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ImmunoGen, Inc. Announces FDA Acceptance of IND for Company's Novel EGFR-Targeting ADC, IMGN289

- *Novel antibody-drug conjugate (ADC) IMGN289 on track to begin human clinical testing for treatment of EGFR-positive tumors in 4Q2013.*
- *IMGN289 is a potential new treatment for lung, head and neck, and other EGFR-positive solid tumors, including ones not effectively treated with EGFR-directed therapies today.*
- *Impressive IMGN289 efficacy in multiple EGFR-positive cancer models presented at 2013 American Association for Cancer Research (AACR).*

WALTHAM, Mass.--(BUSINESS WIRE)-- ImmunoGen, Inc. (Nasdaq: IMGN), a biotechnology company that develops novel anticancer therapeutics using its Targeted Antibody Payload (TAP) ADC technology, today announced that the Company's IMGN289 Investigational New Drug (IND) application has been accepted by the US FDA and is now active. This enables ImmunoGen to advance IMGN289 into human clinical testing, expected to start in 4Q2013. This is the third IND for a novel, wholly owned anticancer compound to be submitted by ImmunoGen and accepted by the FDA in the past two years.

"We believe IMGN289 has the potential to be an important new therapy for many cancers, including squamous cell lung cancers and head and neck cancers, which have highly limited treatment options today," commented Dr. Charles Morris, EVP and Chief Development Officer. "Based on its profile, we expect IMGN289 to be more active than existing EGFR-directed therapies against tumors with high EGFR expression and also to be effective for some tumor types where existing therapies have not demonstrated meaningful efficacy."

About IMGN289

IMGN289, an ADC, is a potential new treatment for lung, head and neck, and other EGFR-positive solid tumors. It is designed to bind to and kill cancer cells that highly express EGFR.

IMGN289 contains an EGFR-targeting antibody developed by ImmunoGen that, in preclinical testing, demonstrated marked anticancer activity against EGFR-positive tumors responsive to EGFR inhibitors, with less skin toxicity than marketed antibodies to this target.[1] The Company's potent DM1 cell-killing agent is attached to the antibody with ImmunoGen's thioether linker. This design is also used in the approved product, Kadcyla®. Both IMGN289 and Kadcyla target members of the ErbB family — EGFR (ErbB1) and HER2 (ErbB2), respectively — found on solid tumors that can act as driver oncoproteins.

Against EGFR-positive tumors responsive to EGFR inhibitors, IMGN289's antibody component alone demonstrated activity comparable to Erbitux® in preclinical models. The complete ADC — with the DM1 component — provided superior activity. [1-3]

Its DM1 component enables IMGN289 to kill EGFR-positive cancer cells by a second mechanism that is not dependent on the EGFR pathway — disruption of the function of cellular microtubules. Thus, IMGN289 would be expected to be active against EGFR-positive cancers that are not responsive to EGFR inhibitors. Preclinical results support this expectation: IMGN289 has been found to demonstrate activity superior to Erbitux and Tarceva® against EGFR-independent and TKI-resistant cancer models, respectively.[1-3]

About the First-in-Human IMGN289 Clinical Trial

IMGN289 will be evaluated in a multi-center, US Phase I trial designed to assess the safety, tolerability, pharmacokinetics, pharmacodynamics and anticancer activity of the compound in patients with non-small cell lung cancer (NSCLC), squamous cell carcinoma of the head and neck cancer (SCCHN), or other EGFR-positive solid tumors. Once its maximum tolerated dose is defined, the activity of IMGN289 will be evaluated in disease-specific patient cohorts. The ones planned include SCCHN, squamous cell NSCLC, and NSCLC resistant to EGFR inhibitors.

About EGFR-Positive Cancers

EGFR is highly expressed on a number of types of solid tumors, including many cases of NSCLC and SCCHN.

Approximately 194,000 people will be diagnosed with NSCLC in the US in 2013 and 135,000 will die from the disease.[4] Among

NSCLC, the most prevalent subtypes are adenocarcinoma (AC), squamous cell carcinoma (SCC), and large cell carcinoma (LCC), accounting for approximately 40%, 25-30%, and 10-15% of NSCLC diagnoses, respectively.[5] Research with tumor samples conducted at ImmunoGen found that approximately 20% of AC cases and about half of SCC and LCC cases strongly express EGFR.[2]

More than 51,000 people will be diagnosed with SCCHN in the US in 2013 and 9,800 will die from the disease.[4] Research conducted at ImmunoGen found that over 90% of SCCHN cases strongly express EGFR.[3]

About ImmunoGen, Inc.

ImmunoGen, Inc. develops targeted anticancer therapeutics. The Company's TAP 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 using ImmunoGen's TAP technology, Kadcyla, is marketed in the US by Genentech, a member of the Roche Group, and undergoing regulatory review in the European Union and Japan. ImmunoGen has four wholly owned clinical-stage compounds, with additional compounds in the clinic through partnerships. More information about ImmunoGen can be found at www.immunogen.com.

References

[1]Setiady et al., AACR 2013, abstract #5463
[2]Chittenden et al., AACR 2013, abstract #5467
[3]Ponte et al., AACR 2013, abstract #5483
[4]American Cancer Society (2013), *Cancer Facts & Figures*
[5]American Cancer Society (2013), *Lung Cancer Detailed Guide*

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 IMGN289, 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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