Elahere™ (mirvetuximab soravtansine-gynx) – New orphan drug approval

- On November 14, 2022, ImmunoGen announced the FDA approval of 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.
    - Patients should be selected 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.
- Ovarian cancer is the leading cause of death from gynecological cancers in the U.S. Each year, roughly 20,000 patients are diagnosed, and 13,000 patients will die.
- The 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.
- Elahere is a first-in-class antibody-drug conjugate comprising a FRα-binding antibody, cleavable linker, and the maytansinoid payload DM4, a potent tubulin inhibitor designed to kill the targeted cancer cells.
- The efficacy of Elahere was established in Study 0417, a single-arm study in 104 patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer. Patients were permitted to receive up to three prior lines of systemic therapy. All patients were required to have received prior bevacizumab. Patients received Elahere every 3 weeks until disease progression or unacceptable toxicity. The major outcome measures were overall response rate (ORR) and duration of response (DOR).
    - The ORR was 31.7% (95% CI: 22.9, 41.6).
    - The median DOR was 6.9 months (95% CI: 5.6, 9.7).
- Elahere carries a boxed warning for ocular toxicity.
- Additional warnings and precautions for Elahere include pneumonitis, peripheral neuropathy, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 20%), including laboratory abnormalities, with Elahere use 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.
- The recommended dose of Elahere is 6 mg/kg adjusted ideal body weight (AIBW) administered once every 3 weeks (21-day cycle) as an intravenous infusion until disease progression or unacceptable toxicity.
    - Patients should be selected for the treatment of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer with Elahere based on the presence of FRα tumor expression using an FDA-approved test.

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  - — Information on FDA-approved tests for the measurement of FRα tumor expression is available at http://www.fda.gov/CompanionDiagnostics.

- ImmunoGen plans to launch Elahere within days. Elahere will be available as a 100 mg/20 mL (5 mg/mL) single-dose vial.