ImmunoGen Announces Accelerated Approval Pathway for Mirvetuximab Soravtansine in Ovarian Cancer

December 17, 2019

Top-Line Data from New Pivotal Single-Arm Trial, SORAYA, Expected in First Half of 2021

Confirmatory MIRASOL Trial for Mirvetuximab on Track to Start by Year-End

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

WALTHAM, Mass.--(BUSINESS WIRE)--Dec. 17, 2019-- ImmunoGen Inc., (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced that the U.S. Food and Drug Administration (FDA) has advised that a new single-arm study in platinum-resistant ovarian cancer could support accelerated approval for mirvetuximab soravtansine. Based on this guidance, the company will initiate SORAYA, a pivotal trial to evaluate mirvetuximab monotherapy in women with folate receptor alpha (FRα)-high platinum-resistant ovarian cancer who have been previously treated with Avastin® (bevacizumab).

"We have engaged in constructive discussions with FDA and evaluated all avenues to bring mirvetuximab to patients more quickly," said Mark Enyedy, ImmunoGen's President and Chief Executive Officer. "Having aligned with the agency that women with FRα-high platinum-resistant ovarian cancer that has progressed after prior treatment with bevacizumab require better therapeutic options, we are pleased to advance mirvetuximab in this patient population with SORAYA, which, if successful, would enable us to submit an application for accelerated approval during the second half of 2021. We anticipate enrolling the first patient in SORAYA next quarter and expect top-line data from the study in mid-2021."

ImmunoGen's mirvetuximab program now includes two new trials, SORAYA and MIRASOL, which will enroll concurrently.

SORAYA: Pivotal Trial
SORAYA is a single-arm trial with mirvetuximab that will enroll approximately 100 patients. Eligibility criteria include patients with platinum-resistant ovarian cancer whose tumors express high levels of FRα using the PS2+ scoring method, and who have been treated with up to three prior regimens – at least one of which included bevacizumab. The primary endpoint of this study is overall response rate by investigator assessment and the key secondary endpoint is duration of response.

MIRASOL: Confirmatory Trial
MIRASOL is a randomized Phase 3 trial in which 430 patients will be randomized 1:1 to receive either mirvetuximab or investigator's choice of single-agent chemotherapy (weekly paclitaxel, pegylated liposomal doxorubicin, or topotecan). Eligibility criteria include patients with platinum-resistant ovarian cancer whose tumors express high levels of FRα using the PS2+ scoring method, and who have been treated with up to three prior regimens. The primary endpoint of this study is progression free survival by investigator assessment. The key secondary endpoints include: overall response rate, overall survival, and patient-reported outcomes.

"We have reviewed the data generated from our Phase 1 and FORWARD I studies using the PS2+ scoring method and have identified 70 patients who would meet the key eligibility criteria for SORAYA. The overall response rate in these patients was 31.4% with 95% CI (20.9%, 43.6%) and a median duration of response of 7.8 months with 95% CI (3.98, -)," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "These data compare quite favorably to the response rate seen with single agent chemotherapy in platinum resistant disease, which was 12% in the AURELIA and CORAIL trials, and included patients naïve to and previously treated with bevacizumab."

Berkenblit continued, "Replicating these data in SORAYA would support an application for accelerated approval in advance of the completion of MIRASOL, which would thereafter provide the randomized data needed for conversion to full approval. We are delighted to advance both studies as soon as possible."

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 7190603. The call may also be accessed through the Investors and Media section of immunogen.com. Following the call, a replay will be available at the same location.

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 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.

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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 pre-clinical, clinical, and regulatory events related to the Company's product candidates. 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: the Company's ability to control future spending to enable it to fund its remaining operations through the release of top-line results from the SORAYA and MIRASOL trials, as well as the risks and uncertainties inherent in the Company's development programs, including clinical studies and regulatory processes, their timings and results. A review of these risks can be found in ImmunoGen's Annual Report on Form 10-K for the year ended December 31, 2018 and other reports filed with the Securities and Exchange Commission.

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