ImmunoGen Provides Regulatory Update on Mirvetuximab Soravtansine Monotherapy in Ovarian Cancer

May 15, 2019

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

WALTHAM, Mass.--(BUSINESS WIRE)--May 15, 2019-- ImmunoGen, Inc., (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced the United States Food and Drug Administration (FDA) has recommended that the Company conduct a new Phase 3 randomized trial to evaluate the safety and efficacy of mirvetuximab soravtansine in patients with high folate receptor alpha (FRα)-positive, platinum-resistant ovarian cancer as part of a Type C meeting held this week.

ImmunoGen requested the meeting to discuss the results of the Phase 3 FORWARD I trial and a potential path to registration for mirvetuximab monotherapy. The agency advised that, because FORWARD I did not meet its primary endpoint under the pre-specified statistical analysis plan, the data generated assessing the secondary endpoints from the study could not be used to support an application for accelerated approval. FDA acknowledged that platinum-resistant ovarian cancer is a disease with unmet need, provided guidance regarding the design and endpoints of a potential registration study, and encouraged the Company to return to discuss a proposed study design.

“We are encouraged by the consistent signal of anti-tumor activity and the favorable benefit-risk profile in patients with high FRα expression in our Phase 3 FORWARD I trial,” said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. “We appreciate the constructive engagement with FDA and look forward to aligning with the agency on the design of a new registration trial in this population.”

“Our meeting with FDA enabled us to clarify a regulatory path forward for mirvetuximab and we are evaluating all avenues to bring this promising therapy to ovarian cancer patients,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer. “The mirvetuximab combination cohorts continue to advance and, with approximately $270 million on the balance sheet as of the end of Q1, we remain focused on developing innovative ADC therapeutics and delivering more good days to people with cancer.”

As previously announced, ImmunoGen is conducting an operational review of the business with the objective of extending the Company’s cash runway.

CONFERENCE CALL INFORMATION
ImmunoGen will host a conference call on May 15, 2019 at 8 a.m. ET to discuss the recent regulatory meeting with FDA. To access the live call by phone, dial 334-323-0505; the conference ID is 5203727. The call may also be accessed through the "Investors and Media" section of the Company's website, www.immunogen.com. Following the live webcast, a replay of the call will be available at the same location through May 29, 2019.

ABOUT FORWARD I
FORWARD I is a Phase 3 trial in which 366 patients were randomized 2:1 to receive either mirvetuximab soravtansine 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 of this study was progression free survival (PFS), which was assessed in the entire study population and in the subset of patients with high FRα expression. ImmunoGen estimates that 12,000-14,000 patients per year in the U.S. meet these criteria, with a comparable number in the major markets in Europe.

ImmunoGen partnered with the GOG Foundation Inc., a leader in clinical research in gynecologic malignancies, on FORWARD I, which was conducted in North America and Europe.

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 (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.” The Company has built a productive platform generating a broad pipeline of ADCs targeting solid tumors and hematologic malignancies.

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 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 and its collaboration partners' product programs; and the presentation of preclinical and clinical data on the Company’s and collaboration partners’ 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 timing and outcome of ImmunoGen's and the Company's collaboration partners' research 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; ImmunoGen's ability to financially support its product programs; ImmunoGen's dependence on collaborative partners; industry merger and acquisition activity; and other factors more fully described 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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