FDA Grants Priority Review of ImmunoGen's Supplemental Biologics License Application for ELAHERE® (mirvetuximab soravtansine-gynx) in Platinum-Resistant Ovarian Cancer

December 5, 2023

Priority Review Granted with PDUFA Date of April 5, 2024

WALTHAM, Mass.--(BUSINESS WIRE)--Dec. 5, 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 US Food and Drug Administration (FDA) has filed the supplemental Biologics License Application (sBLA) supporting the conversion of the accelerated approval of ELAHERE® (mirvetuximab soravtansine-gynx) for the treatment of 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 to full approval. The application has been granted Priority Review designation with a Prescription Drug User Fee Act (PDUFA) action date of April 5, 2024.

"With the FDA's filing of our sBLA, we are one step closer to securing full approval of ELAHERE in the US and establishing this novel ADC as the standard of care in FRα-positive platinum-resistant ovarian cancer," said Michael Vasconcelles, MD, ImmunoGen's Executive Vice President, Research, Development, and Medical Affairs. "This regulatory milestone, achieved just over one year after ELAHERE's accelerated approval, underscores the significance of the confirmatory MIRASOL data and the broader data set seen to date with ELAHERE, as well as the urgency with which our teams worked to bring this potentially practice-changing therapy to eligible patients in need. We look forward to collaborating closely with the FDA throughout the review process."

The confirmatory Phase 3 MIRASOL trial of ELAHERE in platinum-resistant ovarian cancer forms the basis of the sBLA. Top-line data from the MIRASOL trial were disclosed in May 2023 and presented as a late-breaking abstract at the 2023 American Society of Clinical Oncology (ASCO) 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 granted accelerated approval by the FDA in November 2022 based on data from the pivotal SORAYA trial. A Marketing Authorization Application for ELAHERE in Europe has been accepted by the European Medicines Agency and a New Drug Application in China has been accepted by the National Medical Products Administration of China.

ABOUT OVARIAN CANCER

Ovarian cancer is the leading cause of death from gynecological cancers in the US. Each year, roughly 20,000 patients are diagnosed, and 13,000 patients will die. 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. In this setting, standard of care single-agent chemotherapies are associated with low response rates, short durations of response, and significant toxicities.

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

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.

Eye problems are common with ELAHERE and can be severe. ELAHERE also can cause severe or life-threatening inflammation of the lungs that may lead to death and patients may develop nerve problems called peripheral neuropathy during treatment.

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, ImmunoGen's expectations related to the potential of ELAHERE to become the new standard of care for patients with FRα-positive platinum-resistant ovarian cancer and to change the practice of medicine for platinum-resistant ovarian cancer patients; and the outcome of the submissions of a supplemental Biologics License Application in the US, a Marketing Authorization Application in Europe, and a New Drug Application in China. 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 successful execution of the collaboration with Takeda and their development and commercialization efforts; the timing and outcome of the Company's clinical development processes; the difficulties inherent in the development of novel pharmaceuticals, including uncertainties as to the timing, expense, and results of clinical trials and regulatory processes; the timing and outcome of anticipated interactions with regulatory authorities; the risk that the Company may not be able to obtain adequate price and reimbursement for any approved products, including the potential for delays or additional difficulties for ELAHERE in light of the FDA granting 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 March 1, 2023, the Company's Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission on April 28, 2023 and July 31, 2023 and November 2, 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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