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ImmunoGen Reports Roche Has Provided an Update on the MARIANNE Trial

WALTHAM, Mass.--(BUSINESS WIRE)-- ImmunoGen, Inc. (NASDAQ: IMGN), a biotechnology company that develops novel anticancer therapeutics using its antibody-drug conjugate (ADC) technology, today reported that Roche has announced top-line results of its Phase III MARIANNE study.

The study evaluated three HER2-targeted regimens - Kadcyla® (ado-trastuzumab emtansine) plus Perjeta® (pertuzumab), Kadcyla alone, and Herceptin® (trastuzumab) plus taxane chemotherapy - in people with previously untreated HER2-positive metastatic breast cancer (mBC). Kadcyla utilizes ImmunoGen's ADC technology and is already approved to treat patients with HER2-positive mBC who previously received trastuzumab and a taxane.

Roche has reported the MARIANNE study showed the three regimens helped people live without their disease worsening (PFS) for a similar amount of time, meeting its non-inferiority endpoint as assessed by an Independent Review Committee. However, neither Kadcyla-containing treatment arm significantly improved PFS compared to Herceptin and chemotherapy. Adverse events observed in the two experimental arms of the study were generally consistent with those seen in previous studies of Kadcyla and/or Perjeta.

"While we are disappointed by this unexpected outcome, we are pleased that so many patients can benefit from Kadcyla with its already approved use and also with the breadth of Roche's Kadcyla clinical development program," commented Daniel Junius, President and CEO. "Roche has a number of other trials underway with Kadcyla, and in 2015 expects data and - if positive - regulatory submission from its GATSBY study in gastric cancer."

Roche expects data from the MARIANNE study to be reported at an upcoming medical meeting, and to discuss the findings with appropriate regulatory authorities.

This event has no impact on ImmunoGen's financial guidance for the Company's 2015 fiscal year, or on the approved use of Kadcyla.

About Roche's MARIANNE Study

This Phase III study (NCT01120184; BO22589) is an international, randomized, multicenter, three-arm study involving 1,095 people with HER2-positive mBC. People with mBC at diagnosis and those whose disease had worsened following either neoadjuvant or adjuvant treatment were eligible for enrollment in the study.

The primary endpoint of the MARIANNE study is PFS as assessed by an independent review facility. Secondary endpoints include overall survival, response rate, and the incidence of adverse events. Differences in these endpoints were assessed in each of the Kadcyla-containing treatment arms compared to the Herceptin plus chemotherapy arm, and also between the two Kadcyla-containing arms.

About ImmunoGen, Inc.

ImmunoGen, Inc. develops targeted anticancer therapeutics. The Company's ADC technology uses tumor-targeting antibodies to deliver an ImmunoGen cell-killing agent specifically to cancer cells; the Company has also developed antibodies with anticancer activity of their own. The first product with ImmunoGen's ADC technology is Roche's Kadcyla®. ImmunoGen has three wholly owned product candidates in clinical testing with additional compounds in clinical testing through the Company's partnerships with Amgen, Bayer HealthCare, Biotest and Sanofi. 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 Kadcyla, including risks related to clinical studies and regulatory interactions, 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, 2014 and other reports filed with the Securities and Exchange Commission.

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