



ImmunoGen Announces Successful Completion of Interim Analysis for FORWARD I Phase 3 Trial of Mirvetuximab Soravtansine in Platinum-Resistant Ovarian Cancer

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FORWARD I trial has completed full enrollment; top-line results expected in the first half of 2019

WALTHAM, Mass.--(BUSINESS WIRE)--Apr. 26, 2018-- [ImmunoGen, Inc.](#) (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced that the FORWARD I Phase 3 registration trial evaluating mirvetuximab soravtansine as a single-agent therapy for the treatment of platinum-resistant ovarian cancer will continue as planned without modification. The decision follows a recommendation by the Independent Data Monitoring Committee (IDMC) based upon successful completion of a pre-specified interim futility analysis after 80 progression-free survival (PFS) events as determined by blinded, independent central review. ImmunoGen has also completed full enrollment of the trial two months ahead of schedule and expects top-line results from FORWARD I during the first half of 2019.

"Ovarian cancer is the leading cause of death from gynecological cancers, and patients diagnosed with this life-threatening disease have limited treatment options, especially once they develop platinum-resistant disease," said Anna Berkenblit, M.D., vice president and chief medical officer of ImmunoGen. "We are encouraged that the IDMC recommended FORWARD I proceed as planned and are pleased that the trial has reached full enrollment earlier than expected. We look forward to assessing top-line data in the first half of 2019."

FORWARD I is an ongoing Phase 3 trial designed to randomize 333 patients 2:1 to receive either mirvetuximab soravtansine or the physician's choice of single-agent chemotherapy (pegylated liposomal doxorubicin, topotecan, or weekly paclitaxel). Eligibility criteria include patients with platinum-resistant ovarian cancer that express medium or high levels of folate receptor alpha (FR?) who have been treated with up to three prior regimens. The primary endpoint of this study is PFS, which is being assessed in the entire study population and in the subset of patients with high FR? expression. Enrollment was initially planned to be completed by the end of June.

ImmunoGen is partnering with the Gynecologic Oncology Group Foundation Inc., a leader in clinical research in gynecologic malignancies, on FORWARD I, which is being conducted in North America and Europe. This trial is intended to support full marketing approval of mirvetuximab soravtansine for patients with platinum-resistant ovarian cancer.

About Mirvetuximab Soravtansine

Mirvetuximab soravtansine (IMGN853) is the first FR?-targeting ADC. It uses a humanized FR?-binding antibody to target the ADC specifically to FR?-expressing cancer cells and a potent anti-tumor agent, DM4, to kill these targeted cancer cells.

Mirvetuximab is also being assessed in combination regimens for both platinum-resistant and platinum-sensitive disease in the Phase 1b/2 FORWARD II trial.

About Ovarian Cancer and FR?

It is estimated that 22,000 women are diagnosed annually with ovarian cancer in the US. With more than 14,000 deaths each year, ovarian cancer accounts for more deaths than any other cancer of the female reproductive system.¹

Standard first-line therapy for ovarian cancer is a platinum-based combination regimen. Once the cancer becomes platinum-resistant, treatment options include single-agent cytotoxic therapies such as pegylated liposomal doxorubicin, paclitaxel, or topotecan, and combination therapies that include Avastin®.

There is a significant need for more effective, better-tolerated therapies for recurrent ovarian cancer. It is estimated that approximately 19,000 women in the US and approximately 24,000 women in the EU have platinum-resistant ovarian cancer requiring second-line or later treatment.² ImmunoGen estimates that 60% of ovarian cancer cases have medium or high FR? expression.

About ImmunoGen, Inc.

ImmunoGen is a clinical-stage biotechnology company that develops targeted cancer therapeutics using its proprietary ADC technology. The Company's lead product candidate, mirvetuximab soravtansine, is in the FORWARD I Phase 3 trial for FR?-positive platinum-resistant ovarian cancer, and is in the FORWARD II Phase 1b/2 trial in combination regimens for earlier-stage disease. ImmunoGen has three additional clinical-stage product candidates, two of which are being developed in collaboration with Jazz Pharmaceuticals. ImmunoGen's ADC technology is also used in Roche's marketed product, Kadcyła®, and in programs in development by Amgen, Bayer, Biotest, CytomX, Debiopharm, Lilly, Novartis, Sanofi and Takeda. More information about the Company can be found at www.immunogen.com.

Kadcyła® is a registered trademark of Genentech, a member of the Roche Group.

¹American Cancer Society. Cancer Facts & Figures 2018. Atlanta, Ga: American Cancer Society; 2018.

²Decision Resources Group Patientbase.

This press release includes forward-looking statements, including statements related to the expected timing of results. 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 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 year ended December 31, 2017 and other reports filed with the Securities and Exchange Commission.

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