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injection 100 mg

THE FIRST TREATMENT TO SHOW STATISTICALLY SIGNIFICANT IMPROVEMENTS IN FRα+ PLATINUM-RESISTANT OVARIAN CANCER[1-3]

ELAHERE improved PFS, OS, and ORR vs standard single-agent chemotherapy[1,2]

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.

SELECT 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.**

ORR=overall response rate; OS=overall survival; PFS=progression-free survival.

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information, including Boxed WARNING.

TESTING FOR FRα EXPRESSION IS RECOMMENDED AND CAN BE DONE AT DIAGNOSIS[4]

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Testing for FRα expression is an important step in the treatment paradigm[4]

~35% of patients with advanced ovarian cancer have tumors that test positive for FRα expression, which makes them potential candidates for ELAHERE monotherapy once they become resistant to platinum-based chemotherapy[1,3]

- The VENTANA FOLR1 IHC assay* defines FRα positivity as ≥75% of viable tumor cells staining with ≥2+ intensity, which is consistent with a high level of FRα expression[3,5]

FRα

FRα levels have been shown to remain consistent after chemotherapy, so expression can be tested right at diagnosis or anytime thereafter[6,7]

- The test can be performed on fresh or archival tissue[7]

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer recommend tumor molecular analysis, including testing for FRα, in patients with recurrent disease to identify potential benefit from targeted therapeutics[4]

Test all patients for FRα expression at diagnosis, and be ready to treat with ELAHERE as soon as appropriate patients become resistant to platinum-based chemotherapy[1,6†]

Contact your ELAHERE representative or preferred lab for details on testing.

*VENTANA FOLR1 (FOLR1–2.1) RxDx Assay.
†Platinum resistance is defined as disease recurrence within 6 months of treatment with platinum-based chemotherapy.

FOLR1=folate receptor 1; FRα=folate receptor alpha; IHC=immunohistochemistry; NCCN=National Comprehensive Cancer Network® (NCCN®).

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%)

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THE FIRST AND ONLY FRα-TARGETED TREATMENT FOR PLATINUM-RESISTANT OVARIAN CANCER[1]

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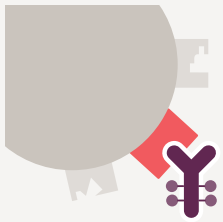
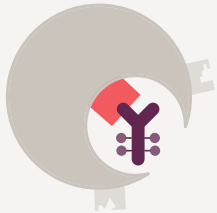
ELAHERE was designed to target FRα-expressing tumor cells[1,7-9]



ELAHERE is an ADC that binds to tumor surface receptor FRα



Upon binding to the FRα receptor, ELAHERE is internalized into the cell

This prompts intracellular release of DM4, a potent cytotoxic tubulin inhibitor, resulting in cell death

DM4 diffuses across the cell membrane and kills neighboring cells (bystander killing)*

*Via cell cycle arrest and apoptotic cell death.
ADC=antibody-drug conjugate; FRα=folate receptor alpha.

IMPORTANT SAFETY INFORMATION (CONT'D)

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

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MIRASOL: THE FIRST AND ONLY POSITIVE PHASE 3 STUDY VS SINGLE-AGENT CHEMOTHERAPY IN FRα+ PROC[2]

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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[2]*

Patient population (N=453)

Key eligibility:
- Platinum-resistant disease: PFI ≤6 months
- FRα positive: ≥75% of viable tumor cells staining with ≥2+ intensity

1:1 Randomization

ELAHERE (n=227)
(6 mg/kg AIBW q3w)

Investigator's choice chemotherapy (n=226)†:
- **41% paclitaxel (n=92)**
- **36% PLD (n=81)**
- **23% topotecan (n=53)**

