May 17, 2017

ImmunoGen Announces New Clinical Data with Mirvetuximab Soravtansine in Ovarian Cancer to be Presented at 2017 ASCO Annual Meeting

Pooled analyses of Phase 1 expansion cohorts demonstrate clinically meaningful activity in patient population being studied in FORWARD I registration trial

Top-line data from FORWARD II indicate favorable safety and efficacy profile in multiple combinations

Conference call scheduled for 8:00am ET on Friday, May 19

WALTHAM, Mass.--(BUSINESS WIRE)-- ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced promising safety and efficacy data from monotherapy and combination studies with mirvetuximab soravtansine in patients with folate receptor alpha (FRα)-positive epithelial ovarian cancer (EOC). These data include results from pooled analyses of three Phase 1 expansion cohorts and from a Phase 1b/2 study, FORWARD II, evaluating mirvetuximab soravtansine in combination with Avastin® (bevacizumab), carboplatin, Doxil® (pegylated liposomal doxorubicin), or Keytruda® (pembrolizumab). These results will be presented at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting, which is being held June 2-7, 2017 in Chicago, IL.

Anti-Tumor Activity and Safety Analyses in Pooled Phase 1 Expansion Cohorts

Data from the pooled analyses demonstrate the safety and efficacy profile of mirvetuximab soravtansine in the patient population eligible for the ongoing Phase 3 registration trial, FORWARD I. These data include 113 EOC patients treated with mirvetuximab soravtansine in three expansion cohorts in the Phase 1 trial. In the subset of 36 patients meeting the key eligibility criteria for FORWARD I, which includes patients with platinum-resistant disease and medium or high levels of FRα and who have received up to three prior lines of therapy, the confirmed overall response rate (ORR) was 47 percent (95% CI 30, 65) and median progression-free survival (mPFS) was 6.7 months (95% CI 4.1, 8.3).

"The data observed with mirvetuximab compare favorably with outcomes typically achieved with currently available single-agent therapies for platinum resistant ovarian cancer. Current single-agent therapies for platinum-resistant ovarian cancer have low response rates of 15 to 20% and short median progression-free survival of three to four months," stated Kathleen Moore, M.D., Associate Professor, Department of Obstetrics and Gynecology at the Stephenson Cancer Center at the University of Oklahoma. "Based on the consistent safety and efficacy seen with mirvetuximab soravtansine reflected in these pooled analyses, particularly in those patients meeting the eligibility criteria for the pivotal study, I am very encouraged about the potential of this compound in patients with platinum-resistant ovarian cancer and look forward to continued progress with the ongoing Phase 3 FORWARD I trial."

For all 113 patients, the median number of prior regimens was 3, 85 percent had platinum-resistant disease, 67 percent had prior bevacizumab, and 22 percent had a prior poly (ADP-ribose) polymerase (PARP) inhibitor. The safety profile of the pooled population was consistent with data previously reported (2016 ASCO Annual Meeting), which consisted primarily of low grade, manageable adverse events. In this heavily pretreated group of patients, the confirmed ORR was 30 percent (95% CI 22, 39) and mPFS was 4.3 months (95% CI 3.9, 5.4).

Initial Safety and Preliminary Efficacy Data from FORWARD II

FORWARD II is a Phase 1b/2 study of mirvetuximab soravtansine in combination with Avastin®, carboplatin, Doxil® or Keytruda® in patients with FRα-positive EOC, primary peritoneal, or fallopian tube tumors. The data from these arms demonstrate mirvetuximab soravtansine may complement currently available therapies for FRα-positive EOC in a range of treatment settings, including earlier lines of therapy.

The safety profiles for these combinations were manageable and as expected, based on known profiles of each agent, with no new safety signals identified. Key findings in over 60 patients from the dose escalation phase of FORWARD II are as follows:

- Patients in the Avastin® arm were heavily pretreated with a median of six prior regimens. The confirmed ORR for this arm was 29 percent (95% CI 8, 58), with a median PFS of 9.5 months (95% CI 3.5, 15.2).

- Patients with recurrent platinum-sensitive disease on the carboplatin arm had received a median of three prior regimens and the confirmed ORR was 65 percent (95% CI 38, 86), with a median PFS of 12.1 months (95% CI 9.0, 15.0).

- Patients on the Doxil® arm received a median of two prior regimens. The confirmed ORR for the Doxil® arm was 13 percent (95% CI 2, 38), with a median PFS of 7.0 months (95% CI 1.7, upper bound not estimated).

- Preliminary data from the Keytruda® arm demonstrate that, similar to the other combinations, full doses of each agent are combinable. At this time, it is too early to assess anti-tumor activity data in this arm; anti-tumor activity will be reported at a subsequent medical meeting.

Based on the encouraging profiles of these combinations in dose escalation, ImmunoGen is moving forward with expansion cohorts for Avastin® and Keytruda® and is evaluating future studies with carboplatin combinations.

