ELAHERE® Demonstrates 35% Reduction in the Risk of Disease Progression or Death Versus Chemotherapy in FRα-Positive Platinum-Resistant Ovarian Cancer

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Results from MIRASOL Also Show ELAHERE is the First Treatment to Demonstrate an Overall Survival Benefit in a Phase 3 Trial in Platinum-Resistant Ovarian Cancer Compared to Chemotherapy

Clinically Meaningful Improvements in Progression Free Survival and Overall Survival Observed with ELAHERE Regardless of Prior Bevacizumab Status

Data Further Support Potential of ELAHERE to Become the New Standard of Care for Patients with FRα-Positive Platinum-Resistant Ovarian Cancer

MIRASOL Results to be Highlighted in Late-Breaking Oral Presentation Today at ASCO Annual Meeting and Selected for the 2023 Best of ASCO Program®

WALTHAM, Mass.--(BUSINESS WIRE)--Jun. 4, 2023-- ImmunoGen Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced detailed results from the Phase 3 confirmatory MIRASOL trial (GOG 3045/ENGOT OV-55) evaluating the safety and efficacy of ELAHERE® (mirvetuximab soravtansine-gynx) compared to chemotherapy in patients with folate receptor alpha (FRα)-positive platinum-resistant ovarian cancer (PROC). The results are being presented by Dr. Kathleen Moore in a late-breaking oral abstract session today at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois. These data have also been selected for the 2023 Best of ASCO program, which will be held this summer following the ASCO Annual Meeting.

"I am thrilled to share these impressive results from the confirmatory MIRASOL trial at ASCO, which further demonstrate the potential of ELAHERE to become the new standard of care for patients with FRα-positive PROC," said Kathleen Moore, Associate Director of Clinical Research and Director of the Oklahoma TSET/Sarah Cannon Phase I Program, Professor of the Section of Gynecologic Oncology at The University of Oklahoma and MIRASOL Principal Investigator. "As we saw in the top-line data announced last month, ELAHERE demonstrated an improvement versus chemotherapy across all efficacy endpoints and, importantly, is the first treatment to show an overall survival benefit in this patient population. The 33% reduction in the risk of death, along with the differentiated and well-characterized safety profile seen in MIRASOL, reinforce the potential of ELAHERE to serve as a transformative option for ovarian cancer patients and change how this disease is treated."

MIRASOL is a randomized Phase 3 trial of ELAHERE versus investigator's choice (IC) of single-agent chemotherapy (weekly paclitaxel, pegylated liposomal doxorubicin, or topotecan). Eligibility criteria include patients with PROC whose tumors express high levels of FRα, using the Ventana FOLR1 Assay, and who have been treated with up to three prior regimens. The primary endpoint of this trial is progression-free survival (PFS) by investigator assessment. Key secondary endpoints include objective response rate (ORR) and overall survival (OS).

MIRASOL enrolled 453 patients. Patients were stratified by number of prior lines of therapy (14% had one prior line of therapy, 40% had two prior lines of therapy, and 46% had three prior lines of therapy) and by IC chemotherapy, with paclitaxel as the most commonly chosen (41%), followed by PLD (36%) and topotecan (23%). 62% of patients received prior bevacizumab; 55% received a prior PARP inhibitor. As of the data cutoff on March 6, 2023, the median follow-up time for OS was 13.1 months; 14% of patients on the ELAHERE arm remained on study drug compared to 3% on the IC chemotherapy arm.

- ELAHERE demonstrated a statistically significant and clinically meaningful improvement in PFS by investigator assessment compared to IC chemotherapy, with a hazard ratio (HR) of 0.65 (95% confidence interval [CI]: 0.52, 0.81; p<0.0001), which represents a 35% reduction in the risk of tumor progression or death in the ELAHERE arm compared to the IC chemotherapy arm. The median PFS in the ELAHERE arm was 5.62 months (95% CI: 4.34, 5.95) compared to 3.98 months (95% CI: 2.86, 4.47) in the IC chemotherapy arm.
- ELAHERE demonstrated a statistically significant and clinically meaningful improvement in OS compared to IC chemotherapy. With 204 OS events reported as of March 6, 2023, the median OS was 16.46 months (95% CI: 14.46, 24.57) in the ELAHERE arm, compared to 12.75 months (95% CI: 10.91, 14.36) in the IC chemotherapy arm, with a HR of 0.67 (95% CI: 0.50, 0.89; p=0.0046). This represents a 33% reduction in the risk of death in the ELAHERE arm in comparison to the IC chemotherapy arm.
- ORR by investigator assessment in the ELAHERE arm was 42.3% (95% CI: 35.8%, 49.0%), including 12 complete responses (CRs), compared to 15.9% (95% CI: 11.4%, 21.4%), with no CRs, in the IC chemotherapy arm.

