ImmunoGen Presents Additional Efficacy and Safety Analyses Evaluating Mirvetuximab Soravtansine in Ovarian Cancer at ASCO

May 26, 2022

Two Data Sets to be Presented at 2022 Annual Meeting

Poster Highlighting Updated Data from SORAYA Characterizing Anti-Tumor Activity Selected for Best of ASCO® Program: Tumor Reduction in 71.4% of Patients and Preliminary Median Overall Survival of 13.8 Months in High Folate Receptor Alpha Patients with Platinum-Resistant Ovarian Cancer

Pooled Data from Mirvetuximab Program in 464 Patients Demonstrate Differentiated and Consistent Safety Profile

WALTHAM, Mass.--(BUSINESS WIRE)--May 26, 2022-- ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced additional efficacy data from the pivotal SORAYA study evaluating mirvetuximab soravtansine (mirvetuximab) monotherapy in patients with folate receptor alpha (FRα)-high platinum-resistant ovarian cancer who have been previously treated with Avastin® (bevacizumab) and an integrated safety summary of single-agent mirvetuximab across multiple studies in patients with FRα-positive recurrent ovarian cancer. These findings will be highlighted in two posters at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, which is being held June 3-7, 2022. The data from SORAYA have been selected for the Best of ASCO® Program.

"Treatment options remain limited for patients with platinum-resistant ovarian cancer, particularly for those who have received prior bevacizumab, and are associated with low response rates, short durations of response, and considerable toxicities," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "We believe these data further reinforce mirvetuximab's potential to become a new standard of care in this population. With our biologics license application accepted and filed by FDA with Priority Review, we look forward to bringing mirvetuximab to patients with the most urgent need later this year."

CHARACTERIZATION OF ANTI-TUMOR ACTIVITY IN THE SORAYA STUDY
SORAYA enrolled 106 platinum-resistant ovarian cancer patients with high FRα expression who have been previously treated with 1 to 3 prior systemic treatments, at least one of which included bevacizumab. The primary endpoint was confirmed objective response rate (ORR) as assessed by investigator. Secondary endpoints included duration of response (DOR) as assessed by investigator, CA-125 response, safety and tolerability, progression-free survival (PFS), overall survival (OS); ORR, DOR, and PFS by blinded independent central review were sensitivity analyses. Data from SORAYA were first presented at the Society of Gynecologic Oncology (SGO) 2022 Annual Meeting; the updated analyses to be presented at ASCO are based on the 120-day cut-off date of April 29, 2022.

- ORR by investigator was 32.4% (95% confidence interval [CI]: 23.6%, 42.2%), including 5 complete responses. Median time to response was 1.5 months (range 1.0 to 5.6) and 71.4% of patients demonstrated tumor reduction.
- The disease control rate (DCR), defined as complete response (CR), partial response, or stable disease maintained for ≥12 weeks, was 51.4%.
- The median DOR was 6.9 months (95% CI: 5.6, 9.7) by investigator, with 5 responders continuing on mirvetuximab as of April 29, 2022.
- The median PFS assessed by investigator was 4.3 months (95% CI: 3.7, 5.2).
- The preliminary median OS was 13.8 months, with 54% of the evaluable patient population event-free.
- In the sensitivity analyses by blinded independent central review, outcomes were similar: ORR 30.2% (95% CI: 21.3%, 40.4%) with 6 CRs; mDOR not reached (95% CI: 5.0, NR); mPFS 5.5 months (95% CI: 3.8, 6.9).
- In responders, depth and duration of response did not appear to be affected by dose reductions.
- Mirvetuximab was well-tolerated, consistent with previous studies. The most common treatment-related adverse events (TRAE) included blurred vision (41% all grade, 6% grade 3+), keratopathy (29% all grade, 9% grade 3+), and nausea (29% all grade, 0% grade 3+).
- TRAEs generally resolved with supportive care or, if needed, dose modifications; the discontinuation rate due to TRAEs was 9%.
- Kaplan-Meier plots for PFS and OS to be included in poster.

