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

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With a Confirmed Overall Response Rate of 64% and Favorable Tolerability in Patients with High FRα Expression, Combination Demonstrates Encouraging Outcomes Relative to Available Regimens

WALTHAM, Mass.--(BUSINESS WIRE)--May 29, 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 were presented in an oral presentation at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program.

“The data presented at ASCO demonstrate the potential of mirvetuximab to serve as the combination agent of choice for both platinum-sensitive and platinum-resistant recurrent ovarian cancer,” said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. “We are particularly encouraged by the overall response rate of 64% observed in patients with high FRα expression, regardless of platinum status. We look forward to the continued evaluation of mirvetuximab with bevacizumab in this increasing population of recurrent ovarian cancer patients for whom a non-platinum based regimen would be appropriate.

“Despite the advances with PARP inhibitors and anti-angiogenic agents in newly diagnosed ovarian cancer, active, well-tolerated therapies for women with recurrent disease regardless of platinum status are still needed,” said Lucy Gilbert, MD, Professor, and Director of the Gynecologic Oncology Division at McGill University Health Center in Montreal, Canada. “With this combination, the overall response rate in the platinum-resistant subset is more than twice the usual response rate for this population and similarly, in the platinum-sensitive subset, the overall response rate is higher than previously seen with platinum-based doublets. Given these responses and the favorable tolerability profile of this combination, these data are exciting and demonstrate the potential of mirvetuximab to address the growing unmet need in this patient population.”

UPDATED DATA FROM FORWARD II DOUBLET COHORT WITH BEVACIZUMAB

Oral Presentation, Abstract 6004

The cohort enrolled 60 patients with a median age of 60 and a median number of 2 prior lines of therapy (range 1-4). Thirty-two patients (53%) had platinum-resistant disease with a platinum-free interval (PFI) of less than or equal to 6 months; 28 patients (47%) had platinum-sensitive disease – of which 20 patients (33%) had a PFI greater than 6 months and less than or equal to 12 months and 8 patients (13%) had a PFI greater than 12 months. 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 today’s oral presentation, key updated data include:

- In the overall patient population, objective responses were seen in 28 patients and the confirmed overall response rate (ORR) was 47% (95% CI, 34, 60).
- In patients with high FRα expression (n=33), the confirmed ORR was 64% (95% CI, 45, 80), with an ORR of 59% (95% CI, 33, 82) in the platinum-resistant subgroup (n=17), and 69% (95% CI, 41, 89) in the platinum-sensitive subgroup (n=16).
- With a median follow-up of 8.5 months and nearly half of patients with high FRα expression remaining on study, the duration of response and progression-free survival data are immature.
- The adverse events (AEs) observed with the doublet were manageable and consistent with the side effect profiles of each agent. The most common treatment-related AEs were low-grade, including diarrhea, blurred vision, fatigue, and nausea; grade 3+ AEs were infrequent.

“Effective, tolerable treatment options for patients with recurrent ovarian cancer unfortunately remain limited,” explained David O'Malley, MD, Professor, Division Director of Gynecology Oncology and Co-Director of the Gyn Onc Phase 1 Program, James Cancer Center and The Ohio State University Wexner Medical Center, and FORWARD II Principal Investigator. “These promising results confirm previously reported mirvetuximab plus bevacizumab data demonstrating a deeper and more durable tumor burden reduction in women whose tumors express high levels of FRα. These results add to the body of evidence that mirvetuximab can potentially be used to treat a broader patient population. I look forward to further evaluating these data as they mature.”

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.

Avastin® and Keytruda® are registered trademarks 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 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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