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]

Patient portrayal.

SURVIVAL+

ELAHERE is the first and only treatment to show **superior efficacy** vs standard single-agent chemotherapy in FRα-positive, **platinum-resistant ovarian cancer**[3-5*†]

Median PFS: 5.6 months (n=227; 95% CI: 4.3, 5.9) with ELAHERE vs 4.0 months (n=226; 95% CI: 2.9, 4.5) with standard chemotherapy, *P*<0.0001 (primary endpoint)[‡]; median OS: 16.5 months (n=227; 95% CI: 14.5, 24.6) with ELAHERE vs 12.7 months (n=226; 95% CI: 10.9, 14.4) with standard chemotherapy, *P*=0.0046 (key secondary endpoint)[§]; ORR: 42% (n=225; 95% CI: 36, 49) with ELAHERE vs 16% (n=224; 95% CI: 12, 22) with standard chemotherapy, *P*<0.0001 (key secondary endpoint).[3,4]

*MIRASOL was a confirmatory, global, multicenter, randomized, open-label study evaluating the efficacy and safety of ELAHERE vs investigator's choice chemotherapy in FRα-positive, platinum-resistant ovarian cancer; ELAHERE (n=227) vs standard single-agent chemotherapy (n=226; paclitaxel, pegylated liposomal doxorubicin, or topotecan).[3,4]
†FRα positive is defined as ≥75% of viable tumor cells with moderate (2+) and/or strong (3+) membrane staining based on an IHC assay.[2]
‡HR: 0.65 (95% CI: 0.52, 0.81).[3]
§HR: 0.67 (95% CI: 0.50, 0.88).[3]
CI=confidence interval; FRα=folate receptor alpha; HR=hazard ratio; IHC=immunohistochemistry; ORR=overall response rate; OS=overall survival; PFS=progression-free survival.

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.**

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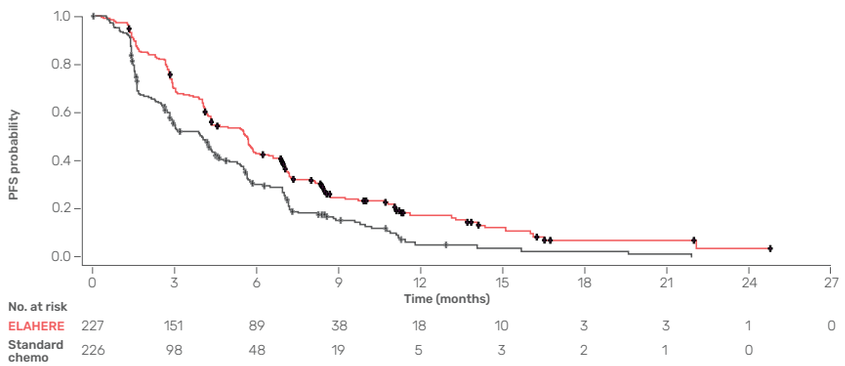
PFS
OS
ORR
SAFETY OVERVIEW
PATIENT-REPORTED OUTCOMES
IMPORTANT SAFETY INFORMATION
REFERENCES
SUMMARY

PFS: ADD THE POTENTIAL FOR MORE PROGRESSION-FREE DAYS WITH ELAHERE[3,4]

In the MIRASOL Phase 3 trial, ELAHERE was studied in a patient population with FRα-positive, platinum-resistant ovarian cancer. Patients were randomized 1:1 between ELAHERE (n=227) vs investigator's choice chemotherapy (n=226; paclitaxel, pegylated liposomal doxorubicin, or topotecan). Primary endpoint was PFS, and key secondary endpoints were ORR by investigator and OS.[3,4]*

*FRα positive is defined as ≥75% of viable tumor cells with moderate (2+) and/or strong (3+) membrane staining.[2]

Primary endpoint: PFS with ELAHERE vs standard chemotherapy (ITT population)[3,4]



35% reduction in risk of disease progression or death vs standard chemotherapy[3†]

