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ImmunoGen Reports Efficacy and Safety Data from a 46-Patient Cohort of Mirvetuximab Soravtansine in FRα-Positive Ovarian Cancer

- *Confirmed objective response rate of 44% and median progression-free survival of 6.7 months seen in cohort subset mirroring patient population selected for planned Phase 3 study.*
- *Company preparing to meet with FDA in early 3Q2016; targeting initiation of Phase 3 study in 4Q2016.*
- *Data will be presented at ASCO Annual Meeting on June 6, 2016.*

WALTHAM, Mass.--(BUSINESS WIRE)-- ImmunoGen, Inc. (Nasdaq: IMGN), a biotechnology company developing novel antibody-drug conjugate (ADC) cancer therapeutics, today reported the clinical data from a 46-patient Phase 1 cohort evaluating the efficacy and safety of mirvetuximab soravtansine as single-agent therapy for platinum-resistant, folate receptor alpha (FRα)-positive ovarian cancer. These results have informed the Company's selection of the patient population and primary endpoint for a Phase 3 study scheduled to begin before year-end.

This Phase 1 cohort, which was expanded from 20 to 46 patients to provide additional information for the design of subsequent trials, enrolled patients with platinum-resistant ovarian cancer who had received up to five previous treatment regimens. Patients also needed to have FRα expressed at or above a predefined level on at least 25% of tumor cells. Patients were classified as having low, medium, or high FRα expression based on the percent of tumor cells meeting this criterion (25-49%, 50-74%, and 75-100%, respectively). Among the 46 patients, 23 had high, 14 had medium, and 9 had low expression of FRα. All had previously received platinum and a taxane.

Among all 46 patients, the confirmed objective response rate (ORR) was 26% and median progression-free survival (PFS) was 4.8 months (95% confidence interval, 3.9-5.7 months). Among the 16 patients who received up to three prior regimens and had high or medium FRα expression - the population selected for the planned Phase 3 trial - the ORR was 44% and median PFS was 6.7 months (95% CI, 3.9-11.0 months). For the 30 patients with low FRα and/or who had received four or five prior regimens, ORR was 17% and median PFS was 4.2 months (95% CI, 2.6-5.5 months).

Current single-agent therapies for platinum-resistant ovarian cancer typically have an ORR of 15-20% and median PFS of 3-4 months, including in patients receiving no more than two prior regimens.[1]

Based upon the findings in this Phase 1 cohort, the planned Phase 3 trial assessing mirvetuximab soravtansine as single-agent therapy for platinum-resistant ovarian cancer will enroll patients who previously received up to three treatment regimens and whose cancer has high or medium FRα expression, with PFS as the primary endpoint.

"There is a significant need for new therapies for ovarian cancer," commented Dr. Kathleen Moore, Christy Everest Endowed Chair in Cancer Research and Director of the Oklahoma TSET Phase I Unit, Stephenson Cancer Center, University of Oklahoma HSC. "We're excited about the findings with mirvetuximab soravtansine from this study and to be advancing this first-in-class agent into a Phase 3 trial for platinum-resistant ovarian cancer."

"We plan to have Phase 3 testing of mirvetuximab soravtansine up and running by year end," commented Dr. Charles Morris, ImmunoGen's EVP and Chief Development Officer. "Now that we have the full results from the 46-patient ovarian cancer cohort, we've submitted a meeting request to the FDA to discuss our proposed path to approval. This meeting should take place early in 3Q2016, and we are targeting initiation of FORWARD I Phase 3 testing in 4Q2016."

Mirvetuximab soravtansine was generally well tolerated, with most side effects Grade 1 or 2 (least severe grades). Of particular note, incidence of blurred vision was reduced from 55%, mostly Grade 2, in the first 20 patients enrolled to 39%, mostly Grade 1, among the 26 patients added with the expansion of the cohort. Other side effects reported in more than 20% of patients were diarrhea, fatigue, nausea, vomiting, peripheral neuropathy, increased AST, keratopathy, and abdominal pain.

Data Presentation at ASCO 2016

"IMGN853 (mirvetuximab soravtansine), a folate receptor alpha (FRα)-targeting antibody-drug conjugate (ADC): single-agent activity in platinum-resistant epithelial ovarian cancer patients" will be presented in the Gynecologic Cancer Poster Session (Poster Board #390) taking place on Monday, June 6, from 1:00-4:30 pm CT. (Abstract #5567).

About the Planned FORWARD I Phase 3 Trial

The FORWARD I Phase 3 trial is intended to support full marketing approval of mirvetuximab soravtansine for the treatment of patients with platinum-resistant ovarian cancer who previously received up to three treatment regimens for whom single-agent therapy is appropriate. The cancer also must have high or medium FRα expression. ImmunoGen estimates that 5,000-7,000 patients per year (US) meet these criteria.

Patients will be randomized 2:1 to mirvetuximab soravtansine or physician's choice, which will include pegylated liposomal doxorubicin, topotecan, and weekly paclitaxel.

PFS will be the primary endpoint of the trial. This study also will be powered for separate assessment of the endpoint in the full study population and in the subset with high FRα expression and will include at least 300 patients.

About Mirvetuximab Soravtansine

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

ImmunoGen is advancing mirvetuximab soravtansine into Phase 3 testing as a single agent for the treatment of platinum-resistant ovarian cancer. The product candidate is also in Phase 1b/2 testing in combination regimens for ovarian cancer.

About Ovarian Cancer and FRα

This year, approximately 22,300 new cases of ovarian cancer will be diagnosed in the US and more than 14,200 women will die from the disease.[2] ImmunoGen estimates that 40% of ovarian cancer cases have high FRα expression, 20% have medium, 20% have low, and 20% have very low levels of FRα.

Standard first-line therapy for ovarian cancer is a platinum-based regimen. Once the cancer becomes platinum-resistant, patients may receive single-agent therapy.

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 being advanced to Phase 3 testing for FRα-positive platinum-resistant ovarian cancer, and is also in Phase 1b/2 testing in combination regimens for earlier-stage disease. The Company's ADC technology is used in three other clinical-stage ImmunoGen product candidates, in Roche's marketed product, Kadcyla®, 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.

[1]From prescribing information and published clinical data

[2]American Cancer Society (2016), *Cancer Facts & Figures*

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 (IMGN853), 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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