February 22, 2013

ImmunoGen, Inc. Announces FDA Approval of Kadcyla (Ado-Trastuzumab Emtansine; Also Known as T-DM1)

- Product demonstrates the power of ImmunoGen's Targeted Antibody Payload (TAP) technology — first antibody-drug conjugate approved for a solid tumor indication.
- Compound to be marketed in the US by Genentech, a member of the Roche Group, under the brand name Kadcyla™; was previously referred to as T-DM1.
- FDA approval triggers $10.5 million milestone payment to ImmunoGen; paves way for royalties on commercial sales.
- Three wholly owned ImmunoGen TAP compounds advancing in clinic along with six additional partner TAP compounds.

WALTHAM, Mass.--(BUSINESS WIRE)-- ImmunoGen, Inc. (Nasdaq: IMGN), a biotechnology company that develops anticancer therapeutics using its TAP technology, today announced that Roche has reported that the U.S. Food and Drug Administration (FDA) has granted marketing approval to Kadcyla for the treatment of people with HER2-positive metastatic breast cancer who have received prior treatment with Herceptin® (trastuzumab) and a taxane chemotherapy.

"This is a big day for the patients with this cancer and for ImmunoGen," commented Daniel Junius, President and CEO. "In clinical testing, the findings with Kadcyla in this patient population have been impressive, and we're delighted the product can now be used by practicing oncologists across the US. In addition to its importance from a medical perspective, commercialization of Kadcyla also marks the start of ImmunoGen earning royalty income."

Mr. Junius continued, "The efficacy and tolerability seen with Kadcyla underscores the transformative potential of our technology. Kadcyla is the most advanced of ten compounds with our TAP technology already in the clinic, with more in earlier stages of development. We are hopeful that in the future many different types of cancers will be routinely treated with TAP compounds."

Kadcyla has gained FDA approval for the treatment of people with HER2-positive metastatic breast cancer who have received prior treatment with Herceptin and a taxane chemotherapy. People should either:

- Have already been treated for their metastatic cancer, or
- Have had their early-stage cancer come back during or within six months after they completed a course of treatment following surgery.

FDA approval of Kadcyla triggers a $10.5 million milestone payment to ImmunoGen. The Company also earns royalties on commercial sales of Kadcyla. Genentech is prepared to launch the product imminently.

"I am thrilled to see our concept of a trastuzumab-DM1 conjugate become a reality today," commented John Lambert, Ph.D., Executive Vice President and Chief Scientific Officer. "We have always believed this product could make an enormous difference for appropriate patients and are delighted to see it move into the hands of practicing oncologists."

Collaboration History

ImmunoGen conceived of the idea of attaching the Company's DM1 maytansinoid cell-killing agent to Genentech's trastuzumab antibody to achieve a highly effective, HER2-targeted anticancer agent. In 2000, Genentech licensed from ImmunoGen exclusive rights to use the Company's maytansinoid TAP technology to develop anticancer products targeting HER2.

In 2006, Genentech advanced the compound that became known as Kadcyla into clinical testing. Genentech has implemented a broad Kadcyla clinical development program that has continued to expand subsequent to Genentech's acquisition by Roche.

Today, multiple Phase III trials are underway or planned evaluating Kadcyla for a number of HER2-positive breast cancer indications. The compound also is being evaluated for the treatment of HER2-positive gastric cancer.

Multiple TAP Compounds Advancing in the Clinic

In addition to Kadcyla, nine other compounds with the Company's TAP technology are in clinical testing for the treatment of an array of cancer types. Three of these compounds are wholly owned by ImmunoGen:

- IMGN901, in Phase II testing for the treatment of small-cell lung cancer;
- IMGN853, in Phase I testing for the treatment of ovarian, lung, and other cancers that over-express folate receptor 1; and
- IMGN529, in Phase I testing for the treatment of non-Hodgkin's lymphoma.

The Company expects to advance a fourth TAP compound, IMGN289, into the clinic in 2013. IMGN289 targets EGFR and is a potential treatment for cancers that overexpress this target, including many head and neck and non-small cell lung cancers.

About ImmunoGen, Inc.

ImmunoGen, Inc. develops targeted anticancer therapeutics. The Company's TAP technology uses a tumor-targeting monoclonal antibody to deliver one of ImmunoGen's highly potent cancer-killing agents specifically to tumor cells. Ten TAP compounds are now in clinical testing, of which three are wholly owned by the Company. The most advanced compound using ImmunoGen's TAP technology, Kadcyla (formerly T-DM1) has been approved for marketing in the US and is undergoing regulatory review in Europe and Japan; it is being commercialized in the US by 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 risks related to preclinical and clinical studies, 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, 2012 and other reports filed with the Securities and Exchange Commission.

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