ImmunoGen, Inc. Announces Results from Kadcyla® Phase III Trial, TH3RESA, Being Presented Today at the European Cancer Congress

- Roche's Kadcyla found to significantly extend duration of progression-free survival in patients with advanced HER2-positive breast cancer in second large randomized trial.
- Kadcyla comprises Roche's trastuzumab antibody and ImmunoGen's ADC technology; it has been approved for marketing in several countries including the US.

WALTHAM, Mass.--(BUSINESS WIRE)-- ImmunoGen, Inc. (Nasdaq: IMGN), a biotechnology company that develops novel anticancer therapeutics using its antibody-drug conjugate (ADC) technology, announced the results from Roche's TH3RESA Phase III trial being presented today at the European Cancer Congress (ECC) in Amsterdam (abstract #LBA15). The findings were accepted as late-breaking data and also included in the Congress's official press program.

The TH3RESA study assessed Kadcyla (ado-trastuzumab emtansine) for the treatment of advanced HER2-positive breast cancer that had progressed despite prior treatment with at least two HER2-targeted medicines. At a minimum, patients must have received Herceptin® (trastuzumab), Tykerb® (lapatinib), and a taxane. The trial included approximately 600 patients who were randomized, on a two-to-one basis, to receive either Kadcyla or a treatment of their physician's choice. Eighty percent of the patients treated with physician's choice received a regimen containing Herceptin plus a second agent.

Kadcyla was found to significantly extend duration of progression-free survival (PFS) compared to treatment with physician's choice (median 6.2 months vs. 3.3 months, respectively) and reduced the risk of disease progression or death by 47 percent (HR=0.528; p < 0.0001). In the planned interim analysis, overall survival (OS) favored Kadcyla, but the data are not yet mature. PFS and OS are co-primary endpoints of the trial. No new safety signals were observed with Kadcyla.

Based on the earlier EMILIA Phase III trial, Kadcyla is approved for marketing in several countries, including the US, Japan, Switzerland, Canada, and Australia, with additional approvals expected. EMILIA assessed Kadcyla for the treatment of patients with HER2-positive metastatic breast cancer who had received prior treatment with Herceptin and a taxane chemotherapy. To be eligible for inclusion in the TH3RESA trial, patients would also need to have previously received treatment with Tykerb.

"The TH3RESA trial provides further support of improved progression-free survival with Kadcyla in patients with advanced HER2-positive breast cancer," commented Dan Junius, President and CEO. "We are delighted that our technology is helping make such an important difference to patients."

Kadcyla consists of Roche's trastuzumab antibody and ImmunoGen's DM1 cytotoxic agent. The DM1 is attached to the antibody using one of ImmunoGen's linkers. Roche has global development and commercialization rights for Kadcyla; ImmunoGen is entitled to receive specified milestone payments and royalties on product sales.

Roche is conducting a number of studies assessing Kadcyla for potential additional uses. These include for the first-line treatment of HER2-positive metastatic breast cancer, for early stage HER2-positive breast cancer and for advanced HER2-positive gastric cancer.

About ImmunoGen, Inc.

ImmunoGen, Inc. develops targeted anticancer therapeutics. The Company's ADC technology uses a tumor-targeting engineered antibody to deliver one of ImmunoGen's highly potent cancer-cell killing agents specifically to tumor cells. The most advanced compound with ImmunoGen's ADC technology is Roche's Kadcyla, which is marketed in the US by Genentech and is also gaining approvals internationally. ImmunoGen has four wholly owned clinical-stage product candidates, with additional compounds in the clinic through its partnerships with Amgen, Bayer HealthCare, Biotest and Sanofi. More information about the Company can be found at www.immunogen.com.

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