3-5

NCCN CATEGORY 1 RECOMMENDED

Mirvetuximab soravtansine-gynx (ELAHERE®) is recommended by the National Comprehensive Cancer Network® (NCCN®) as the only **Category 1, Preferred** option for FRα-positive (≥75% positive tumor cells), platinum-resistant ovarian cancer[1,2]

# TEST FOR FRα EARLY TO UNDERSTAND HER TREATMENT OPTIONS AT PLATINUM RESISTANCE[1]

## Why does FRα matter?

**90%**
of patients
with ovarian cancer express FRα[3-5]

**~35%**
of patients
with advanced ovarian cancer have tumors that express FRα at a level that may make them candidates for ELAHERE monotherapy[6,7]

ADC ELAHERE is an ADC designed to target FRα[7]

Knowing your patients' FRα status can help you be ready to treat with ELAHERE as soon as an appropriate patient's disease becomes platinum resistant[2,7]

ADC=antibody-drug conjugate; FRα=folate receptor alpha.

### INDICATION

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.

### IMPORTANT SAFETY INFORMATION

### 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.**

**Please see additional Important Safety Information, including BOXED WARNING, throughout.**

**Please see Full Prescribing Information, including BOXED WARNING.**

ELAHERE®
mirvetuximab soravtansine-gynx
injection 100 mg

# SPECIFICALLY REQUEST FRα TESTING FOR YOUR PATIENTS, AS IT MAY NOT BE AUTOMATIC[2,8]

## Test for FRα with the FDA-approved VENTANA FOLR1 IHC assay[2,6,9,10]*

- **Testing can be done on formalin-fixed, paraffin-embedded (FFPE) tissue collected at any time, including at diagnosis, at debulking, or after chemotherapy**
- FRα expression is identified via IHC, not with genomic testing, and it may need to be requested as an add-on (for example: in addition to a broad NGS panel)

*VENTANA FOLR1 (FOLR1-2.1) RxDx Assay.

**≥75%**

## Act on the results for appropriate patients[2,7]

- **Tumors with ≥75% of viable tumor cells staining at ≥2+ intensity are considered FRα positive**
- Patients who meet the above criteria and have platinum-resistant ovarian cancer may be candidates for ELAHERE

NCCN Guidelines® for Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer V.3.2025 recommend mirvetuximab soravtansine-gynx (ELAHERE®) as an NCCN **Category 1, Preferred** option for recurrence therapy in patients with folate receptor-alpha positive (FRα-expressing tumors [≥75% positive tumor cells]), platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer[1,2]

Test for FRα and see if your patients are eligible for treatment with ELAHERE as soon as their disease becomes platinum resistant[7,9]

FOLR1=folate receptor 1; IHC=immunohistochemistry; NCCN=National Comprehensive Cancer Network® (NCCN®); NGS=next-generation sequencing.

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# INDICATION AND IMPORTANT SAFETY INFORMATION

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### 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 59% of patients with ovarian cancer treated with ELAHERE. Eleven percent (11%) of patients experienced Grade 3 ocular adverse reactions, including blurred vision, keratopathy (corneal disorders), dry eye, cataract, photophobia, and eye pain; two patients (0.3%) experienced Grade 4 events (keratopathy and cataract). The most common (≥5%) ocular adverse reactions were blurred vision (48%), keratopathy (36%), dry eye (27%), cataract (16%), photophobia (14%), and eye pain (10%).

The median time to onset for first ocular adverse reaction was 5.1 weeks (range: 0.1 to 68.6). Of the patients who experienced ocular events, 53% had complete resolution; 38% 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 1% of patients.

Premedication and use of lubricating and ophthalmic topical steroid 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 1% with Grade 3 events and 1 patient (0.1%) with a Grade 4 event. One patient (0.1%) died due to respiratory failure in the setting of pneumonitis and lung metastases. One patient (0.1%) died due to respiratory failure of unknown etiology. Pneumonitis led to permanent discontinuation of ELAHERE in 3% of patients.

Monitor patients for pulmonary signs and symptoms of pneumonitis, which may include hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams. Infectious, neoplastic, and other causes for such 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.

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# INDICATION AND IMPORTANT SAFETY INFORMATION (CONT'D)

## WARNINGS and PRECAUTIONS (cont'd)

### Peripheral Neuropathy (PN)

Peripheral neuropathy occurred in 36% of patients with ovarian cancer treated with ELAHERE across clinical trials; 3% of patients experienced Grade 3 peripheral neuropathy. Peripheral neuropathy adverse reactions included peripheral neuropathy (20%), peripheral sensory neuropathy (9%), paraesthesia (6%), neurotoxicity (3%), hypoaesthesia (1%), peripheral motor neuropathy (0.9%), polyneuropathy (0.3%), and peripheral sensorimotor neuropathy (0.1%). Monitor patients for signs and symptoms of neuropathy, such as paresthesia, tingling or a burning sensation, neuropathic pain, muscle weakness, or dysesthesia. 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

The most common (≥20 %) adverse reactions, including lab abnormalities, were increased aspartate aminotransferase, fatigue, increased alanine aminotransferase, blurred vision, nausea, increased alkaline phosphatase, diarrhea, abdominal pain, keratopathy, peripheral neuropathy, musculoskeletal pain, decreased lymphocytes, decreased platelets, decreased magnesium, decreased hemoglobin, dry eye, constipation, decreased leukocytes, vomiting, decreased albumin, decreased appetite, and decreased neutrophils.

## DRUG INTERACTIONS

DM4 is a CYP3A4 substrate. 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 1 month after the last dose.

### Hepatic Impairment

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

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ULN=upper limit of normal.

**References: 1.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer V.3.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed August 27, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **2.** VENTANA FOLR1 (FOLR1-2.1) RxDx Assay. Package insert. Roche; 2022. **3.** Toffoli G, Cernigoi C, Russo A, Gallo A, Bagnoli M, Boiocchi M. *Int J Cancer.* 1997;74(2):193-198. doi:10.1002/(sici)1097-0215(19970422)74:2<193::aid-ijc10>3.0.co;2-f **4.** Markert S, Lassmann S, Gabriel B, et al. *Anticancer Res.* 2008;28(6A):3567-3572. **5.** Parker N, Turk MJ, Westrick E, Lewis JD, Low PS, Leamon CP. *Anal Biochem.* 2005;338(2):284-293. doi:10.1016/j.ab.2004.12.026 **6.** Matulonis UA, Lorusso D, Oaknin A, et al. *J Clin Oncol.* 2023;41(13):2436-2445. doi:10.1200/JCO.22.01900 **7.** ELAHERE. Package insert. AbbVie; 2025. **8.** Provider FAQs. Foundation Medicine. Accessed April 28, 2025. https://www.foundationmedicine.com/faq/provider-faqs **9.** Despierre E, Lambrechts S, Leunen K, et al. *Gynecol Oncol.* 2013;130(1):192-199. doi:10.1016/j.ygyno.2013.03.024 **10.** US Food and Drug Administration. Premarket approval letter for VENTANA FOLR1 (FOLR1-2.1) RxDx Assay. November 14, 2022. Accessed April 28, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf22/P220006A.pdf

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