ImmunoGen Announces Positive Top-Line Results from Pivotal SORAYA Trial of Mirvetuximab Soravtansine in Ovarian Cancer

November 30, 2021

Trial Met Primary Endpoint with Confirmed Objective Response Rate of 32.4%

Median Duration of Response at Data Cutoff is 5.9 Months

Continued Demonstration of Favorable Tolerability Profile

BLA Submission on Track for First Quarter of 2022

Conference Call to be Held at 8:00 a.m. ET Today

WALTHAM, Mass.--(BUSINESS WIRE)--Nov. 30, 2021-- ImmunoGen Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced positive top-line data from the pivotal SORAYA trial evaluating the safety and efficacy 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).

"Despite advances in the platinum-sensitive setting, most patients with ovarian cancer eventually develop platinum-resistant disease, for which there are limited treatment options, especially for those patients who have previously received bevacizumab," said Robert Coleman, MD, Chief Scientific Officer of US Oncology Research and SORAYA Co-Principal Investigator. "Data from SORAYA have the potential to redefine the standard of care for patients with FRα-high platinum-resistant ovarian cancer, as this trial has demonstrated that mirvetuximab delivers clinically meaningful benefit in this setting, with significant and durable responses and a favorable tolerability profile."

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 up 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, including complete and partial responses, 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 with available single agent chemotherapy from the AURELIA study in patients with platinum-resistant ovarian cancer and one to two prior lines of therapy.

Key Findings from SORAYA

SORAYA enrolled 106 patients with a median of three prior lines of therapy (range one to four); 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. As of the data cutoff on November 16, 2021, the median follow-up time was 8.1 months.

- 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. Responses were observed regardless of prior PARP inhibitor or number of prior lines of therapy.
- The median DOR is currently 5.9 months (95% CI: 5.6, 7.7). With nearly half of responders continuing on therapy, the duration of response continues to evolve and, with longer follow-up, median DOR could range from 5.7 to just above 7 months.
- 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 included blurred vision (41% all grade; 6% grade 3+), keratopathy (35% all grade; 9% grade 3+), and nausea (29% all grade; 0% grade 3+).

"These data have the potential to be transformative for ovarian cancer patients and their physicians," 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. "In the platinum-resistant setting and particularly in later-line treated patients, response rates with available therapy are in the single digits with significant toxicities. With an ORR above 30%, a duration of response of around six months, and a treatment-related discontinuation rate below 10%, mirvetuximab shows impressive activity and tolerability for patients with platinum-resistant ovarian cancer. If approved, mirvetuximab will become a critical therapeutic option for patients with FRα-high ovarian cancer."

"We are extremely pleased with the top-line data from SORAYA, which support our strategy to position mirvetuximab as the standard of care for patients with FRα-high ovarian cancer," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "Mirvetuximab's efficacy far exceeds that which is expected with available therapies. This is particularly encouraging given the majority of patients in SORAYA were fourth-line, and the safety profile and anti-tumor activity replicate those previously generated in the program. We are deeply grateful to all of the patients and physicians who participated in this study, and we look forward to presenting the full SORAYA data at a medical meeting next year."

"This is an exciting moment, both for the field of ovarian cancer and for ImmunoGen, and the outcomes from SORAYA further validate our longstanding history of innovation in ADCs," said Mark Enyedy, ImmunoGen's President and Chief Executive Officer. "We are moving forward expeditiously to complete the BLA for mirvetuximab, with the goal of submitting the application to FDA for accelerated approval in the first quarter of

2022. In parallel, commercial preparations are well underway to support the potential launch of mirvetuximab next year. To this end, we recently hired our Chief Commercial Officer and are focused on having the right talent, resources, and infrastructure in place to maximize the potential impact of mirvetuximab for women living with ovarian cancer. Beyond SORAYA, we expect to generate top-line data from our confirmatory MIRASOL trial in the third quarter of 2022 to support the potential full approval of mirvetuximab. We are also working to expand mirvetuximab monotherapy into later-line platinum-sensitive disease and, as part of our efforts to establish mirvetuximab as the combination agent of choice, evaluating mirvetuximab doublets in earlier lines of treatment, all with the goal of furthering our mission to offer more patients more good days."

CONFERENCE CALL INFORMATION

ImmunoGen will hold a conference call today at 8:00 a.m. ET to discuss these results. To access the live call by phone, dial (877) 621-5803; the conference ID is 7577328. The call may also be accessed through 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 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 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; the potential of mirvetuximab to become a standard of care and transform the Company into a fully integrated oncology company; the potential of mirvetuximab to become a combination agent of choice; 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. 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: top-line data may change as more patient data become available and are subject to audit and verification procedures; 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 March 1, 2021, and other reports filed with the Securities and Exchange Commission.

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