# ImmunoGen Submits Biologics License Application to the US Food and Drug Administration for Mirvetuximab Soravtansine in Ovarian Cancer

March 29, 2022

*Submission Based on Positive Results from Pivotal Phase 3 SORAYA Trial*

WALTHAM, Mass.--(BUSINESS WIRE)--Mar. 29, 2022-- ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced that it has submitted a Biologics License Application (BLA) under the accelerated approval pathway to the US Food and Drug Administration (FDA) 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 submission 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 this month at the Society of Gynecologic Oncology (SGO) 2022 Annual Meeting.

"The BLA submission for mirvetuximab soravtansine is a key inflection point on our journey to delivering a safe and effective treatment option to patients with platinum-resistant ovarian cancer and moves us one step closer to transforming ImmunoGen into a fully-integrated oncology company," said Mark Enyedy, ImmunoGen's President and Chief Executive Officer. "Platinum-resistant ovarian cancer is an area with high unmet need, and we look forward to working with FDA to secure mirvetuximab soravtansine's first approval and bringing this novel therapy to patients as quickly as possible."

The FDA has a 60-day review period to determine whether the BLA is complete and acceptable for filing. ImmunoGen has requested priority review of the application and, if granted, the review will be completed within six months of the filing date. The BLA was submitted under the FDA's accelerated approval pathway, 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. ImmunoGen continues to enroll patients in the confirmatory MIRASOL trial designed to generate the randomized data needed for full approval and expects to announce top-line data from this study in the third quarter of 2022.

The FDA granted Orphan Drug Designation to mirvetuximab soravtansine for the treatment of ovarian cancer in July 2014. In June 2018, the FDA granted mirvetuximab soravtansine Fast Track Designation for the treatment of patients with medium to high FRα-positive platinum-resistant ovarian cancer who received at least one, but no more than three, prior systemic treatment regimens, and for whom single-agent chemotherapy is appropriate as the next line of therapy. This designation is intended to facilitate the development and expedite the review of drugs that treat serious and life-threatening conditions.

**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; and the presentation of preclinical and clinical data on the Company's product candidates, including top-line data from the MIRASOL trial in the third quarter of 2022. 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, including that the FDA may determine that our BLA for mirvetuximab does not meet the conditions for accelerated approval; 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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