ImmunoGen Announces Mature Data from FORWARD II Study Evaluating Mirvetuximab Soravtansine in Combination with Avastin® in Recurrent Ovarian Cancer, Regardless of Platinum Status

May 19, 2021

Results to be Presented in an Oral Session at 2021 ASCO Annual Meeting

Combination Demonstrates Strong Anti-Tumor Activity in Patients with High FRα Expression, with a Confirmed Overall Response Rate of 64%, Median Duration of Response of 11.8 Months and Median Progression-Free Survival of 10.6 Months

High Response Rate, Durable Benefit, and Favorable Tolerability Profile Reinforce Potential of Mirvetuximab to Serve as Combination Agent of Choice for Patients with High FRα Recurrent Ovarian Cancer

WALTHAM, Mass.--(BUSINESS WIRE)--May 19, 2021-- ImmunoGen Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced mature data from the FORWARD II study evaluating mirvetuximab soravtansine in combination with Avastin® (bevacizumab) in patients with medium and high folate receptor alpha (FRα)-expressing recurrent ovarian cancer for whom a non-platinum based combination regimen is appropriate. These findings will be highlighted in an oral presentation at the 2021 American Society of Clinical Oncology (ASCO) Virtual Annual Meeting, which is being held June 4-8, 2021. Two posters highlighting mirvetuximab combination regimens will also be presented by ImmunoGen's collaborators during the meeting.

"Due to the introduction of effective maintenance therapies, patients with recurrent ovarian cancer are living longer and comprise an increasing population in need of effective, well-tolerated non-platinum based regimens," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "With a 64% ORR, 11.8 month mDOR, and 10.6 month mPFS, the combination of mirvetuximab plus bevacizumab shows compelling activity in patients with high FRα recurrent ovarian cancer. We are extremely pleased to present these data during an oral presentation at ASCO, as they build on previous findings and provide us with further evidence of mirvetuximab's potential to become the combination agent of choice for ovarian cancer patients."

MATURE DATA FROM FORWARD II DOUBLET COHORT WITH BEVACIZUMAB

The cohort enrolled 60 patients with a median age of 60 and a median number of 2 prior lines of therapy (range 1-4). 53% had platinum-resistant disease with a platinum-free interval (PFI) of less than or equal to 6 months; 33% had partially platinum-sensitive disease with a PFI greater than 6 months and less than or equal to 12 months; and 13% had a PFI greater than 12 months. 40% of patients in the cohort were previously treated with bevacizumab and 35% of patients in the cohort were previously treated with a PARP inhibitor. The combination of mirvetuximab with bevacizumab in this cohort demonstrates promising anti-tumor activity with a favorable tolerability profile, particularly among patients with high levels of FRα expression, and is encouraging relative to outcomes with available therapies reported in similar populations. In the oral presentation, key updated data include:

- In the overall patient population, objective responses were seen in 30 patients and the confirmed overall response rate (ORR) was 50% (95% CI, 34, 60), with a median duration of response (mDOR) of 9.7 months (95% CI 6.7, 12.9) and median progression-free survival (mPFS) of 8.3 months (95% CI 5.6, 10.1).
- In patients with high FRα expression (n=33), the confirmed ORR was 64% (95% CI, 45, 80), mDOR was 11.8 months (95% CI 6.7, 13.7), and mPFS was 10.6 months (95% CI 8.3, 13.3).
    - In high FRα platinum-sensitive patients, who represent a growing population, the combination of mirvetuximab plus bevacizumab achieved a 69% ORR, 12.7 month mDOR, and a 13.3 month mPFS.
    - In high FRα platinum-resistant patients, the combination of mirvetuximab plus bevacizumab achieved a 59% ORR, 9.4 month mDOR, and a 9.7 month mPFS.
- The adverse events (AEs) observed with the doublet were manageable and consistent with the side effect profiles of each agent. Treatment-related AEs were generally low grade, with diarrhea (62%), blurred vision (60%), fatigue (60%), and nausea (57%) being the most common. The most common grade 3+ events were hypertension (17%) and neutropenia (13%).

"Despite advances in the maintenance setting of ovarian cancer, a high unmet need for novel, well-tolerated, targeted treatments exists in those patients with recurrent high-grade epithelial ovarian cancer," said David O'Malley, MD, Professor, Director of Gynecologic Oncology and Co-Director, Gynecologic Oncology Phase 1 Program at The Ohio State University and the James Cancer Center, and FORWARD II Principal Investigator. "The data we continue to see when mirvetuximab is combined with bevacizumab in recurrent disease are extremely encouraging, particularly in light of outcomes reported with available therapies in even less heavily pre-treated populations. The strength of these mature data warrant further development of this novel, targeted combination and I look forward to evaluating this regimen in earlier lines of therapy."

ORAL PRESENTATION SESSION

- **Title:** "Mirvetuximab Soravtansine, a Folate Receptor Alpha-Targeting Antibody-Drug Conjugate, in Combination with Bevacizumab in Patients with Platinum-Agnostic Ovarian Cancer - Final Analysis"
- **Day/Time:** Monday, June 7 from 8:00 a.m. to 11:00 a.m. ET
- **Lead Author:** David M. O'Malley, MD, The Ohio State University College of Medicine

- **Abstract:** 5504

POSTER SESSIONS

The following posters will be available on Friday, June 4 at 9:00 a.m. ET in the ASCO Meeting Library:

- **Title:** "A Phase I Study of Mirvetuximab Soravtansine and Gemcitabine in Patients with FRα-Positive Solid Tumors: Results from the Ovarian Cancer Cohort"
- **Lead Author:** Mihaela C. Cristea, MD, City of Hope National Medical Center
- **Abstract:** 5542

- **Title:** "A Phase 2, Two-Stage Study of Mirvetuximab Soravtansine in Combination with Pembrolizumab in Patients with Microsatellite Stable Endometrial Cancer"
- **Lead Author:** Rebecca L. Porter, MD, PhD, Dana-Farber Cancer Institute
- **Abstract:** TPS5611

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

ABOUT MIRVETUXIMAB SORAVTANSINE

Mirvetuximab soravtansine (IMGN853) is a first-in-class ADC comprising a folate receptor alpha (FRα)-binding antibody, cleavable linker, and the maytansinoid payload DM4, a potent tubulin-targeting agent, to kill the targeted cancer cells.

ABOUT FORWARD II

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

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™.

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

Avastin® and Keytruda® are registered trademarks of Genentech, a member of the Roche Group and Merck Sharp & Dohme Corp., respectively.

FORWARD-LOOKING STATEMENTS

This press release includes forward-looking statements based on management's current expectations. These statements include, but are not limited to, ImmunoGen's expectations related to: the occurrence, timing, and outcome of potential preclinical, clinical, and regulatory events related to the Company's product candidates and the presentation of preclinical and clinical data on the Company's product candidates. 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. Factors that could cause future results to differ materially from such expectations include, but are not limited to: the timing and outcome of the Company's preclinical and clinical development processes; the difficulties inherent in the development of novel pharmaceuticals, including uncertainties as to the timing, expense, and results of preclinical studies, clinical trials, and regulatory processes; the Company's ability to financially support its product programs; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and the resulting impact on ImmunoGen's industry and business; and other factors as set forth in the Company's Annual Report on Form 10-K for the year ending December 31, 2020 filed with the Securities and Exchange Commission on March 1, 2021, and other reports filed with the Securities and Exchange Commission.

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