+ Censored — ELAHERE: 5.6 months mPFS (95% CI: 4.3, 5.9) — Standard chemotherapy: 4.0 months mPFS (95% CI: 2.9, 4.5)

HR: 0.65 (95% CI: 0.52, 0.81), *P*<0.0001[3‡]
Median follow-up of 13.1 months[6]

†Risk reduction derived from the hazard ratio (HR: 0.65).[3]
‡Two-sided *P* value is based on stratified log-rank test.[3]

CI=confidence interval; FRα=folate receptor alpha; HR=hazard ratio; ITT=intent-to-treat; mPFS=median progression-free survival; ORR=overall response rate; OS=overall survival; PFS=progression-free survival.

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

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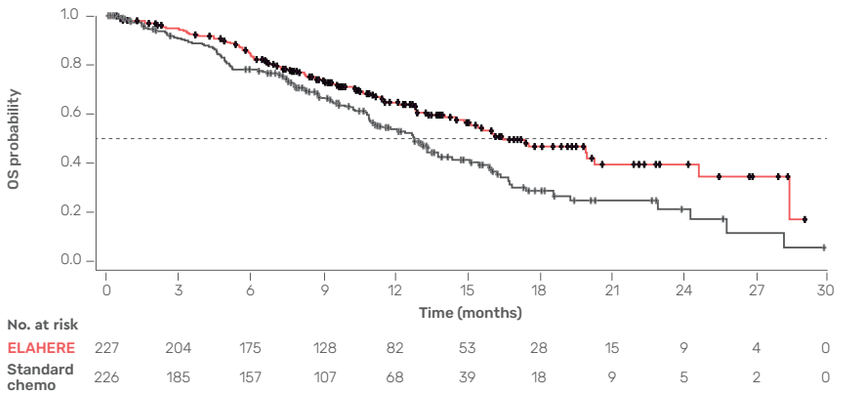
OS: ADD THE POSSIBILITY OF MORE TIME WITH ELAHERE[4,5]

Secondary endpoint: OS with ELAHERE vs standard chemotherapy[3]



ELAHERE reduced risk of death by

33%

vs standard chemotherapy[3]*

\+ Censored — **ELAHERE: 16.5 months mOS** (95% CI: 14.5, 24.6) — **Standard chemotherapy: 12.7 months mOS** (95% CI: 10.9, 14.4)

HR: 0.67 (95% CI: 0.50, 0.88), *P*=0.0046[3†]

Median follow-up of 13.1 months[4]

Investigators selected the chemotherapy prior to randomization in order to avoid selection bias.

*Risk reduction derived from the hazard ratio (HR: 0.67).[3]

†Two-sided *P* value is based on stratified log-rank test.[3]

CI=confidence interval; HR=hazard ratio; mOS=median overall survival; OS=overall survival.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS and PRECAUTIONS (cont'd)
Ocular Disorders (cont'd)

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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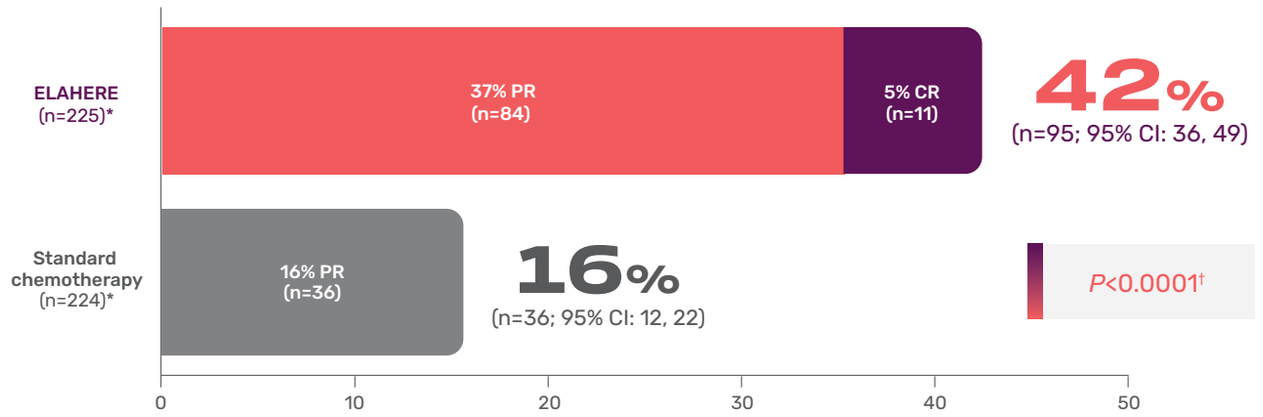
ORR: ADD THE OPPORTUNITY FOR A 2.5X GREATER RESPONSE RATE WITH ELAHERE[3]

