ImmunoGen Announces FDA Accelerated Approval of ELAHERE™ (mirvetuximab soravtansine-gynx) for the Treatment of Platinum-Resistant Ovarian Cancer

ELAHERE is the First ADC Approved by FDA for Platinum-Resistant Ovarian Cancer

Indication Covers Patients with One to Three Prior Systemic Treatment Regimens, Regardless of Prior Avastin® Use

VENTANA FOLR1 (FOLR1-2.1) RxDx Assay, the Companion Diagnostic to Identify Ovarian Cancer Patients Eligible for ELAHERE, Contemporaneously Approved by FDA

Approval Transitions ImmunoGen to a Fully-Integrated Oncology Company

Conference Call to be Held Tomorrow at 8:00 AM ET

Waltham, MA – November 14, 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 granted accelerated approval for ELAHERE™ (mirvetuximab soravtansine-gynx) 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. ELAHERE was approved under FDA's accelerated approval program based on objective response rate (ORR) and duration of response (DOR) data from the pivotal SORAYA trial. Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial. ELAHERE is a first-in-class ADC directed against FRα, a cell-surface protein highly expressed in ovarian cancer, and is the first FDA approved ADC for platinum-resistant disease.

"The approval of ELAHERE is significant for patients with FRα-positive platinum-resistant ovarian cancer, which is characterized by limited treatment options and poor outcomes," said Ursula Matulonis, MD, Chief of the Division of Gynecologic Oncology at the Dana-Farber Cancer Institute, Professor of Medicine at the Harvard Medical School, and SORAYA Co-Principal Investigator. “ELAHERE’s impressive anti-tumor activity, durability of response, and overall tolerability observed in SORAYA demonstrate the benefit of this new therapeutic option, and I look forward to treating patients with ELAHERE."

"With an indication for use regardless of prior treatment with Avastin, we believe ELAHERE is positioned to become the new standard of care for patients with FRα-positive platinum-resistant ovarian cancer,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer. “ELAHERE’s accelerated approval is a testament to the decades of work dedicated to developing the next generation of ADCs and marks ImmunoGen’s transition to a fully-integrated oncology company and the start of an exciting new chapter for us as a leader in the development and commercialization of innovative oncology products. With a highly experienced commercial and medical team in place, we are well prepared to support a successful launch and deliver ELAHERE rapidly to patients across the US."

ELAHERE was evaluated in the pivotal SORAYA trial, a single-arm study in 106 patients with platinum-resistant ovarian cancer whose tumors expressed high levels of FRα and who had been treated with one to three prior systemic treatment regimens – at least one of which included Avastin® (bevacizumab). The primary endpoint was confirmed ORR as assessed by investigator and the key secondary endpoint was DOR. Per the label, ELAHERE demonstrated an ORR by investigator of 31.7% (95% confidence interval [CI]: 22.9, 41.6), including five complete responses (CRs). The median DOR was 6.9 months (95% CI: 5.6, 9.7) as assessed by investigator. The safety of ELAHERE has been evaluated in a pooled analysis from three studies among a total of 464 patients with FRα-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who

received at least one dose of ELAHERE (6 mg/kg adjusted ideal body weight (AIBW) administered intravenously once every 3 weeks).

The prescribing information for ELAHERE includes a boxed warning for ocular toxicity, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis. The most common adverse reactions (greater than or equal to 20% of patients), 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.

"Platinum-resistant ovarian cancer is a notoriously challenging disease to treat. Given there have been no new therapies approved by FDA for this indication since 2014, ELAHERE's accelerated approval is a tremendous advance for the ovarian cancer treatment paradigm," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "We are thrilled with today's approval and extend our sincere thanks to the patients, families, caregivers, and investigators who helped make this achievement a reality and have supported the broader mirvetuximab development program. As we work to deliver more good days to patients, we look forward to the continued evaluation of mirvetuximab in earlier lines of treatment, in combination, and across a wider range of levels of FRα expression."

