

May 1, 2017

## ImmunoGen Announces Results from Mirvetuximab Soravtansine Phase 1 First-in-Human Dose-Escalation Trial Published in *Cancer*

*Data informed dosing in expansion cohorts and Phase 3 FORWARD I registration trial*

WALTHAM, Mass.--(BUSINESS WIRE)-- [ImmunoGen, Inc.](#) (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced that the results from a Phase 1 dose-escalation study evaluating mirvetuximab soravtansine (IMGN853) in patients with folate receptor alpha (FR $\alpha$ )-positive solid tumors were published in the journal *Cancer*. The previously disclosed data demonstrated encouraging clinical activity and a manageable safety profile for mirvetuximab soravtansine (IMGN853), and informed the dose that was used in Phase 1 expansion cohorts and the ongoing Phase 3 FORWARD I trial of patients with platinum-resistant ovarian cancer.

"These Phase 1 results have played an important role in determining the appropriate dose for mirvetuximab soravtansine in the recently initiated Phase 3 FORWARD I trial of patients with platinum-resistant ovarian cancer," said Kathleen Moore, M.D., Associate Professor, Department of Obstetrics and Gynecology at the Stephenson Cancer Center at the University of Oklahoma. "The combination of these data and the recent data published in the *Journal of Clinical Oncology* further support the dose that has been chosen and patients who have been selected for FORWARD I."

The open-label, Phase 1 dose-escalation study treated a total of 44 patients with recurrent ovarian (52%) or endometrial cancer (25%), along with renal cell carcinoma and non-small cell lung cancer (11% and 9%, respectively). Patients received mirvetuximab soravtansine on day 1 of a 21-day cycle (Q3W dosing) with cycles repeated until dose-limited toxicity or progression, concluding the recommended dose for future trials is 6.0 mg/kg of mirvetuximab (based on adjusted ideal body weight) dosed once every three weeks. On the basis of the study findings, and additional data that demonstrated the importance of FR $\alpha$  expression levels for optimal mirvetuximab soravtansine activity, the Company designed the Phase 3 FORWARD I trial utilizing this dose in patients with platinum-resistant ovarian cancer, along with a Phase 1b trial evaluating mirvetuximab in combination with standard-of-care chemotherapy and targeted agents.<sup>1</sup>

Mirvetuximab soravtansine exhibited a manageable safety profile and encouraging preliminary clinical activity. Adverse events (AEs) were generally mild with the majority being grade 1 or grade 2 (least severe grades). The most commonly observed AEs were fatigue, blurred vision and diarrhea.<sup>1</sup>

The publication, "Phase I dose-escalation study of mirvetuximab soravtansine (IMGN853), a folate receptor alpha-targeting antibody-drug conjugate, in patients with solid tumors," is available on the [Cancer](#) website.

### About Mirvetuximab Soravtansine

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

Mirvetuximab soravtansine is ImmunoGen's lead program and is in Phase 3 testing as a single agent for the treatment of platinum-resistant ovarian cancer. The candidate is also being assessed in combination regimens for both platinum-resistant and platinum-sensitive disease in Phase 1b/2 FORWARD II trial.

### About Ovarian Cancer and FR $\alpha$

In 2016, approximately 22,300 new cases of ovarian cancer will be diagnosed in the U.S. and more than 14,200 women will die from the disease.<sup>2</sup> ImmunoGen estimates that 60% of ovarian cancer cases have medium or high FR $\alpha$  expression.

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

### About ImmunoGen

ImmunoGen is a clinical-stage biotechnology company that develops targeted cancer therapeutics using its proprietary ADC technology. ImmunoGen's lead product candidate, mirvetuximab soravtansine, is in a Phase 3 trial for FR $\alpha$ -positive

platinum-resistant ovarian cancer, and is in Phase 1b/2 testing in combination regimens for earlier-stage disease. ImmunoGen's ADC technology is used in Roche's marketed product, Kadcyła<sup>®</sup>, in three other clinical-stage ImmunoGen product candidates, and in programs in development by partners Amgen, Bayer, Biotest, CytomX, Lilly, Novartis, Sanofi and Takeda. More information about the Company can be found at [www.immunogen.com](http://www.immunogen.com).

Kadcyła<sup>®</sup> is a registered trademark of Genentech, a member of the Roche Group.

<sup>1</sup>Moore KN, et al: Phase I dose-escalation study of mirvetuximab soravtansine (IMGN853), a folate receptor alpha-targeting antibody-drug conjugate, in patients with solid tumors, *Cancer*, 25 April 2017

<sup>2</sup>American Cancer Society, Cancer Facts & Figures 2016

*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, and risks related to clinical studies, their timing and results. A review of these risks can be found in ImmunoGen's transition report on Form 10-K for the six-month transition period ended December 31, 2016 and other reports filed with the Securities and Exchange Commission.*

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