ImmunoGen Presents Final Data From Phase 1b FORWARD II Triplet Cohort Evaluating Mirvetuximab Soravtansine in Combination With Carboplatin and Avastin® at ESMO

September 17, 2020

Triplet Combination Demonstrates Encouraging Anti-Tumor Activity and Tolerability in Recurrent Platinum-Sensitive Ovarian Cancer

WALTHAM, Mass.--(BUSINESS WIRE)--Sep. 17, 2020-- ImmunoGen, Inc., (Nasdaq: IMGN) a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced final data from the FORWARD II triplet cohort evaluating mirvetuximab soravtansine in combination with carboplatin and Avastin® (bevacizumab) in patients with folate receptor alpha (FRα)-positive recurrent, platinum-sensitive ovarian cancer at the European Society for Medical Oncology (ESMO) 2020 Virtual Congress.

“Although there have been advances in the treatment of platinum-sensitive disease with targeted and maintenance therapies, there remains a significant need for additional active, well-tolerated combinations in the platinum-sensitive setting,” 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 efficacy outcomes demonstrated by combining full dose mirvetuximab with bevacizumab and carboplatin in more heavily pretreated platinum-sensitive ovarian cancer patients is encouraging relative to current standard of care triplet regimens.”

In the FORWARD II triplet cohort Phase 1b trial, 41 patients with a median age of 63 years received the combination of full dose mirvetuximab with carboplatin and bevacizumab. Eligibility criteria included patients with recurrent platinum-sensitive ovarian cancer that expressed medium or high levels of FRα, who had been treated with up to two prior lines of therapy. 73% of patients had one prior line of therapy and 27% had two prior lines of therapy, while 42% of patients had received prior PARP inhibitors, and 24% had received prior treatment with bevacizumab.

Key Findings from FORWARD II Triplet Cohort

- In 41 patients with recurrent platinum-sensitive ovarian cancer with medium or high levels of FRα who have received up to two prior lines of therapy, the confirmed overall response rate (ORR) for the triplet was 83%, with a median duration of response (DOR) of 10.9 months and median progression free survival (PFS) of 12.8 months.
- These efficacy outcomes are encouraging relative to those reported in less heavily pretreated patient populations for other carboplatin and bevacizumab-based triplets.
- Mirvetuximab was readily combined and well tolerated with standard dosing of carboplatin and bevacizumab, with a manageable adverse event (AE) profile as anticipated for this triplet based on the side effect profiles of each agent. Thrombocytopenia, a common adverse event with carboplatin treatment, was the most common cause of drug-related discontinuations.
- Post-carboplatin (median 6 cycles), mirvetuximab soravtansine and bevacizumab continuation/maintenance was well tolerated.

“Having generated a wealth of data demonstrating encouraging efficacy and favorable tolerability, mirvetuximab continues to show promise in combination – not only as a triplet but also when combined with bevacizumab or carboplatin as a doublet. In the future, we look forward to defining a formal path to registration for mirvetuximab in combination with approved agents with the goal of expanding use into earlier lines of therapy and becoming the combination agent of choice in ovarian cancer,” said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen.

ESMO Poster Details

In addition, the City of Hope will present data from their study of mirvetuximab in combination with gemcitabine in patients with recurrent FRα-positive ovarian cancer, endometrial cancer, and triple negative breast cancer.

- **Title**: “A Phase I Study of Mirvetuximab Soravtansine (MIRV) and Gemcitabine (G) in Patients (Pts) with Selected FRα-positive Solid Tumors: Results in the Endometrial Cancer (EC) Cohort” (Presentation #863P)
- **Date**: Thursday, September 17, 2020
- **Time**: 9:00 a.m. CEST/3:00 a.m. ET
- **Lead Author**: Mihaela C. Cristea, MD, Associate Clinical Professor, Department of Medical Oncology and Therapeutics Research, Gynecologic Oncology Peritoneal Malignancy Program, City of Hope Comprehensive Cancer Care Center

Additional information can be found at www.esmo.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 folate receptor alpha (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 a first-in-class 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 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 trademark of their respective owners.

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 pre-clinical, clinical, and regulatory events related to ImmunoGen’s product candidates; and the presentation of pre-clinical and 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 pre-clinical and 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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