Secondary endpoint: ORR[3]



COMPLETE RESPONSE[3]

5%
of patients experienced complete response with **ELAHERE**

VS

0%
of patients with **standard chemotherapy**

*N values are based on the number of patients with measurable disease at baseline.
†Two-sided *P* value is based on the stratified Cochran-Mantel-Haenszel (CMH) test.[3,4]

CI=confidence interval; CR=complete response; ORR=overall response rate; PR=partial response.

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.

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AN OVERVIEW OF SAFETY TO HELP SUPPORT YOUR PATIENTS THROUGH TREATMENT[3]

Adverse events in ≥10% of patients who received ELAHERE in MIRASOL[3]

Adverse event	ELAHERE (n=218)		Standard chemotherapy* (n=207)	
	All Grades (%)	Grades 3-4 (%)	All Grades (%)	Grades 3-4 (%)
GASTROINTESTINAL DISORDERS[3]				
Abdominal pain†	34	3	23	2
Diarrhea	29	1	17	0.5
Constipation	27	0	19	1
Nausea	27	2	29	2
Vomiting	18	3	18	1
EYE DISORDERS[3]				
Blurred vision‡	45	9	3	0
Keratopathy§	37	11	0	0
Dry eye¶	29	3	5	0
Photophobia	18	0.5	0.5	0
Cataract#	16	3	0.5	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS[3]				
Fatigue‖	47	3	41	7

Adverse event	ELAHERE (n=218)		Standard chemotherapy* (n=207)	
	All Grades (%)	Grades 3-4 (%)	All Grades (%)	Grades 3-4 (%)
NERVOUS SYSTEM DISORDERS[3]				
Peripheral neuropathy**	37	4	23	4
Headache	14	0	10	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS[3]				
Musculoskeletal pain††	31	1	21	2
METABOLISM AND NUTRITION DISORDERS[3]				
Decreased appetite	18	1	14	1
RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS[3]				
Pneumonitis‡‡	10	0.5	0.5	0

*Chemotherapy: paclitaxel, PLD, topotecan.[3]
†Abdominal pain includes abdominal pain, abdominal pain upper, abdominal pain lower, and abdominal discomfort.[3]
‡Blurred vision includes vision blurred, vitreous floaters, visual acuity reduced, diplopia, accommodation disorder, and visual impairment.[3]
§Keratopathy includes corneal disorder, corneal epithelial microcysts, keratitis, keratopathy, corneal deposits, punctate keratitis, and corneal opacity.[3]
¶Dry eye includes dry eye and lacrimation increased.[3]
#Cataract includes cataract and cataract nuclear.[3]
‖Fatigue includes fatigue and asthenia.[3]
**Peripheral neuropathy includes neuropathy peripheral, peripheral sensory neuropathy, peripheral motor neuropathy, paresthesia, hypoesthesia, polyneuropathy, neurotoxicity, and peripheral sensorimotor neuropathy.[3]
††Musculoskeletal pain includes back pain, myalgia, neck pain, arthralgia, musculoskeletal pain, noncardiac chest pain, bone pain, pain in extremity, musculoskeletal stiffness, musculoskeletal chest pain, and musculoskeletal discomfort.[3]
‡‡Pneumonitis includes pneumonitis, interstitial lung disease, respiratory failure, and organizing pneumonia.[3]

PLD=pegylated liposomal doxorubicin.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS and PRECAUTIONS (cont'd)

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.

