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# ImmunoGen and Merck Establish Collaboration for Clinical Evaluation of Mirvetuximab Soravtansine in Combination with Keytruda® (pembrolizumab) for the Treatment of Ovarian Cancer

 ImmunoGen's mirvetuximab soravtansine folate receptor alpha (FRα)-targeting antibody-drug conjugate (ADC) to be assessed in combination with Merck's anti-PD-1 therapy -

WALTHAM, Mass.--(BUSINESS WIRE)-- <u>ImmunoGen, Inc.</u> (Nasdaq: IMGN), a biotechnology company that develops novel anticancer therapeutics using its ADC technology, and Merck, known as MSD outside the United States and Canada, announced today that they have entered into a clinical research collaboration for the assessment of ImmunoGen's mirvetuximab soravtansine in combination with Merck's anti-PD-1 therapy, Keytruda<sup>®</sup> (pembrolizumab), for the treatment of patients with FRα-positive ovarian cancer.

Mirvetuximab soravtansine is an experimental ADC for FR $\alpha$ -positive cancers that has shown notable activity for FR $\alpha$ -positive ovarian cancer in early clinical testing. Mirvetuximab soravtansine contains a monoclonal antibody that enables it to bind to FR $\alpha$ -positive tumor cells with ImmunoGen's DM4, a maytansinoid cancer-killing agent, attached to kill these cells. In preclinical research conducted by ImmunoGen and academics, ADCs with maytansinoids have been found to enhance the maturation and activation of the dendritic cells of the immune system that stimulate antitumor responses. <sup>1,2</sup> Keytruda is a humanized monoclonal antibody that works by increasing the ability of the body's immune system to help detect and fight tumor cells. Keytruda blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T-lymphocytes, which may affect both tumor cells and healthy cells.

"We look forward to evaluating our mirvetuximab soravtansine ADC in combination with Merck's anti-PD-1 therapy, Keytruda," said Daniel Junius, ImmunoGen President and Chief Executive Officer. "In early clinical testing, mirvetuximab soravtansine has demonstrated notable activity as a single agent for FRα-positive ovarian cancer, and we are aggressively advancing it for this use. At the same time, we believe mirvetuximab soravtansine should be evaluated in different combination regimens to potentially provide the greatest benefit to the most patients. Keytruda has a different mechanism of action than the other agents being assessed."

"Fully realizing the potential for Keytruda to help patients with cancer requires strategic collaborations, such as this agreement with ImmunoGen, that explore how complementary approaches might result in improved outcomes for patients," said Dr. Eric Rubin, vice president and therapeutic area head, oncology early-stage development, Merck Research Laboratories. "We look forward to evaluating the data from this combined approach in patients with  $FR\alpha$ -positive ovarian cancer."

ImmunoGen is conducting a Phase 1b/2 clinical trial, FORWARD II, that evaluates mirvetuximab soravtansine for FRα-positive ovarian cancer used in doublet combination with other anticancer agents. The assessment of mirvetuximab soravtansine with Keytruda will be added to this trial, with Merck supplying the Keytruda. ImmunoGen expects this cohort to open for patient enrollment in the second half of 2016.

The agreement is between ImmunoGen and Merck, through a subsidiary. The agreement includes a provision for potential expansion of the collaboration to include a subsequent Phase 3 clinical trial. Additional details were not disclosed.

# **About Mirvetuximab Soravtansine**

ImmunoGen developed mirvetuximab soravtansine as a potential treatment for ovarian cancer and other FR $\alpha$ -positive solid tumors. In early clinical testing, mirvetuximab soravtansine demonstrated notable activity when used as a single agent to treat platinum-resistant FR $\alpha$ -positive ovarian cancer. ImmunoGen is assessing the ADC used as a single agent for pretreated FR $\alpha$ -positive ovarian cancer in its Phase 2 trial, FORWARD I, which is intended to support an Accelerated Approval pathway. Mirvetuximab soravtansine is also now being assessed in separate combinations with pegylated liposomal doxorubicin (Doxil®), bevacizumab (Avastin®), and carboplatin in the Phase 1b/2 trial, FORWARD II.

#### **About Ovarian Cancer**

Each year there are approximately 240,000 new cases of ovarian cancer diagnosed and 140,000 deaths from the disease

on a global basis. Among all gynecologic cancers, ovarian cancer accounts for the most deaths on an annual basis.

### About ImmunoGen, Inc.

ImmunoGen is a clinical-stage biotechnology company that develops targeted anticancer therapeutics using its proprietary ADC technology. The Company's lead product candidate, mirvetuximab soravtansine, is a potential treatment for folate receptor α-positive ovarian cancer and other solid tumors. A number of major healthcare companies have licensed limited rights to use ImmunoGen's ADC technology to develop anticancer therapies; it is used in Roche's marketed product, Kadcyla<sup>®</sup>. More information about the Company can be found at <a href="https://www.immunogen.com">www.immunogen.com</a>.

Doxil<sup>®</sup>, Avastin<sup>®</sup>, Kadcyla<sup>®</sup>, and Keytruda<sup>®</sup> are registered trademarks of their respective owners.

## ImmunoGen Forward-Looking Statement

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 mirvetuximab soravtansine, including risks related to clinical studies and regulatory processes, 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, 2015 and other reports filed with the Securities and Exchange Commission.

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<sup>&</sup>lt;sup>1</sup>ImmunoGen internal research

<sup>&</sup>lt;sup>2</sup>Martin, Müller, et. al, *Cancer Immunol Immunother* (2014) 63:925-938

<sup>&</sup>lt;sup>3</sup>ASCO 2015, abstract 5518 and AACR-NCI-EORTC 2015, abstract C47

<sup>&</sup>lt;sup>4</sup>WHO GLOBOCAN 2012