"I believe these additional analyses from SORAYA further support mirvetuximab's potential to become the first biomarker-directed agent indicated for patients with platinum-resistant ovarian cancer," said Ursula Matulonis, MD, Chief of the Division of Gynecologic Oncology at the Dana-Farber Cancer Institute, Professor of Medicine at the Harvard Medical School, and SORAYA Co-Principal Investigator. "The tumor reduction observed in over 70% of patients, along with the PFS curve and the preliminary median overall survival of 13.8 months, are impressive. If approved, I look forward to being able to offer mirvetuximab to my patients and continuing to support its further development in patients with ovarian cancer."

INTEGRATED SAFETY SUMMARY OF SINGLE-AGENT MIRVETUXIMAB SORAVTANSINE
This retrospective pooled analysis included 464 patients with FRα-positive, recurrent ovarian cancer across three studies: a Phase 1 first-in-human trial, the Phase 3 FORWARD I trial, and the pivotal Phase 3 SORAYA trial.

- Mirvetuximab monotherapy has a differentiated safety profile consisting primarily of low-grade gastrointestinal and ocular events; adverse events generally resolved and were managed with supportive care and, if needed, dose modifications. The

discontinuation rate due to TRAEs was 7%.
- The most common TRAEs included blurred vision (42% all grade, 3% grade 3+), nausea (40% all grade, 2% grade 3+), diarrhea (33% all grade, 2% grade 3+), fatigue (31% all grade, 2% grade 3+), keratopathy (26% all grade, 3% grade 3+), and dry eye (22% all grade, 1% grade 3+).
- Mirvetuximab monotherapy did not result in any corneal ulcers or perforations, and no patients had permanent ocular sequelae.
- The majority of patients with ocular events did not require dose delay or dose reduction; <1% of patients discontinued mirvetuximab due to an ocular event.

"Having personally treated over 100 patients with mirvetuximab, I have helped my colleagues better understand how to manage the associated ocular events," said Kathleen Moore, Director of the Oklahoma TSET Phase I Program, Professor of the Section of Gynecologic Oncology at The University of Oklahoma College of Medicine, and MIRASOL Principal Investigator. "With prevention and mitigation strategies in place, patients presenting with ocular events have been able to complete their treatment, maintain their responses, and had no permanent sequelae from these events. These data demonstrate mirvetuximab's differentiated safety profile and I look forward to the potential approval and launch later this year."

POSTER SESSION DETAILS
The following posters will be available on Saturday, June 4 in the ASCO Meeting Library:

Title: Integrated Safety Summary of Single-Agent Mirvetuximab Soravtansine in Patients with Folate Receptor α (FRα) Positive Recurrent Ovarian Cancer: Phase I and III Clinical Trials
Lead Author: Kathleen N. Moore, MD
Date/Time: June 4, 2022, 2:15 PM – 5:15 PM EDT
Abstract: 5574
Poster: 450

Title: Mirvetuximab Soravtansine (MIRV) in Patients with Platinum-Resistant Ovarian Cancer with High Folate Receptor Alpha (FRα) Expression: Characterization of Anti-Tumor Activity in the SORAYA Study
Lead Author: Ursula A. Matulonis, MD
Date/Time: June 4, 2022, 5:30 PM – 7:00 PM EDT
Abstract: 5512
Poster: 391

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

ABOUT MIRVETUXIMAB SORAVTANSINE
Mirvetuximab soravtansine (IMGN853) is a first-in-class ADC comprising a folate receptor alpha-binding antibody, cleavable linker, and the maytansinoid payload 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® is a registered trademark of Genentech, a member of the Roche Group.

FORWARD-LOOKING STATEMENTS
This press release includes forward-looking statements. These statements include, but are not limited to, ImmunoGen's expectations related to: the occurrence, timing, and outcome of potential preclinical, clinical, and regulatory events related to, and the potential benefits of, the Company's product candidates, including, but not limited to, the review of the Company's BLA to the FDA for mirvetuximab and full approval of mirvetuximab, the commercial launch of mirvetuximab and the potential of mirvetuximab to serve as a new standard of care for patients with platinum-resistant ovarian cancer; and the timing and presentation of preclinical and clinical data on the Company's product candidates. 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 the Company's preclinical 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; the Company's ability to financially support its product programs; the timing and outcome of the Company's anticipated interactions with regulatory authorities; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and the resulting impact on ImmunoGen's industry and business; and other factors as set forth in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2022, and other reports filed with the Securities and Exchange Commission. The forward-looking statements in this press release speak only as of the date of this press release. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by applicable law.

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