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AN OVERVIEW OF SAFETY TO HELP SUPPORT YOUR PATIENTS THROUGH TREATMENT[3] (CONT'D)

Select laboratory abnormalities ≥10% for all grades in patients who received ELAHERE in MIRASOL[3]

Laboratory abnormality		ELAHERE (n=218)		Standard chemotherapy (n=207)	
		All Grades (%)	Grades 3-4 (%)	All Grades (%)	Grades 3-4 (%)
Liver function tests	Increased AST	57	0	14	0
	Increased ALT	38	1	15	1
	Increased alkaline phosphatase	30	1	13	1
Chemistry	Decreased albumin	21	1	27	2
	Decreased magnesium	21	1	29	2
	Decreased sodium	16	0	18	0
	Decreased potassium	15	1	11	1
	Increased calcium	12	0	5	0
	Decreased bicarbonate	11	0	11	0
	Increased creatinine	10	0	11	0
Hematology*	Decreased lymphocytes	27	3	42	11
	Decreased leukocytes	23	1	53	10
	Decreased neutrophils	22	1	45	17
	Decreased hemoglobin	18	1	63	8
	Decreased platelets	17	1	20	5

*The denominator used to calculate the rate varied from 63 to 214 (ELAHERE) and from 63 to 194 (IC chemotherapy) based on the number of patients with a baseline value and at least 1 posttreatment value.[3]

ALT=alanine aminotransferase; AST=aspartate aminotransferase; IC=investigator's choice.

IMPORTANT SAFETY INFORMATION (CONT'D)

USE IN SPECIAL POPULATIONS

Hepatic Impairment

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

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

Please see full Prescribing Information, including BOXED WARNING.

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AN OVERVIEW OF SAFETY TO HELP SUPPORT YOUR PATIENTS THROUGH TREATMENT[3] (CONT'D)

Adverse events seen in MIRASOL

	ELAHERE (n=218)[3,4]
Serious AEs (%)	**24** (n=52)
Discontinuations due to AEs (%)	**9** (n=20)
Common reasons for discontinuation (≥1%)	Pneumonitis (2%), blurred vision (1%), and peripheral neuropathy (1%)

The most common serious AEs with ELAHERE (≥2%) were intestinal obstruction (5%), abdominal pain (3%), and pleural effusion (3%). Fatal AEs occurred in 3% of patients and included intestinal obstruction, dyspnea in the setting of subileus, neutropenic sepsis, cardiopulmonary failure, respiratory failure, ischemic stroke, and pulmonary embolus[3]

AE=adverse event.

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

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EXPLORATORY ANALYSIS OF ELAHERE AND STANDARD CHEMOTHERAPY: ABDOMINAL AND GASTROINTESTINAL SYMPTOMS PROs IN MIRASOL

