biotest. Other ImmunoGen collaborative partners include Bayer Schering Pharma AG and Amgen. More information about ImmunoGen can be found at http://www.immunogen.com/wt/home/home.

This press release includes forward-looking statements based on management’s current expectations. These statements include, but are not limited to, ImmunoGen’s expectations related to: the occurrence, timing and outcome of potential pre-clinical, clinical and regulatory events related to the Company’s and its collaboration partners’ product programs, including, without limitation, Genentech’s T-DM1 program; and the timing and outcome of product development, regulatory and business development events. 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. Various factors could cause ImmunoGen’s actual results to

differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this release. Factors that could cause future results to differ materially from such expectations include, but are not limited to: the timing and outcome of FDA reviews; the timing and outcome of ImmunoGen's and the Company's collaboration partners' research and clinical development processes; the difficulties inherent in the development of novel pharmaceuticals, including uncertainties as to the timing, expense and results of preclinical studies, clinical trials and regulatory processes; ImmunoGen's ability to financially support its product programs; ImmunoGen's dependence on collaborative partners; industry merger and acquisition activity; and other factors more fully described in ImmunoGen's Annual Report on Form 10-K for the fiscal year ended June 30, 2009 and other reports filed with the Securities and Exchange Commission.

Contacts

**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