ImmunoGen Announces Positive Findings from the FORWARD II Study of Mirvetuximab Soravtansine Combination Regimens with Avastin® and Carboplatin in Ovarian Cancer

May 16, 2018

Data from Avastin Cohort to be Presented at 2018 ASCO Annual Meeting

Updated Data from Carboplatin Dose-Escalation Cohort Demonstrate Increased Response Rate and Durable Benefit with Longer-Term Follow Up

Conference Call Scheduled for 8 a.m. ET on Thursday, May 17

WALTHAM, Mass.--(BUSINESS WIRE)--May 16, 2018-- ImmunoGen, Inc., (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer today announced positive data from the FORWARD II trial evaluating mirvetuximab soravtansine in multiple combination cohorts in patients with folate receptor alpha (FRα)-positive ovarian cancer. Results from the cohort assessing mirvetuximab in combination with Avastin (bevacizumab) in patients with platinum-resistant disease will be presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting, which is being held June 1-5 in Chicago, IL. In addition, ImmunoGen reported updated data from the dose-escalation cohort evaluating mirvetuximab in combination with carboplatin in patients with recurrent platinum-sensitive ovarian cancer.

“Building upon the encouraging data generated with mirvetuximab monotherapy, we have looked to expand our addressable patient population through combination regimens with both currently approved and experimental agents in ovarian cancer. In dose escalation, we have demonstrated that full dose mirvetuximab can be combined safely with full doses of Avastin, carboplatin, or Keytruda, with encouraging preliminary clinical activity,” said Anna Berkenblit, MD, Vice President and Chief Medical Officer of ImmunoGen. “The promising new data reported in the FORWARD II Avastin and carboplatin arms support the potential of mirvetuximab combinations in earlier lines of therapy. Together, these results have informed the triplet combination study with mirvetuximab plus carboplatin and Avastin, which we initiated last quarter.”

Berkenblit continued, “In addition, we plan to present initial data from the Keytruda expansion cohort later this year, building upon the dose escalation data recently presented at SGO. The totality of these data from FORWARD II will guide the next stages of development of mirvetuximab and support a path to registration for combination regimens.”

DATA FROM FORWARD II EXPANSION COHORT WITH AVASTIN
Mirvetuximab soravtansine in combination with Avastin in patients with platinum-resistant ovarian cancer has demonstrated anti-tumor activity with durable responses and a favorable tolerability profile, particularly among the subset of patients who have received up to three prior lines of therapy and have medium or high levels of FRα expression. This is the population being studied in the FORWARD I Phase 3 registration trial.

Key findings in 59 patients with platinum-resistant ovarian cancer include:

- In the subset of 23 patients evaluable for response with medium or high FRα expression levels who have received up to three prior lines of therapy, the confirmed overall response rate (ORR) was 48 percent (95% CI 27,69), with a median progression-free survival (PFS) of 9.9 months (95% CI 4.6,14.5) and a median duration of response (DOR) of 10.6 months (95% CI 3.3,12.0).
- For the 54 patients evaluable for response, the confirmed ORR was 43 percent (95% CI 29,57), with a median PFS of 7.8 months (95% CI 5.6,10.2); patients in this cohort had received a median of 3 prior lines of systemic therapy, with 58 percent of patients having received prior bevacizumab.
- The combination continues to display a safety profile in-line with the known profiles of each agent, with no new safety signals identified.

“The mirvetuximab and Avastin combination has demonstrated very encouraging initial clinical activity in ovarian cancer patients and a consistently favorable safety profile,” stated David O'Malley, M.D., Professor, Director of Gynecology Clinical Trial and Phase 1 Program, James Cancer Center and The Ohio State University Wexner Medical Center, and FORWARD II Investigator. “There is a significant need for new therapeutic options to improve outcomes and tolerability for this difficult-to-treat patient population, and I believe these results support further clinical evaluation of this combination regimen."

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: maturing safety and activity profile from the FORWARD II Phase 1b study*
Presenter: David M. O’Malley, MD, The Ohio State University College of Medicine
Day/Time: Monday, June 4, 1:15-4:45 pm CDT
Location: Hall A
Abstract: 5549

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

UPDATED DATA FROM FORWARD II DOSE-ESCALATION COHORT WITH CARBOPLATIN
Initial findings from a dose escalation cohort of mirvetuximab in combination with carboplatin were presented at ASCO 2017. The data have matured and updated findings in heavily pre-treated patients with platinum-sensitive ovarian cancer include:

- In the subset of 10 patients with medium or high FRα expression levels, the confirmed ORR was 80 percent (95% CI

44,98), with a median PFS of 15 months (95% CI 9.9,-), and with median DOR not reached.

- For all 17 evaluable patients, the confirmed ORR was 71 percent (95% CI 44,90), with a median PFS of 15 months (95% CI 9.9, -), and with median DOR not reached; 50 percent of patients in this cohort had received 3 or more prior lines of systemic therapy.
- The combination continues to display a favorable safety profile in-line with the known profiles of each agent, with no new safety signals identified.

Based on the findings from the carboplatin and Avastin cohorts, ImmunoGen recently initiated an additional cohort assessing a triplet combination of mirvetuximab plus carboplatin and Avastin in patients with recurrent platinum-sensitive ovarian cancer as part of the FORWARD II trial.

DATA FROM FORWARD II DOSE-ESCALATION COHORT WITH KEYTRUDA

Additionally, ImmunoGen recently announced encouraging activity and favorable tolerability data from the FORWARD II cohort assessing mirvetuximab in combination with Merck's anti-PD-1 therapy Keytruda ® (pembrolizumab) in patients with platinum-resistant ovarian cancer at the Society of Gynecologic Oncology Annual Meeting. Based on these data, ImmunoGen is completing enrollment in an expansion cohort that includes an additional 35 patients with medium or high FRα expression levels. ImmunoGen plans to report initial findings from this cohort in the second half of this year.

CONFERENCE CALL INFORMATION

ImmunoGen will host a conference call on Thursday, May 17 at 8:00am ET to discuss new data from the FORWARD II trial. To access the live call by phone, dial 323-794-2423; the conference ID is 5718620. The call may also be accessed through the "Investors" section of the Company's website, www.immunogen.com. Following the live webcast, a replay of the call will be available at the same location through June 7, 2018.

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 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." Our lead product candidate, mirvetuximab soravtansine, is in Phase 3 study for folate receptor alpha (FRα)-positive platinum-resistant ovarian cancer, and in Phase 1b/2 testing in combination regimens. Our novel IGN candidates for hematologic malignancies, IMGN779 and IMGN632, are in Phase 1 studies.

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

This press release includes forward-looking statements based on management's current expectations. These statements include, but are not limited to, ImmunoGen's ability to expand the addressable patient population for mirvetuximab soravtansine and the regulatory and commercial potential of mirvetuximab combinations in earlier lines of therapy. 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. It should be noted that there are risks and uncertainties related to the development of novel anticancer products, including risks related to preclinical and clinical studies, their timings and results, and the potential that earlier clinical studies may not be predictive of future results. A review of these risks can be found in ImmunoGen's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and other reports filed with the Securities and Exchange Commission.

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