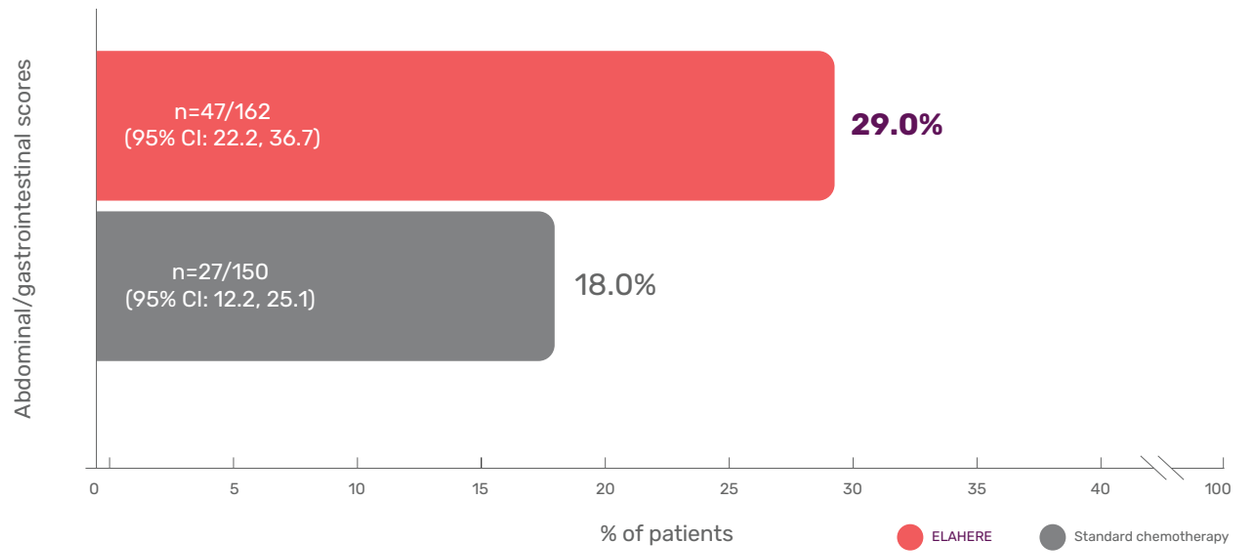
The EORTC QLQ-OV28 is a 28-item, ovarian cancer–specific questionnaire. With 7 multi-item symptom scales, it assesses abdominal and gastrointestinal symptoms, peripheral neuropathy, hormonal or menopausal symptoms, other chemotherapy side effects, body image, attitude toward disease or treatment, and sexual functioning. A 4-point Likert response scale is used for all items on the QLQ-OV28. The QLQ-OV28 has been validated in patients with ovarian cancer.[7]

The 15.0-point abdominal/GI QLQ-OV28 analysis was a key secondary endpoint of MIRASOL that did not meet statistical significance; therefore, no formal inferences may be drawn from the following numerical differences.[8]

Fifteen-point abdominal/GI pain threshold data[8]:
- ELAHERE 21.0% (n=34; 95% CI: 15.0, 28.1) vs IC chemotherapy 15.3% (n=23; 95% CI: 10.0, 22.1)

A 10% difference in QLQ-OV28 scores has been considered a minimal clinically important difference in other studies.[8]

Patients with ≥10% improvement from baseline in the QLQ-OV28 sensitivity analysis (11.1-point threshold) at week 8 or 9[8,9]



- **There was no prespecified statistical procedure controlling for type 1 error; therefore, no formal inferences may be drawn from the numerical difference**
- **While reported in literature, the 10% threshold has not been validated with clinical outcomes in this study**[8]

CI=confidence interval; EORTC QLQ=European Organization for Research and Treatment of Cancer quality of life questionnaire; GI=gastrointestinal; IC=investigator's choice; PRO=patient-reported outcome.

IMPORTANT SAFETY INFORMATION (CONT'D)

DRUG INTERACTIONS

DM4 is a CYP3A4 substrate. Closely monitor patients for adverse reactions with ELAHERE when used concomitantly with strong CYP3A4 inhibitors.