MIRASOL, the confirmatory randomized trial designed to convert the accelerated approval of ELAHERE to full approval, is fully enrolled and top-line data are expected in early 2023. During the Biologics License Application review, FDA requested ImmunoGen submit preliminary ORR and DOR data from both arms of MIRASOL. To maintain data integrity for the ongoing MIRASOL trial, an independent third-party statistician performed the analyses and submitted the outputs directly to FDA.

FDA has also granted approval of the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay, the only companion diagnostic to aid in identifying patients eligible for treatment with ELAHERE, developed by Roche. Approximately 35-40% of ovarian cancer patients express high levels of FRα, which is defined as greater than or equal to 75% tumor cells staining with 2+ intensity. Testing can be done on fresh or archived tissue; newly diagnosed patients can test at diagnosis to determine if ELAHERE will be an option for them at the time of progression to platinum resistance. Testing is now available in the US through four centralized laboratories and is expected to expand to additional laboratories over time. For the current list of US laboratories that offer testing, please visit https://usinfo.roche.com/folr1ihc.html.

ImmunoGen is committed to helping eligible platinum-resistant ovarian cancer patients gain access to treatment with ELAHERE and is providing support through our ELAHERE Support Services program. For more information, call 1-833-ELAHERE or visit http://www.elahere.com/.

CONFERENCE CALL INFORMATION
ImmunoGen will hold a conference call tomorrow, November 15 at 8:00 a.m. ET to discuss the FDA approval of ELAHERE. To access the live call by phone, please register here. A dial-in and unique PIN will be provided to join the call. The call may also be accessed through the Investors and Media section of the Company's website, www.immunogen.com. Following the call, a replay will be available at the same location.

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 ELAHERE (MIRVETUXIMAB SORAVTANSINE-GYNX)
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.

Indication and Usage
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.

Important Safety Information
BOXED WARNING: OCULAR TOXICITY

- 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.

WARNINGS and PRECAUTIONS

Ocular Disorders
ELAHERE can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis.

Ocular adverse reactions occurred in 61% of patients with ovarian cancer treated with ELAHERE. Nine percent (9%) of patients experienced Grade 3 ocular adverse reactions, including visual impairment, keratopathy/keratitis (corneal disorders), dry eye, photophobia, and eye pain; and one patient (0.2%) experienced Grade 4 keratopathy. The most common (≥5%) ocular adverse reactions were visual impairment (49%), keratopathy (36%), dry eye (26%), cataract (15%), photophobia (13%), and eye pain (12%).

The median time to onset for first ocular adverse reaction was 1.2 months (range: 0.03 to 12.9). Of the patients who experienced ocular events, 49% had complete resolution and 39% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade) at last follow up. Ocular adverse reactions led to permanent discontinuation of ELAHERE in 0.6% of patients.

Premedication and use of lubricating and ophthalmic topical steroids eye drops during treatment with ELAHERE are recommended. Advise patients to avoid use of contact lenses during treatment with ELAHERE unless directed by a healthcare provider.

Refer patients to an eye care professional for an ophthalmic exam including visual acuity and slit lamp exam prior to treatment initiation, every other cycle for the first 8 cycles, and as clinically indicated. Promptly refer patients to an eye care professional for any new or worsening ocular signs and symptoms.

Monitor for ocular toxicity and withhold, reduce, or permanently discontinue ELAHERE based on severity and persistence of ocular adverse reactions.

Pneumonitis
Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with ELAHERE. Pneumonitis occurred in 10% of patients treated with ELAHERE, including 0.8% with Grade 3 events, and 1 patient (0.2%) with a Grade 4 event. One patient (0.2%) died due to respiratory failure in the setting of pneumonitis and lung metastases.

Monitor patients for pulmonary signs and symptoms of pneumonitis. Infectious, neoplastic, and other causes for symptoms should be excluded through appropriate investigations.

