ImmunoGen Announces European Medicines Agency Acceptance of Marketing Authorization Application for Mirvetuximab Soravtansine in Platinum-Resistant Ovarian Cancer

October 27, 2023

WALTHAM, Mass.--(BUSINESS WIRE)--Oct. 27, 2023-- ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced that the European Medicines Agency (EMA) has accepted the Marketing Authorization Application (MAA) for mirvetuximab soravtansine (ELAHERE®) for the treatment of patients with folate receptor alpha (FRα)-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer.

"The acceptance of our MAA is another important regulatory milestone in the next chapter of ELAHERE's story as we work diligently to deliver this new treatment option to patients with platinum-resistant ovarian cancer globally," said Michael Vasconcelles, MD, ImmunoGen's Executive Vice President, Research, Development, and Medical Affairs. "As the first novel medicine to have demonstrated an overall survival benefit in platinum-resistant ovarian cancer compared to chemotherapy in a Phase 3 clinical trial, we are pleased to initiate the review process that moves us one step closer to providing access to ELAHERE for eligible patients in Europe. We look forward to working closely with the EMA throughout the review process and to potentially bring this novel ADC to Europe as early as 2024."

The MAA is supported by positive data from the Phase 3 MIRASOL trial of ELAHERE in platinum-resistant ovarian cancer, which was disclosed in May 2023 and subsequently presented as a late-breaking abstract at the 2023 American Society of Clinical Oncology Annual Meeting. In the MIRASOL trial, ELAHERE demonstrated statistically significant and clinically meaningful improvements in progression-free survival, objective response rate, and overall survival compared to investigator's choice (IC) of single-agent chemotherapy. ELAHERE demonstrated a tolerable safety profile compared to IC chemotherapy consisting predominantly of low-grade ocular and gastrointestinal events.

ELAHERE was approved by the US Food and Drug Administration in November 2022.

ABOUT OVARIAN CANCER

Ovarian cancer is the leading cause of death from gynecological cancers worldwide. Each year, more than 66,000 patients are diagnosed and 45,000 patients will die in the United States and Europe combined. Most patients present with late-stage disease and will typically undergo surgery followed by platinum-based chemotherapy. Unfortunately, the majority of patients eventually develop platinum-resistant disease, which is difficult to treat.

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.

ABOUT ELAHERE (MIRVETUXIMAB SORAVTANSINE)

ELAHERE (mirvetuximab soravtansine-gynx) is a first-in-class ADC comprising a folate receptor alpha-binding antibody, cleavable linker, and the maytansinoid payload DM4, a potent tubulin inhibitor designed to kill the targeted cancer cells.

ELAHERE is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

The prescribing information includes a boxed warning. ELAHERE can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis. Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of ELAHERE, every other cycle for the first 8 cycles, and as clinically indicated. Administer prophylactic artificial tears and ophthalmic topical steroids. Withhold ELAHERE for ocular toxicities until improvement and resume at the same or reduced dose. Discontinue ELAHERE for Grade 4 ocular toxicities.

Serious adverse reactions occurred in 31% of patients. The most common (≥2%) serious adverse reactions were intestinal obstruction (8%), ascites (4%), infection (3%), and pleural effusion (3%). Fatal adverse reactions occurred in 2% of patients, including small intestinal obstruction (1%) and pneumonitis (1%).The most common (≥20%) adverse reactions, including laboratory abnormalities, were vision impairment, fatigue, increased aspartate aminotransferase, nausea, increased alanine aminotransferase, keratopathy, abdominal pain, decreased lymphocytes, peripheral neuropathy, diarrhea, decreased albumin, constipation, increased alkaline phosphatase, dry eye, decreased magnesium, decreased leukocytes, decreased neutrophils, and decreased hemoglobin.

Please see full Prescribing Information, including Boxed Warning for ELAHERE.

FORWARD-LOOKING STATEMENTS

This press release includes forward-looking statements. These statements include, but are not limited to, the Company's expectations related to the EMA review process and the outcome of the Marketing Authorization Application for mirvetuximab soravtansine in Europe. 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 regulatory processes; the timing and outcome of the Company's anticipated interactions with regulatory authorities; and other factors as set forth in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 1, 2023, the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on April 28, 2023 and July 31, 2023, 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. ImmunoGen undertakes 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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