ImmunoGen Presents Initial Data from FORWARD II Expansion Cohort Assessing Mirvetuximab Soravtansine in Combination with KEYTRUDA at ESMO 2018 Congress

October 20, 2018

Preliminary Data Demonstrate Favorable Safety Profile and Encouraging Activity in Heavily Pretreated Patients with Ovarian Cancer

WALTHAM, Mass.--(BUSINESS WIRE)--Oct. 20, 2018-- ImmunoGen, Inc., (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced initial safety and preliminary anti-tumor activity from the FORWARD II expansion cohort assessing mirvetuximab soravtansine in combination with Merck's anti-PD-1 therapy, KEYTRUDA ® (pembrolizumab). The data are being presented at the European Society for Medical Oncology (ESMO) 2018 Congress, which is being held October 19-23, in Munich, Germany.

"A high unmet need exists in patients with platinum-resistant ovarian cancer, particularly for heavily pretreated patients, and the goal of this study is to assess whether the addition of a checkpoint inhibitor prolongs the clinical benefit of mirvetuximab soravtansine in later-line patients through concomitant activation of the immune system," said Ursula Matulonis, M.D., Chief, Division of Gynecologic Oncology, Dana-Farber Cancer Institute. "Preliminary activity seen with the mirvetuximab soravtansine and pembrolizumab combination is encouraging, especially when considering other combinations involving pembrolizumab used in this patient population, where recent clinical trials have reported overall response rates below 20 percent."

The data presented at ESMO were for 56 patients with platinum-resistant ovarian cancer, of whom 40 have medium or high folate receptor alpha (FRα) expression. Patients had received a median of 3 prior therapies (range 2-7).

The combination of mirvetuximab soravtansine (6 mg/kg adjusted ideal body weight) and pembrolizumab (200 mg, supplied by Merck) demonstrates favorable tolerability and encouraging activity. Adverse events were predominantly mild to moderate (≤ Grade 2), consistent with the known safety profiles of each agent.

Preliminary findings related to activity include:

- 83% of patients (45/54 with at least one post-baseline scan) experienced tumor shrinkage of target lesions in response to treatment with mirvetuximab soravtansine and pembrolizumab, with more robust reductions observed in patients with tumors expressing FRα at medium or high levels.
    - Confirmed partial responses (PRs) were observed in 16 patients, with another 9 patients having unconfirmed PRs at the time of data analysis.
- In the subset of patients with medium or high FRα expression levels, the confirmed overall response rate (ORR) was 31 percent (95% CI, 17, 48), with a median progression-free survival (PFS) of 5.5 months (95% CI 2.8, 6.3) and a median duration (DOR) of 8.1 months (95% CI 4.2, upper bound not yet reached).
    - At the time of analysis, the data were immature with 16 patients still on study (all with medium or high FRα expression) and a median follow-up of 8.3 months.
- For all patients evaluable for activity, the confirmed ORR was 30 percent (95% CI 18, 44), with a median PFS of 4.2 months (95% CI 2.8, 5.9). The median DOR data of 6.9 months (95% CI 4.2, 8.3) suggest a trend towards improvement over mirvetuximab soravtansine monotherapy.

"The combination of mirvetuximab soravtansine with pembrolizumab continues to demonstrate a favorable tolerability profile in women with platinum-resistant ovarian cancer, with preliminary activity consistent with mirvetuximab monotherapy in heavily pretreated patients," said Anna Berkenblit, M.D., Vice President and Chief Medical Officer of ImmunoGen. "The early duration of response data from the expansion cohort suggest a trend towards improvement over mirvetuximab monotherapy. As the data from this cohort continue to mature, we will use it to guide the further development of this novel combination, as part of our broader strategy to establish mirvetuximab soravtansine as the preferred combination therapy in ovarian cancer."

POSTER PRESENTATION DETAILS

- **Title:** "Mirvetuximab soravtansine, a folate receptor alpha (FRα-targeting antibody-drug conjugate (ADC), with pembrolizumab in platinum-resistant ovarian cancer (PROC): Initial results of an expansion cohort from FORWARD II, a Phase Ib study" (abstract #949P)
- **Date:**October 20, 2018
- **Time:**12:30 CEST
- **Lead author:**Ursula Matulonis, M.D., Chief, Division of Gynecologic Oncology, Dana-Farber Cancer Institute, Boston, MA

Additional information can be found at www.esmo.org.

About FORWARD II

FORWARD II is a Phase 1b/2 study of mirvetuximab soravtansine in combination with AVASTIN® (bevacizumab), or KEYTRUDA® (pembrolizumab) in patients with FRα-positive platinum-resistant ovarian cancer, primary peritoneal, or fallopian tube tumors, as well as a combination with carboplatin and a triplet combination of mirvetuximab plus carboplatin and AVASTIN in patients with platinum-sensitive ovarian cancer.

ABOUT MIRVETUXIMAB SORAVTANSINE
Mirvetuximab soravtansine (IMGN853) is the first folate receptor alpha (FRα)-targeting ADC. It uses a humanized 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.

ABOUT IMMUNOGEN
ImmunoGen is developing the next generation of antibody-drug conjugates (ADCs) to improve outcomes for cancer patients. By generating targeted therapies with enhanced anti-tumor activity and favorable tolerability profiles, we aim to disrupt the progression of cancer and offer our patients more good days. We call this our commitment to “target a better now.” Our lead product candidate, mirvetuximab soravtansine, is in a Phase 3 study for folate receptor alpha (FRα)-positive platinum resistant ovarian cancer, and in Phase 1b/2 testing in combination regimens. Our novel IGN candidates for hematologic malignancies, IMGN779 and IMGN632, are in Phase 1 studies.

Learn more about who we are, what we do, and how we do it at www.immunogen.com.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. AVASTIN® is a registered trademark of Genentech, Inc., a member of the Roche Group.

This press release includes forward-looking statements based on management's current expectations. These statements include, but are not limited to, ImmunoGen's ability to expand the addressable patient population for mirvetuximab soravtansine and the regulatory and commercial potential of mirvetuximab combinations in earlier lines of therapy. 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. Various factors could cause ImmunoGen's actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this release. It should be noted that there are risks and uncertainties related to the development of novel anticancer products, including risks related to preclinical and clinical studies, their timings and results, and the potential that earlier clinical studies may not be predictive of future results. A review of these risks can be found in ImmunoGen's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and other reports filed with the Securities and Exchange Commission.

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