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

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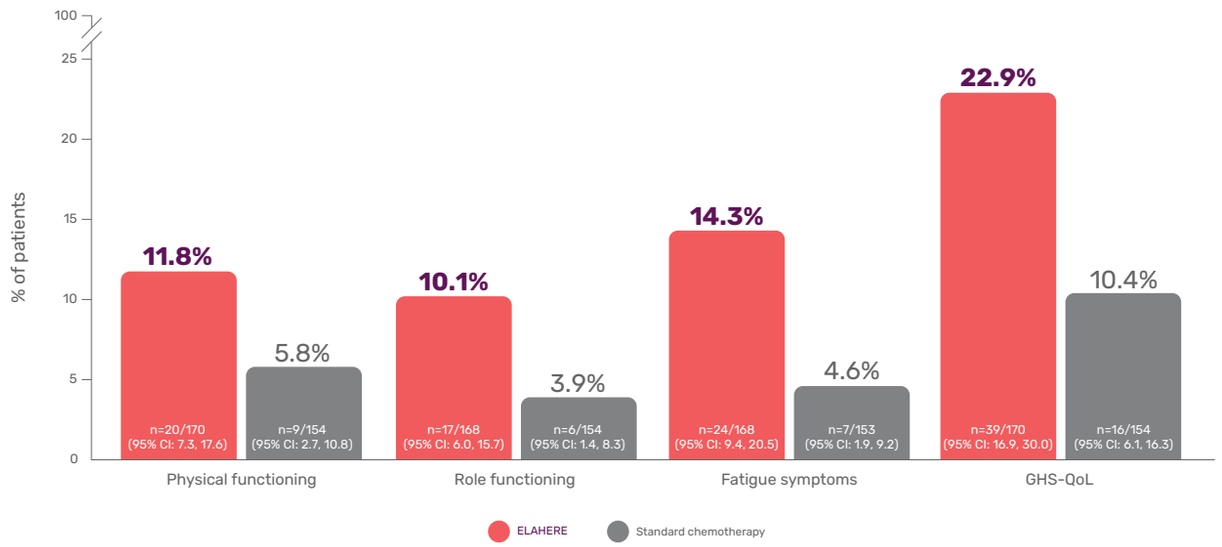
EXPLORATORY ANALYSIS OF ELAHERE AND STANDARD CHEMOTHERAPY ACROSS MULTIPLE PROs IN MIRASOL

The QLQ-C30 is a 30-item, multidimensional, cancer-specific questionnaire. It includes 5 multi-item function scales (physical, role, cognitive, emotional, and social), 3 multi-item symptom scales (fatigue, nausea and vomiting, and pain), 5 single-item symptom scales (dyspnea, insomnia, loss of appetite, constipation, and diarrhea), a financial impact question, and a 2-item global QoL scale. A 4-point Likert scale is used for all items except for the global health status/QoL scale, which uses a 7-point scale. The QLQ-C30 has been validated in patients with ovarian cancer.[7]

A 10% difference in QLQ-C30 scores has been considered a minimal clinically important difference in other studies.[8]

Patients with ≥10% improvement from baseline for the QLQ-C30 results[8,10]



- **There was no prespecified statistical procedure controlling for type 1 error; therefore, no formal inferences may be drawn from the numerical difference**
- **While reported in literature, the 10% threshold has not been validated with clinical outcomes in this study[8]**

CI=confidence interval; GHS-QoL=global health status/quality of life; PRO=patient-reported outcome; QLQ=quality of life questionnaire; QoL=quality of life.

IMPORTANT SAFETY INFORMATION (CONT'D)

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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ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

INDICATION AND IMPORTANT SAFETY INFORMATION

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.**

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.

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IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS and PRECAUTIONS (cont'd)

Pneumonitis (cont'd)

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.

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).

ULN=upper limit of normal.

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

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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.2.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed May 23, 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. ELAHERE. Package insert. AbbVie; 2024.
4. Moore KN, Angelergues A, Konecny GE, et al. *N Engl J Med*. 2023;389(23):2162-2174. doi:10.1056/NEJMoa2309169
5. Matulonis UA, Lorusso D, Oaknin A, et al. *J Clin Oncol*. 2023;41(13):2436-2445. doi:10.1200/JCO.22.01900
6. Coffman L, You B, Hamilton E, et al. Phase 3 MIRASOL trial: updated overall survival results of mirvetuximab soravtansine (MIRV) versus investigator's choice (IC) chemotherapy in patients (pts) with platinum-resistant ovarian cancer (PROC) and high folate receptor-alpha (FRα) expression. Poster presented at: European Society for Medical Oncology Congress; September 13-17, 2024; Barcelona, Spain.
7. van Stein RM, Hendriks FJ, Retèl VP, et al. *Gynecol Oncol Rep*. 2023;50:101293. doi:10.1016/j.gore.2023.101293
8. Van Gorp T, Moore KN, Konecny GE, et al. *Lancet Oncol*. 2025;26(4):503-515. doi:10.1016/S1470-2045(25)00021-X
9. Data on file, AbbVie Inc. ABVRRTI81196.
10. Data on file, AbbVie Inc. ABVRRTI81194.
11. Despierre E, Lambrechts S, Leunen K, et al. *Gynecol Oncol*. 2013;130(1):192-199. doi:10.1016/j.ygyno.2013.03.024
12. González-Martín A, Harter P, Leary A, et al. *Ann Oncol*. 2023;34(10):833-848. doi:10.1016/j.annonc.2023.07.011
13. Vanderpuye VD, Clemenceau JRV, Temin S, et al. *JCO Glob Oncol*. 2021;7:1032-1066. doi:10.1200/GO.21.00085

