ImmunoGen Presents Full Results from Positive Pivotal SORAYA Trial of Mirvetuximab Soravtansine in Ovarian Cancer at SGO Annual Meeting

March 19, 2022

Trial Met Primary Endpoint with Confirmed Objective Response Rate of 32.4%, including 5 Complete Responses; Updated Median Duration of Response of 6.9 Months

Mirvetuximab Demonstrated Meaningful Anti-Tumor Activity, Consistent Safety, and Favorable Tolerability in FRα-High Platinum-Resistant Ovarian Cancer

BLA Submission Expected this Month

Investor Event to be Held on Sunday, March 20 at 7:30 am MST/10:30 am EDT

WALTHAM, Mass.--(BUSINESS WIRE)--Mar. 19, 2022-- ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced full results from the pivotal SORAYA trial evaluating the efficacy and safety of mirvetuximab soravtansine (mirvetuximab) monotherapy in patients with folate receptor alpha (FRα)-high platinum-resistant ovarian cancer who have been previously treated with Avastin® (bevacizumab). The results are being presented by Dr. Ursula Matulonis in the late-breaking abstract plenary session on Saturday, March 19 at the Society of Gynecologic Oncology (SGO) 2022 Annual Meeting in Phoenix, AZ.

“Patients with platinum-resistant ovarian cancer have limited treatment options, and these are associated with low response rates and significant toxicity," 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. "With an objective response rate of 32.4%, far exceeding that seen with current therapies, and a median duration of response approaching seven months, mirvetuximab continues to demonstrate impressive efficacy in patients with platinum-resistant disease who have already received bevacizumab. The anti-tumor activity and consistent safety and tolerability data from the SORAYA trial further underscore the potential of mirvetuximab, if approved, to become a practice-changing, biomarker-driven standard of care for these patients.”

SORAYA is a single-arm study of mirvetuximab in patients with platinum-resistant ovarian cancer whose tumors express high levels of FRα and who have been treated with one to three prior regimens – at least one of which included bevacizumab. The primary endpoint for the study is confirmed objective response rate (ORR) as assessed by investigator and the key secondary endpoint is duration of response (DOR). ORR was also assessed by blinded independent central review (BICR). The study is designed to rule out a 12% ORR, based on expected outcomes of 4% to 13% with available single agent chemotherapy. Data previously generated in a post-hoc pooled analysis of seventy patients from prior studies of mirvetuximab in platinum-resistant disease formed the basis for the design of SORAYA, with an investigator-assessed ORR of 31.4%, median DOR of 7.8 months, and median progression-free survival (PFS) of 4.4 months.

Key Findings from SORAYA

SORAYA enrolled 106 patients with a median of three prior lines of therapy; 51% had three prior lines of therapy and 48% had one to two prior lines of therapy. All patients received prior bevacizumab; 48% of patients received a prior PARP inhibitor (PARPi).

- Confirmed ORR by investigator was 32.4% (95% confidence interval [CI]: 23.6%, 42.2%), including five complete responses (CRs). ORR by BICR was 31.6% (95% CI: 22.4%, 41.9%), including five CRs. Response rates were consistent regardless of number of prior lines of therapies or prior PARPi.
    - 1-2 prior lines of therapy: ORR by investigator was 35.3% (95% CI: 22.4%, 49.9%).
    - 3 prior lines of therapy: ORR by investigator was 30.2% (95% CI: 18.3%, 44.3%).
    - Prior PARPi exposure: ORR by investigator was 38.0% (95% CI: 24.7%, 52.8%).
    - Without prior PARPi exposure: ORR by investigator was 27.5% (95% CI: 15.9%, 41.7%).
- The median DOR was 6.9 months (95% CI: 5.6, 8.1) by investigator as of the March 3, 2022 data cut-off.
- The median PFS was 4.3 months (95% CI: 3.7, 5.1) by investigator and 5.5 months (95% CI: 3.8, 6.9) by BICR.
- Mirvetuximab was well-tolerated, consistent with the known safety profile seen in more than 700 patients treated in the broader mirvetuximab program. Treatment-related adverse events led to dose reductions in 19% of patients, dose delays in 32% of patients, and discontinuations in 7% of patients. The most common treatment-related adverse events were low-grade and generally reversible, including blurred vision (41% all grade; 6% grade 3), keratopathy (36% all grade; 8% grade 3+), and nausea (29% all grade; 0% grade 3).

“We are thrilled with the SORAYA results, which are remarkably consistent with data previously generated with mirvetuximab in a heavily-pretreated population of platinum-resistant ovarian cancer patients that included prior exposure to bevacizumab. Based on the impressive anti-tumor activity, durability of response, and safety profile observed in SORAYA, we believe mirvetuximab has the potential to displace single-agent chemotherapy as the standard of care for FRα-high platinum-resistant ovarian cancer,” said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. “We are very grateful for all of the patients and physicians who committed their time and effort to this study, and with these positive results, we expect to submit the BLA for mirvetuximab this month to support potential accelerated approval in the US this year. The strength and consistency of the SORAYA data give us confidence in a positive outcome in the ongoing confirmatory MIRASOL trial, intended to support the potential full approval of mirvetuximab, with top-line data anticipated in the third quarter.”

Oral Presentation Details

Title: Efficacy and Safety of Mirvetuximab Soravtansine in Patients with Platinum-Resistant Ovarian Cancer with High Folate Receptor Alpha Expression: Results from the SORAYA Study
Session: Scientific Plenary IV: Late-Breaking Abstracts
Session Date: Saturday, March 19, 2022
Session Time: 4:15 pm to 5:45 pm MST/7:15 pm to 8:45 pm EDT

Other Presentations

Trial in progress posters from ImmunoGen's MIRASOL and PICCOLO trials of mirvetuximab in ovarian cancer and a Phase 2 investigator-sponsored combination trial of mirvetuximab with carboplatin as a neoadjuvant therapy for patients with newly diagnosed ovarian cancer will also be presented. Final data from the mirvetuximab plus bevacizumab platinum-agnostic combination, which were originally shared at ASCO 2021, will also be featured in a seminal presentation.

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

INVESTOR EVENT INFORMATION

ImmunoGen will hold an investor event to discuss the SORAYA oral presentation, featuring a roundtable with key opinion leaders, on Sunday, March 20 at 7:30 am MST/10:30 am EDT in the Moly Meeting Room at the Westin Phoenix Downtown. To access the live event by phone, dial (877) 621-5803; the conference ID is 1986619. The event may also be accessed via webstream on the Investors and Media section of the Company's website, www.immunogen.com. Following the call, a replay will be available at the same location.

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 the Company's product candidates, including the submission of the Company's BLA to the FDA for mirvetuximab and full approval of mirvetuximab; the potential of mirvetuximab to become a standard of care; the presentation of preclinical and clinical data on the Company's product candidates, including MIRASOL data in the third quarter of 2022; and the Company's business and product development strategies. 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; 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.

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