"The favorable safety profile of mirvetuximab soravtansine lends itself well to combination, as evidenced by the data from FORWARD II, showing the full dose of mirvetuximab soravtansine combines with the full doses of bevacizumab (Avastin®), carboplatin, pembrolizumab (Keytruda®) and pegylated liposomal doxorubicin (Doxil®) in ovarian cancer," stated David O'Malley, M.D., Associate Professor, Director of Gynecology Clinical Trial and Phase 1 Program, James Cancer Center and The Ohio State University Wexner Medical Center.

FORWARD I Trial

The Phase 3 FORWARD I trial was designed based on the promising monotherapy mirvetuximab soravtansine data from the Phase 1 trial and reflects the fastest registration strategy to obtain full approval of mirvetuximab soravtansine as single-agent therapy.

FORWARD I is a registration trial in which 333 patients will be randomized 2:1 and will receive either mirvetuximab soravtansine or the physicians' choice of therapy (Doxil®, paclitaxel, or topotecan). The study is currently enrolling in North America and Europe, with more than 100 sites expected to be activated in these geographies.

"The Phase 1 expansion cohort data being presented at ASCO support the potential of mirvetuximab soravtansine in the patient population eligible for FORWARD I," said Mark Enyedy, ImmunoGen's president and chief executive officer. "With the safety and efficacy profile demonstrated by these data, we look forward to completing enrollment in FORWARD I and evaluating mirvetuximab soravtansine with other therapies, including novel agents, in earlier lines of treatment."

ASCO Presentation Details:

Saturday, June 3, 2017

Title: *Mirvetuximab soravtansine (IMGN853), a folate receptor alpha (FRα)-targeting antibody-drug conjugate (ADC), in platinum-resistant epithelial ovarian cancer (EOC) patients (pts): Activity and safety analyses in phase I pooled expansion cohorts.*
Presenter: Kathleen N. Moore, M.D., Associate Professor, Department of Obstetrics and Gynecology at the Stephenson Cancer Center at the University of Oklahoma
Time: 1:15pm - 4:45pm CDT
Location: Poster Board No.: 369, Location: Hall A
Abstract: 5547

Title: *Safety findings from FORWARD II: A phase 1b study evaluating the folate receptor alpha (FRα)-targeting antibody-drug conjugate (ADC) mirvetuximab soravtansine (IMGN853) in combination with bevacizumab, carboplatin, pegylated liposomal doxorubicin (PLD), or pembrolizumab in patients (pts) with ovarian cancer.*
Presenter: David O'Malley, M.D., Associate Professor, Director of Gynecology Clinical Trial and Phase 1 Program, James Cancer Center and The Ohio State University Wexner Medical Center
Time: 1:15pm - 4:45pm CDT
Location: Poster Board No.: 375, Location: Hall A
Abstract: 5553

Title: *FORWARD I (GOG 3011): A randomized phase 3 study to evaluate the safety and efficacy of mirvetuximab soravtansine (IMGN853) versus chemotherapy in adults with folate receptor alpha (FRα)-positive, platinum-resistant epithelial ovarian cancer (EOC), primary peritoneal cancer, or primary fallopian tube cancer.*
Presenter: Kathleen N. Moore, M.D., Associate Professor, Department of Obstetrics and Gynecology at the Stephenson

Cancer Center at the University of Oklahoma
Time: 1:15pm - 4:45pm CDT
Location: Poster Board No.: 425b, Location: Hall A
Abstract: TPS5607

Additional information - including presentation schedule and full abstracts - can be found www.asco.org.

Conference Call Information

ImmunoGen will host a conference call on Friday, May 19 at 8:00am ET. At this briefing, ImmunoGen will discuss the data being presented at the 2017 ASCO Annual Meeting. To access the live call by phone, dial 719-325-2402; the conference ID is 4522749. 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 1, 2017.

About ImmunoGen, Inc.

ImmunoGen is a clinical-stage biotechnology company that develops targeted cancer therapeutics using its proprietary ADC technology. ImmunoGen's lead candidate, mirvetuximab soravtansine, is in a Phase 3 trial for FRα-positive platinum-resistant ovarian cancer, and is in Phase 1b/2 testing in combination regimens for earlier-stage disease. ImmunoGen's ADC technology is used in Roche's marketed product, Kadcyla®, in three other clinical-stage ImmunoGen product candidates, and in programs in development by partners Amgen, Bayer, Biotest, CytomX, Lilly, Novartis, Sanofi and Takeda. More information about the Company can be found at www.immunogen.com.

Avastin®, Doxil®, Keytruda® and Kadcyla® are registered trademarks of their respective owners.

About Mirvetuximab Soravtansine

Mirvetuximab soravtansine (IMGN853) is the first FRα-targeting ADC. It uses a 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.

This press release includes forward-looking statements. 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. It should be noted that there are risks and uncertainties related to the development of novel anticancer products, including mirvetuximab soravtansine, including risks related to preclinical and clinical studies, their timings and 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, 2016 and other reports filed with the Securities and Exchange Commission.

View source version on businesswire.com: http://www.businesswire.com/news/home/20170517006236/en/

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