In addition to data on the primary and key secondary endpoints, further safety and efficacy analyses from MIRASOL will be presented:

- In the bevacizumab-naïve subset (n=172), the PFS HR was 0.66, (95% CI: 0.46, 0.94; p=0.0210); in the bevacizumab-pretreated subset (n=281), the PFS HR was 0.64 (95% CI: 0.49, 0.84; p=0.0011).
- In the bevacizumab-naïve subset, the OS HR was 0.51 (95% CI: 0.31, 0.86; p=0.0099); in the bevacizumab-pretreated subset, the OS HR was 0.74 (95% CI: 0.54, 1.04; p=0.0789).
- PFS and ORR results by blinded independent central review (BICR) were concordant with investigator assessment.
    - The HR for PFS by BICR was 0.72 (95% CI: 0.56, 0.92; p=0.0082).
    - ORR by BICR in the ELAHERE arm was 36.1% (95% CI: 29.9, 42.7), including 16 complete responses (CRs),

compared to 14.6% (95% CI: 10.3, 19.9), with 4 CRs, in the IC chemotherapy arm.

- ELAHERE was well-tolerated, consistent with the known safety profile seen in the broader development program. No new safety signals were identified in MIRASOL.
  - Compared with IC chemotherapy, ELAHERE was associated with lower rates of grade 3 or greater treatment-emergent adverse events (TEAEs) (42% vs 54%) and serious adverse events (24% vs 33%).
  - Dose delays due to TEAEs occurred in 54% of patients on both arms; dose reductions due to TEAEs occurred in 34% of ELAHERE treated patients vs 24% of IC chemotherapy patients; discontinuations due to TEAEs occurred in 9% of ELAHERE treated patients vs 16% of IC chemotherapy patients.
  - The safety profile of ELAHERE consists of predominantly low-grade ocular and gastrointestinal TEAEs.
- Detailed safety data will be presented, including rates of all grade and grade 3+ ocular, gastrointestinal, neuropathy, and hematologic TEAEs for ELAHERE vs IC chemotherapy (paclitaxel, PLD, topotecan).

"We are incredibly pleased the MIRASOL results were selected as a late-breaking presentation at ASCO," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "As the first novel therapy to extend overall survival in platinum-resistant disease, and with consistent efficacy regardless of prior bevacizumab use, ELAHERE is a much-needed advance in the ovarian cancer treatment paradigm. We look forward to submitting the MAA and sBLA for ELAHERE in the EU and US, respectively, during the second half of the year, and to progressing the broader ELAHERE development program as we work to deliver this biomarker-directed ADC to eligible patients."

In November 2022, the US Food and Drug Administration (FDA) granted accelerated approval for ELAHERE for the treatment of adult patients with FRα-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens based on ORR and duration of response data from the pivotal SORAYA trial.

LATE-BREAKING ORAL PRESENTATION
Title: Phase III MIRASOL (GOG 3045/ENGOT-ov55) Study: Initial Report of Mirvetuximab Soravtansine vs. Investigator's Choice of Chemotherapy in Platinum-Resistant, Advanced High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers with High Folate Receptor-Alpha Expression
Presenter: Dr. Kathleen Moore, Associate Director of Clinical Research and Director of the Oklahoma TSET/Sarah Cannon Phase I Program, Professor of the Section of Gynecologic Oncology at The University of Oklahoma and MIRASOL Principal Investigator
Session: Late-Breaking Abstract Session: Presentation and Discussion of LBA5507
Date: Sunday, June 4, 2023
Time: 7:30 am to 8:05 am CT / 8:30 am to 9:05 am ET

POSTER PRESENTATIONS
ImmunoGen is also presenting two trial-in-progress posters at ASCO.

Title: GLORIOSA: A Randomized, Open-Label, Phase 3 Study of Mirvetuximab Soravtansine with Bevacizumab vs. Bevacizumab as Maintenance in Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer
Presenter: Dr. David O'Malley, Professor, Director of Gynecologic Oncology at the Ohio State University and the James Cancer Center
Abstract: TPS5622
Poster Board: 312a

Title: A Phase 1b/2 Study of Pivekimab Sunirine in Combination with Venetoclax/Azacitidine or Magrolimab for Patients with CD123-Positive Acute Myeloid Leukemia
Presenter: Dr. Naval Daver, Associate Professor in the Department of Leukemia at The University of Texas MD Anderson Cancer Center
Abstract: TPS7073
Poster Board: 203a

Additional information can be found at www.asco.org.

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
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, 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.

ELAHERE® is a trademark of ImmunoGen, Inc.

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 standard of care in FRα-positive ovarian cancer, to serve as a transformative option for ovarian cancer patients and to change how this disease is treated*; the potential full approval of ELAHERE in the US and expansion to Europe, including the submission of a MAA in Europe and a sBLA in the US anticipated in the second half 2023; 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: top-line data may change as more patient data become available and are subject to audit and verification procedures; the timing and outcome of the Company's preclinical and clinical development processes; the results of the ongoing MIRASOL trial may not support full approval of ELAHERE and, if so, additional studies may be required; 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 timing and outcome of the Company's 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 Report on Form 10-Q filed with the Securities and Exchange Commission on April 28, 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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