ImmunoGen Presents Additional Analyses Evaluating Mirvetuximab Soravtansine in Ovarian Cancer at ESMO

September 11, 2022

Patient-Reported Outcomes with Mirvetuximab Versus Chemotherapy in FORWARD I Study Reinforces Differentiated Tolerability Profile

WALTHAM, Mass.--(BUSINESS WIRE)--Sep. 11, 2022-- ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced findings from an analysis of patient-reported outcomes (PROs) with mirvetuximab soravtansine (mirvetuximab) versus chemotherapy in the randomized Phase 3 FORWARD I study in platinum-resistant ovarian cancer. The Company also announced population pharmacokinetic (PK) and exposure response (ER) analyses across multiple clinical trials evaluating mirvetuximab monotherapy in folate receptor alpha (FRα)-positive ovarian cancer. These findings will be highlighted in three posters at the European Society for Medical Oncology (ESMO) Congress in Paris, France.

"The data presented at ESMO continue to support mirvetuximab's potential to displace single-agent chemotherapy in FRα-positive ovarian cancer and will serve as a guide as we seek to advance the broader development program," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "With our biologics license application for mirvetuximab under Priority Review with FDA, we look forward to potentially bringing this novel therapy to patients later this year."

ANALYSES OF PATIENT-REPORTED OUTCOMES WITH MIRVETUXIMAB SORAVTANSINE VERSUS STANDARD CHEMOTHERAPY IN THE RANDOMIZED PHASE 3 FORWARD I STUDY IN OVARIAN CANCER (GOG 3011)
Lead Author: Kathleen N. Moore, MD
Date/Time: September 11, 2022, 12:00 – 1:00 PM CEST / 6:00 – 7:00 AM ET
Poster: #532P

The Phase 3 FORWARD I trial enrolled 366 patients who were randomized 2:1 to receive either mirvetuximab or the physician's choice of single-agent chemotherapy (pegylated liposomal doxorubicin, topotecan, or weekly paclitaxel). Eligible patients were diagnosed with platinum-resistant ovarian cancer that expresses medium or high levels of FRα and were treated with up to three prior regimens. The primary endpoint was progression-free survival (PFS), which was assessed in the entire study population and in the subset of patients with high FRα expression. Patients completed PRO assessments during screening, on day 1 of cycle 1, every 9 weeks thereafter (±1 week) until disease progression, and at the end of treatment visit.

Key findings:

- In the intent-to-treat (ITT) population, a statistically significant improvement in the number of patients achieving a 15-point improvement in gastrointestinal (GI) symptoms was observed at week 8/9 in patients treated with mirvetuximab versus chemotherapy (31.7% vs 14.0% P = 0.0162).
- The likelihood of GI symptom deterioration was 70% lower with mirvetuximab in the ITT population compared with chemotherapy (95% CI, 0.15–0.60; P=0.0007).
- In the FRα-high population, the likelihood of GI symptom deterioration was 80% lower with mirvetuximab compared with chemotherapy (95% CI, 0.10–0.54; P=0.0007).
- In both the ITT and FRα-high patient populations, improvements were seen with mirvetuximab compared with chemotherapy across multiple side effects, including sexuality, hair loss, pain severity, body image, and general improvement in ovarian cancer–specific symptoms.
- In both the ITT and FRα-high patient populations, there were statistically significant benefits in physical functioning for mirvetuximab over chemotherapy.

"An unmet need remains for safe, effective, and well-tolerated therapeutic options for patients with platinum-resistant ovarian cancer, despite treatment advancements seen in this setting," 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 FORWARD I Co-Principal Investigator. "The improved PROs associated with mirvetuximab compared to chemotherapy reinforce the differentiated tolerability profile of mirvetuximab and, coupled with its compelling anti-tumor activity and favorable safety, support its potential to serve as a new standard of care for patients with FRα-positive ovarian cancer."

EXPOSURE RESPONSE ANALYSIS FOR EFFICACY AND SAFETY OF MIRVETUXIMAB SORAVTANSINE IN PATIENTS WITH FOLATE RECEPTOR ALPHA-POSITIVE CANCER
Lead Author: Ursula A. Matulonis, MD
Date/Time: September 11, 2022, 12:00 -1:00 PM CEST / 6:00 – 7:00 AM ET
Poster: #592P

An ER analysis was conducted across three studies - the Phase 1 IMGN853-0401 trial, the Phase 3 FORWARD I trial, and the Phase 3 SORAYA trial - to understand the relationship between exposure to single-agent mirvetuximab and the efficacy and safety responses observed in patients with FRα-positive tumors.

Key findings:

- Both efficacy, in terms of objective response rate (ORR) and PFS, and ocular adverse events (AEs) were higher with

increased exposure to mirvetuximab.
- These data highlight the importance of adherence to recommended mirvetuximab dosing guidelines in clinical practice.

POPULATION PHARMACOKINETIC ANALYSIS OF MIRVETUXIMAB SORAVTANSINE IN PATIENTS WITH FOLATE RECEPTOR ALPHA-POSITIVE CANCER
Lead Author: Kathleen N. Moore, MD
Date/Time: September 11, 2022, 12:00 – 1:00 PM CEST / 6:00 – 7:00 AM ET
Poster: #605P

A PK analysis, taking into account patient demographics and clinical characteristics, was conducted across three studies - IMGN853-0401, FORWARD I, and SORAYA - to understand the efficacy and safety of mirvetuximab in patients with FRα-positive tumors.

Key findings:

- Dosing adjustments do not appear to be necessary for patients with mild or moderate renal impairment or mild hepatic impairment.
- The analyses support the final recommended dose of 6 mg/kg based on adjusted ideal body weight (AIBW) every 3 weeks with balanced efficacy and safety.

Additional information can be found at www.esmo.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.

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, and the potential of mirvetuximab to serve as a new standard of care for patients with platinum-resistant ovarian cancer; the timing and presentation of clinical data for mirvetuximab; 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; 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, the Company's Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission on May 6, 2022 and August 1, 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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