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ImmunoGen Announces Mirvetuximab Soravtansine Phase 1 Expansion Cohort Results in Platinum-Resistant Ovarian Cancer Published in the Journal of Clinical Oncology

Positive Results Form Basis for FORWARD I Phase 3 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 results from the Phase 1 expansion cohort evaluating mirvetuximab soravtansine (IMGN853) in patients with folate receptor alpha (FR α)-positive platinum-resistant ovarian cancer were published in the *Journal of Clinical Oncology*. The data demonstrate the potential clinical benefit of mirvetuximab soravtansine for the treatment of platinum-resistant ovarian cancer.

"Standard single-agent therapy for patients with platinum-resistant ovarian cancer typically has a response rate below 20% and median progression-free survival below four months," said Kathleen Moore, M.D., Associate Professor, Stephenson Cancer Center, University of Oklahoma, and lead author of the publication. "Mirvetuximab soravtansine generated encouraging efficacy and tolerability data in the Phase 1 trial that suggest the potential to improve clinical outcomes for this patient population."

The Phase 1 expansion cohort enrolled 46 patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer whose tumors were positive for FR α . Patients were dosed with mirvetuximab soravtansine once every three weeks. Mirvetuximab soravtansine demonstrated single-agent activity in the 46-patient cohort with a 26% confirmed response rate and median progression free survival (PFS) of 4.8 months. In a subset of 23 patients with low, medium or high FR α , who had received three or fewer prior lines of therapy, there was a 39% objective response rate (ORR) and median PFS of 6.7 months. On the basis of the study findings and additional data demonstrating the importance of FR α expression levels with mirvetuximab soravtansine, the Company has designed the Phase 3 FORWARD I study to enroll patients with platinum-resistant ovarian cancer with one to three prior therapies and with medium or high FR α . This group of patients in the Phase 1 expansion cohort exhibited a 44% ORR and a median PFS of 6.7 months.¹

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

"These results demonstrate that mirvetuximab soravtansine is active in platinum-resistant ovarian cancer, with encouraging response rates and progression-free survival combined with a manageable safety profile," said Anna Berkenblit, M.D., Vice President and Chief Medical Officer of ImmunoGen. "On the basis of these findings, we have moved confidently into a Phase 3 registration study evaluating this promising agent against the standard of care in the platinum-resistant setting. In addition, we are evaluating combination regimens to assess mirvetuximab soravtansine in expanded patient populations and will begin reporting data from these combinations in mid-2017."

The publication, "Safety and Activity of Mirvetuximab Soravtansine (IMGN853), a Folate Receptor Alpha-Targeting Antibody-Drug Conjugate, in Platinum-Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer: A Phase I Expansion Study," is available on the [Journal of Clinical Oncology website](#).

About Mirvetuximab Soravtansine

Mirvetuximab soravtansine (IMGN853) is the first FR α -targeting ADC. It uses a FR α -binding antibody to target the ADC specifically to FR α -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 now 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 α

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.² ImmunoGen estimates that 60% of ovarian cancer cases have medium or high FR α 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 α -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[®], 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.

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

¹Moore KN, Martin LP, Matulonis UA et al: IMGN853 (mirvetuximab soravtansine), a folate receptor alpha (FR α)-targeting antibody-drug conjugate (ADC): single-agent activity in platinum-resistant epithelial ovarian cancer (EOC) patients, presented at American Society of Clinical Oncology, June 2016, abstract # 5567

²American 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, 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, 2016 and other reports filed with the Securities and Exchange Commission.

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