Find more helpful resources to use throughout treatment with ELAHERE here.

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

SEE WHAT YOU CAN ADD WITH ELAHERE AS YOUR FIRST CHOICE FOR FRα-POSITIVE PROC[3*†]

Primary endpoint: PFS with ELAHERE vs standard chemotherapy (ITT population)[4]

35%
reduction
in risk of disease progression or death vs standard chemotherapy[3‡]

Median PFS: 5.6 months (95% CI: 4.3, 5.9) vs 4.0 months (95% CI: 2.9, 4.5), *P*<0.0001[§]
Median follow-up of 13.1 months[6]

Secondary endpoint: OS with ELAHERE vs standard chemotherapy[4]

33%
reduction
in risk of death vs standard chemotherapy[3]

Median OS: 16.5 months (95% CI: 14.5, 24.6) vs 12.7 months (95% CI: 10.9, 14.4), *P*=0.0046[¶]
Median follow-up of 13.1 months[6]

Secondary endpoint: ORR[4]

More than 2.5x
as many patients responded with ELAHERE vs standard chemotherapy[3]

ORR: 42% (95% CI: 36, 49) vs 16% (95% CI: 12, 22), *P*<0.0001[#]

*MIRASOL was a confirmatory, global, multicenter, randomized, open-label study evaluating the efficacy and safety of ELAHERE vs investigator's choice chemotherapy in FRα-positive, platinum-resistant ovarian cancer; ELAHERE (n=227) vs standard single-agent chemotherapy (n=226; paclitaxel, pegylated liposomal doxorubicin, or topotecan).[3,4]
†FRα positive is defined as ≥75% of viable tumor cells with moderate (2+) and/or strong (3+) membrane staining.[2]
‡Risk reduction derived from the hazard ratio (HR: 0.65).[3]
§Reduced risk of disease progression or death by 35%; HR: 0.65 (95% CI: 0.52, 0.81).[3]
¶Reduced risk of death by 33%; HR: 0.67 (95% CI: 0.50, 0.88).[3]
#Investigator-assessed ORR; ELAHERE (n=225) vs standard chemotherapy (n=224) based on the number of patients with measurable disease at baseline.[3]

In the MIRASOL Phase 3 trial, ELAHERE was studied in a patient population with FRα-positive, platinum-resistant ovarian cancer. Patients were randomized 1:1 between ELAHERE (n=227) vs investigator's choice chemotherapy (n=226; paclitaxel, pegylated liposomal doxorubicin, or topotecan). Primary endpoint was PFS, key secondary endpoints were ORR by investigator and OS.[3,4]

Test appropriate patients with ovarian cancer for FRα as early as diagnosis to determine eligibility for ELAHERE monotherapy as soon as their disease becomes platinum resistant[3,11-13]

ELAHERE SAFETY PROFILE

- **Rate of serious AEs in MIRASOL: 24% with ELAHERE[3]**
- **The most common (≥20%) AEs in the pooled safety population, including laboratory 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[3]**

AE=adverse event; CI=confidence interval; FRα=folate receptor alpha; HR=hazard ratio; ITT=intent-to-treat; ORR=overall response rate; OS=overall survival; PFS=progression-free survival; PROC=platinum-resistant ovarian cancer.

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.**

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