

**Category**

Best Medical Technology

**Drug / Device Name**

Mirvetuximab soravtansine-gynx

**Compound/ Tech Name**

Antibody-drug conjugates (ADCs)

**Trade Name**

ELAHERE

**Date of Approval**

2022-11-14

**Indications**

ELAHERE is indicated for the treatment of adult patients with folate receptor-alpha (FR $\alpha$ ) 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.

**Therapeutic Categories**

Ovarian cancer

Attached Files:

- Patient Branded Lite Product Brochure\_Digital.pdf

**Background information and need for drug/device**

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.

**History of the development of the drug/device**

ELAHERE (mirvetuximab soravtansine-gynx) is the first and only FR $\alpha$ -targeted antibody drug conjugate for platinum-resistant ovarian cancer. On November 14, 2022, the US Food and Drug Administration granted accelerated approval to ELAHERE for the treatment of FR $\alpha$ -positive platinum-resistant ovarian cancer. ELAHERE is the first new therapeutic option approved specifically for platinum-resistant ovarian cancer since 2014. The development of mirvetuximab began in 2014 with a Phase 1 study evaluating the safety and efficacy of mirvetuximab in platinum-resistant ovarian cancer to address a substantial unmet in this difficult to treat patient population. The encouraging activity led to the initiation of a Phase 1b trial evaluating mirvetuximab in combination with carboplatin,

bevacizumab, pegylated liposomal doxorubicin (PLD), or pembrolizumab in patients with ovarian cancer (FORWARD II) and the initiation of a pivotal Phase 3 study evaluating mirvetuximab monotherapy in platinum-resistant ovarian cancer (FORWARD I). The data generated from the FORWARD II trial ultimately led to the inclusion of mirvetuximab plus bevacizumab in NCCN guidelines and compendium in December 2022. The data generated from the FORWARD I trial led to the design of the pivotal SORAYA trial, which resulted in the accelerated approval of mirvetuximab in November 2022, and the design of the confirmatory MIRASOL trial, for which topline results were shared in May 2023, showing an overall survival benefit, the first drug to do so in this patient population. These data will support the Marketing Authorization Application (MAA) in Europe and a supplemental Biologics License Application (sBLA) in the US for the conversion to a regular approval of ELAHERE. Our goal is to deliver ELAHERE to patients worldwide and become the new standard-of-care for FR $\alpha$ -positive patients.

**Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition**

ELAHERE (mirvetuximab soravtansine-gynx) is a first-in-class ADC, a potent tubulin inhibitor designed to kill the targeted cancer cells. ImmunoGen Inc., is a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, announced positive top-line data from the Phase 3 confirmatory MIRASOL trial (GOG 3045/ENGOT OV-55) evaluating the safety and efficacy of ELAHERE® compared to chemotherapy in patients with folate receptor alpha (FR $\alpha$ )-positive platinum-resistant ovarian cancer who have received one to three prior lines of therapy. This is the first medicine to demonstrate an Overall Survival advantage in Platinum-Resistant Ovarian Cancer.

**Please provide appropriate references (ie Pubmed links)**

<https://pubmed.ncbi.nlm.nih.gov/36736157/>  
<https://pubmed.ncbi.nlm.nih.gov/36716407/>  
<https://pubmed.ncbi.nlm.nih.gov/32081463/>  
<https://pubmed.ncbi.nlm.nih.gov/33667670/>  
<https://pubmed.ncbi.nlm.nih.gov/30093227/>  
<https://pubmed.ncbi.nlm.nih.gov/28440955/>  
<https://pubmed.ncbi.nlm.nih.gov/28029313/>

**Attached Files:**

- 2020 Gynecol Oncol OMalley v157 p379 MirvBev.pdf