Withhold ELAHERE for patients who develop persistent or recurrent Grade 2 pneumonitis until symptoms resolve to ≤ Grade 1 and consider dose reduction. Permanently discontinue ELAHERE in all patients with Grade 3 or 4 pneumonitis. Patients who are asymptomatic may continue dosing of ELAHERE with close monitoring.

Peripheral Neuropathy (PN)
PN occurred in 36% of patients with ovarian cancer treated with ELAHERE across clinical trials; 2% of patients experienced Grade 3 PN. PN adverse reactions included peripheral neuropathy (19%), peripheral sensory neuropathy (9%), paraesthesia (6%), neurotoxicity (3%), hypoaesthesia (2%), peripheral motor neuropathy (1%), neuralgia (0.4%), polyneuropathy (0.2%) and oral hypoesthesia (0.2%).

Monitor patients for signs and symptoms of neuropathy. For patients experiencing new or worsening PN, withhold dosage, dose reduce, or permanently discontinue ELAHERE based on the severity of PN.

Embryo-Fetal Toxicity
Based on its mechanism of action, ELAHERE can cause embryo-fetal harm when administered to a pregnant woman because it contains a genotoxic compound (DM4) and affects actively dividing cells.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ELAHERE and for 7 months after the last dose.

ADVERSE REACTIONS
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%).

Permanent discontinuation of ELAHERE due to adverse reactions occurred in 11% of patients. The most common (≥2%) adverse reactions leading to permanent discontinuation were intestinal obstruction (2%) and thrombocytopenia (2%). One patient (0.9%) permanently discontinued ELAHERE due to visual impairment (unilateral decrease to BCVA < 20/200 that resolved to baseline after discontinuation).

Dosage delays of ELAHERE due to an adverse reaction occurred in 39% of patients. Adverse reactions which required dosage delays in ≥3% of patients included visual impairment (15%), keratopathy (11%), neutropenia (6%), dry eye (5%), cataracts (3%) and increased gamma-glutamyltransferase (3%).

Dose reductions of ELAHERE due to an adverse reaction occurred in 20% of patients. Adverse reactions which required dose reductions in ≥3% of patients included visual impairment (9%) and keratopathy (7%).

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.

DRUG INTERACTIONS

Strong CYP3A4 Inhibitors
DM4 is a CYP3A4 substrate. Concomitant use of ELAHERE with strong CYP3A4 inhibitors may increase unconjugated DM4 exposure, which may increase the risk of ELAHERE adverse reactions. Closely monitor patients for adverse reactions with ELAHERE when used concomitantly with strong CYP3A4 inhibitors.

USE IN SPECIAL POPULATIONS

Lactation
Advise women not to breastfeed during treatment with ELAHERE and for at least 1 month after the last dose.

Pediatric Use
Safety and effectiveness of ELAHERE have not been established in pediatric patients.

Hepatic Impairment
Avoid use of ELAHERE in patients with moderate or severe hepatic impairment (total bilirubin >1.5 ULN).

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

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 preclinical, clinical, and regulatory events related to, and the potential benefits of, the Company's product candidates, including, but not limited to: the potential for ELAHERE to become a new standard of care, the potential for additional accelerated approval indications for ELAHERE, and the MIRASOL confirmatory trial converting the accelerated approval of ELAHERE to full approval; the commercial launch of ELAHERE and bringing ELAHERE to eligible patients; the timing and presentation of preclinical and clinical data on the Company's product candidates, including top-line data from the MIRASOL trial; the availability of VENTANA FOLR1 (FOLR1-2.1) RxDx Assay in additional laboratories; and the Company's business and product development strategies. 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 results of the ongoing MIRASOL trial may fail to support full approval of ELAHERE and, if not, additional studies may be required; the timing and outcome of the Company's anticipated interactions with regulatory authorities; the risk that we 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 February 28, 2022, the Company's Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission on May 6, 2022 and August 1, 2022, 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. We undertake 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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