ImmunoGen Announces Acceptance of Biologics License Application for Mirvetuximab Soravtansine in Ovarian Cancer by US Food and Drug Administration with Priority Review

May 23, 2022

PDUFA Date is November 28, 2022

WALTHAM, Mass.--(BUSINESS WIRE)--May 23, 2022-- ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced that the US Food and Drug Administration (FDA) has accepted and filed the Biologics License Application (BLA) for mirvetuximab soravtansine monotherapy in patients with folate receptor alpha (FRα)-high platinum-resistant ovarian cancer who have been previously treated with 1 to 3 prior systemic treatments. The application has been granted Priority Review designation and FDA has set a Prescription Drug User Fee Act (PDUFA) action date of November 28, 2022.

"FDA's acceptance of our BLA under Priority Review reinforces our belief in the potential for mirvetuximab soravtansine to serve as a new standard of care for patients with FRα-high platinum-resistant ovarian cancer," said Mark Enyedy, ImmunoGen's President and Chief Executive Officer. "We are pleased to be one step closer to realizing the promise of our technology and are working closely with FDA to support the evaluation of our application. We are moving quickly to build out the commercial and medical infrastructure required for a successful launch and look forward to the prospect of delivering mirvetuximab soravtansine to patients later this year."

Priority Review designation is granted to applications for therapies that may offer significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications and shortens the FDA review period to six months following acceptance.

The BLA seeks approval of mirvetuximab soravtansine under the FDA's accelerated approval pathway, which was instituted to allow for expedited development of drugs that treat serious conditions and provide a meaningful advantage over available therapies based on a surrogate endpoint and is based on results from the pivotal Phase 3 SORAYA trial. Top-line data from SORAYA were announced in November 2021 and full data from the study were presented at the Society of Gynecologic Oncology (SGO) 2022 Annual Meeting. ImmunoGen continues to enroll patients in the confirmatory MIRASOL trial, which is intended to convert the potential accelerated approval to full approval, and expects to announce top-line data from this study in early 2023.

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 clinical and regulatory events related to the Company's product candidates, including 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 presentation of preclinical and clinical data on the Company's product candidates, including top-line data from the MIRASOL trial in early 2023. 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.

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