ImmunoGen Announces Mature Data from FORWARD II Expansion Cohort Evaluating Mirvetuximab Soravtansine in Combination with Avastin® in Ovarian Cancer

May 15, 2019

Results to be Presented at 2019 ASCO Annual Meeting

Combination Demonstrates Significant Anti-Tumor Activity and Favorable Safety and Tolerability in Platinum-Resistant Disease

Findings Support Ongoing Studies of Doublet Combination in Platinum-Agnostic Disease and Triplet in Platinum-Sensitive Patients

WALTHAM, Mass.--(BUSINESS WIRE)--May 15, 2019-- 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 expansion cohort evaluating mirvetuximab soravtansine in combination with Avastin® (bevacizumab) in patients with folate receptor alpha (FRα)-positive platinum-resistant ovarian cancer. These findings will be presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting, which is being held May 31 – June 4 in Chicago, IL.

“We are pleased that the combination of mirvetuximab plus Avastin has generated significant anti-tumor activity in patients with platinum-resistant disease, with trends toward deeper, more durable responses seen in individuals with higher FRα expression and a favorable tolerability profile. The outcomes observed in patients with medium or high FRα expression are encouraging with respect to those reported in similar patient populations for Avastin plus chemotherapy,” said Anna Berkenblit, M.D., Vice President and Chief Medical Officer of ImmunoGen. “Our goal remains to establish mirvetuximab as the combination agent of choice in ovarian cancer, supporting its use in earlier lines of therapy. These mature data support further exploration of this doublet, as well as the ongoing expansion study evaluating a triplet combination of mirvetuximab with Avastin and carboplatin in patients with platinum-sensitive disease.”

DATA FROM FORWARD II EXPANSION COHORT WITH AVASTIN

Mirvetuximab soravtansine in combination with Avastin in patients with FRα-positive platinum-resistant ovarian cancer continues to demonstrate anti-tumor activity with durable responses and a favorable tolerability profile, particularly among the subset of patients who have received up to two prior lines of therapy and have medium or high levels of FRα expression.

Key findings in 66 patients with platinum-resistant disease include:

- In the subset of 16 Avastin-naïve patients with medium or high FRα expression who have received up to two prior lines of therapy, the confirmed overall response rate (ORR) was 56 percent (95% CI 30,80), with a median progression-free survival (PFS) of 9.9 months (95% CI 4.1,15.9) and a median duration of response (DOR) of 12 months (95% CI 6,14.9).
- In the overall patient population, the confirmed ORR was 39 percent (95% CI 28,52), with a median PFS of 6.9 months (95% CI 4.9,8.6) and a median DOR of 8.6 months (95% CI 4.9, 14.9).
- The combination continues to display a safety profile in-line with the known profiles of each agent, with no new safety signals identified.

“Current treatment options for patients with platinum-resistant ovarian cancer have, unfortunately, exhibited limited efficacy with challenging side effects,” stated David O’Malley, M.D., Professor, Director of Gynecology Clinical Trials and Phase 1 Program, James Cancer Center and The Ohio State University Wexner Medical Center, and FORWARD II Principal Investigator. “Final results from the combination of mirvetuximab soravtansine and Avastin expansion cohort demonstrate very encouraging activity and good tolerability in platinum-resistant ovarian cancer patients, especially those with medium or high FRα expression levels. I look forward to further evaluating mirvetuximab in combination with Avastin as well as in the triplet with carboplatin.”

ASCO PRESENTATION DETAILS

- **Title:** “Mirvetuximab soravtansine, a folate receptor alpha (FRα)-targeting antibody-drug conjugate (ADC), in combination with bevacizumab in patients (pts) with platinum-resistant ovarian cancer: Final findings from the FORWARD II study”
- **Day/Time:** Saturday, June 1, 1:15pm - 4:15pm CDT and discussed at the Poster Discussion Session, 4:30pm-6pm CDT in S406
- **Lead Author:** David M. O’Malley, M.D., The Ohio State University College of Medicine
- **Location:** Hall A
- **Abstract:** 5520

Initial data from an investigator-sponsored trial through the National Comprehensive Cancer Network evaluating mirvetuximab in combination with gemcitabine in patients with FRα-positive recurrent epithelial ovarian, endometrial, or triple negative breast cancer will also be presented. Full dose mirvetuximab appears to combine well with gemcitabine, with a safety profile as expected for these agents and with encouraging anti-tumor activity seen in all three tumor types.

- **Title:** “A phase 1 study of mirvetuximab soravtansine (IMGN853) and gemcitabine (G) in patients with FOLR1-positive recurrent epithelial ovarian (EOC), endometrial cancer (EC), or triple-negative breast cancer (TNBC)”
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 platinum-resistant or platinum-agnostic ovarian cancer, primary peritoneal, or fallopian tube tumors, as well as 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.” The Company has built a productive platform generating a broad pipeline of ADCs targeting solid tumors and hematologic malignancies.

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

Avastin® is a registered trademark of Genentech, a member of the Roche Group.

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 the Company's and its collaboration partners' product programs; and the presentation of preclinical and clinical data on the Company's and collaboration partners' 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 and the Company's collaboration partners' research 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; ImmunoGen's ability to financially support its product programs; ImmunoGen's dependence on collaborative partners; industry merger and acquisition activity; and other factors more fully described in ImmunoGen's Annual Report on Form 10-K for the year ended December 31, 2018 and other reports filed with the Securities and Exchange Commission.

View source version on businesswire.com: https://www.businesswire.com/news/home/20190515005891/en/

Source: ImmunoGen, Inc.

INVESTOR RELATIONS CONTACT
Sarah Kiely
781-895-0600
sarah.kiely@immunogen.com

MEDIA CONTACT
Courtney O’Konek
781-895-0600
courtney.okonek@immunogen.com

OR
FTI Consulting
Robert Stanislaro
212-850-5657
robert.stanislaro@fticonsulting.com