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

May 13, 2020

Combination Demonstrates Promising Anti-Tumor Activity and Favorable Tolerability, with a Confirmed Overall Response Rate of >60% in Patients with High FRα Expression

Results to be Presented in an Oral Session at ASCO 2020 Virtual Scientific Program

WALTHAM, Mass.--(BUSINESS WIRE)--May 13, 2020-- ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced initial 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 American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program on May 29, 2020. Three "trial in progress" posters will also be presented during the meeting.

"With the benefit of the clinical profile demonstrated by mirvetuximab monotherapy, we have pursued a development strategy to establish mirvetuximab as the agent of choice in combination regimens to treat expanded populations of patients with recurrent ovarian cancer. To this end, we are encouraged by the compelling anti-tumor activity and favorable tolerability observed with the combination of mirvetuximab plus bevacizumab in patients for whom a non-platinum based regimen is appropriate," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "These findings show greater depth and duration of tumor reduction in women whose tumors express high levels of FRα, regardless of platinum status, reinforcing the potential of this doublet in these patients. As these data mature, we look forward to further evaluating this combination in the recurrent ovarian cancer setting."

INITIAL DATA FROM FORWARD II DOUBLET COHORT WITH BEVACIZUMAB

This cohort enrolled 60 patients with FRα-positive recurrent ovarian cancer for whom a non-platinum based combination regimen is appropriate, with a median age of 60 years and a median number of 2 prior lines of therapy (range 1-4). The combination of mirvetuximab soravtansine with bevacizumab in this cohort demonstrates encouraging anti-tumor activity with a favorable tolerability profile, particularly among the subset of patients with high levels of FRα expression.

Key findings include:

- In the overall patient population, objective responses were seen in 26 patients and the confirmed overall response rate (ORR) was 43% (95% CI, 31, 57).
- In patients with high FRα expression (n=33), the confirmed ORR was 61% (95% CI, 42, 77), with an ORR of at least 50% in each of the platinum-resistant and platinum-sensitive subgroups.
- With many patients remaining on study, the duration of response and progression free survival data are immature.
- The adverse events (AEs) observed with the doublet were as expected based on the side effect profiles of each agent. The most common treatment-related low grade AEs were diarrhea, blurred vision, nausea, and fatigue; grade 3+ AEs were infrequent, with the most common being hypertension and neutropenia.

"With the increasing need for non-platinum regimens in recurrent ovarian cancer, we are excited to further advance mirvetuximab in combination with bevacizumab, building on the prior data for this combination in women with platinum resistant disease," stated Lucy Gilbert, MD, Professor, and Director of the Gynecologic Oncology Division at McGill University Health Center in Montreal, Canada. "These initial data demonstrate meaningful clinical benefit in women with recurrent disease, regardless of platinum status, and I look forward to reporting longer-term follow up and further evaluating the doublet in this expanded patient population."

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"
- **Day/Time:** Friday, May 29 at 8:00 AM ET
- **Lead Author:** Lucy Gilbert, MD, McGill University Health Center, Montreal, Canada
- **Abstract:** 6004

TRIAL IN PROGRESS POSTERS

The following posters will be available on Friday, May 29 at 8:00 AM ET in the ASCO Meeting Library:

- **Title:** "MIRASOL (GOG 3045/ENGOT OV-55): A Randomized, Open-label, Phase 3 study of Mirvetuximab Soravtansine versus Investigator's Choice of Chemotherapy in Advanced High-grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers with High Folate Receptor Alpha (FRα) Expression"
- **Lead Author:** Kathleen Moore, MD, University of Oklahoma Health Sciences Center
- **Abstract:** TPS6103 (Poster 274)

- **Title:** “A Phase 1/2 Study of IMGN632, a Novel CD123-Targeting Antibody-Drug Conjugate, in Patients with Relapsed/Refractory Acute Myeloid Leukemia, Blastic Plasmacytoid Dendritic Cell Neoplasm, and Other CD123-Positive Hematologic Malignancies”
- **Lead Author:** Naval Daver, MD, MD Anderson Cancer Center
- **Abstract:** TPS7563 (Poster 336)

- **Title:** “A Phase 1b/2 Study of the CD123-Targeting Antibody-Drug Conjugate IMGN632 as Monotherapy or in Combination with Venetoclax and/or Azacitidine for Patients with CD123-Positive Acute Myeloid Leukemia”
- **Lead Author:** Naval Daver, MD, MD Anderson Cancer Center
- **Abstract:** TPS7564 (Poster 337)

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

ABOUT FORWARD II
FORWARD II is a Phase 1b/2 study of mirvetuximab 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 MIRVETUXIMAB SORAVTANSINE
Mirvetuximab soravtansine (IMGN853) is an antibody-drug conjugate (ADC) comprising a folate receptor alpha (FRα)-binding antibody, cleavable linker, and the maytansinoid DM4, a potent tubulin-targeting agent 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 delivering 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.

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 clinical and regulatory events related to ImmunoGen’s product candidates; and the presentation of clinical data on ImmunoGen’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 ImmunoGen’s clinical development processes; the difficulties inherent in the development of novel pharmaceuticals, including uncertainties as to the timing, expense, and results of pre-clinical studies, clinical trials, and regulatory processes; ImmunoGen’s ability to financially support its product programs; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting impact on ImmunoGen’s industry and business; and other factors more fully described in ImmunoGen’s Annual Report on Form 10-K for the year ended December 31, 2019 and other reports filed with the Securities and Exchange Commission.

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