Primary endpoint:
PFS by investigator

Key secondary endpoints:
- OS
- ORR by investigator
- PRO

*Includes epithelial ovarian, fallopian tube, or primary peritoneal cancer.
†Paclitaxel was administered intravenously on days 1, 8, 15, and 22 of a 4-week cycle (80 mg/m² of BSA); PLD was administered intravenously on day 1 of a 4-week cycle (40 mg/m²); and topotecan was administered intravenously on days 1, 8, and 15 of a 4-week cycle (4 mg/m²) or was administered intravenously on days 1–5 of a 3-week cycle (1.25 mg/m²).[2]

AIBW=adjusted ideal body weight; BSA=body surface area; FRα=folate receptor alpha; ORR=overall response rate; OS=overall survival; PFI=platinum-free interval; PFS=progression-free survival; PLD=pegylated liposomal doxorubicin; PRO=patient-reported outcome; PROC=platinum-resistant ovarian cancer; q3w=every 3 weeks.

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

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MIRASOL: THE FIRST AND ONLY POSITIVE PHASE 3 STUDY VS SINGLE-AGENT CHEMOTHERAPY IN FRα+ PROC[2] (CONT'D)

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- Patients received 1–3 lines of prior systemic therapy; prior bevacizumab and PARPi therapy allowed[2]
- Patients with *BRCA* mutations were allowed in the study[2]
- Patients with primary platinum-refractory disease, defined as progression-free interval <3 months, were excluded[2]
- Patients were excluded if they had corneal disorders, ocular conditions requiring ongoing treatment, Grade >1 peripheral neuropathy, or noninfectious interstitial lung disease[1]

ELAHERE received accelerated approval based on SORAYA, a single-arm study of patients with FRα-positive, platinum-resistant ovarian cancer (N=106). Patients had received up to 3 lines of prior systemic therapy and prior treatment with bevacizumab was required. The primary endpoint was investigator-assessed ORR and the key secondary endpoint was investigator-assessed DOR.[1,3] See SORAYA results.

BRCA=breast cancer gene; DOR=duration of response; FRα=folate receptor alpha; ORR=overall response rate; PARPi=poly(ADP-ribose) polymerase inhibitor; PROC=platinum-resistant ovarian cancer.

IMPORTANT SAFETY INFORMATION (CONT'D)

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

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MIRASOL PATIENT CHARACTERISTICS[2,10]

Characteristics, n (%)		ELAHERE (n=227)	Standard chemotherapy (n=226)
Median age (range)	Age in years	64 (32–88)	62 (29–87)
Stage at initial diagnosis	I-II	9 (4)	9 (4)
	III	137 (60)	147 (65)
	IV	76 (34)	65 (29)
***BRCA* mutation**	Yes	33 (15)	36 (16)
	No or unknown	198 (87)	190 (84)
Prior exposure	Bevacizumab	138 (61)	143 (63)
	PARPi	124 (55)	127 (56)
	Taxanes	227 (100)	224 (99)
Primary platinum-free interval	≤12 months	146 (64)	142 (63)
	>12 months	80 (35)	84 (37)
Platinum-free interval	≤3 months	88 (39)	99 (44)
	>3 to ≤6 months	138 (61)	124 (55)
Number of prior systemic therapies	1	29 (13)	34 (15)
	2	90 (40)	88 (39)
	3	108 (48)	104 (46)

In the overall MIRASOL patient population: 14% of patients had received 1 prior line of systemic therapy, 39% of patients had received 2 prior lines of systemic therapy, and 47% of patients had received 3 prior lines of systemic therapy; 37% of patients received prior systemic therapy for platinum-resistant disease; and 62% of patients received prior bevacizumab and 55% had received a prior PARPi.[1]

BRCA=breast cancer gene; PARPi=poly(ADP-ribose) polymerase inhibitor.

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IMPORTANT SAFETY INFORMATION (CONT'D)

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.

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MIRASOL PATIENT CHARACTERISTICS[2,10] (CONT'D)

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Characteristics, n (%)		ELAHERE (n=227)	Standard chemotherapy (n=226)
Investigator's choice of chemotherapy[a] (Selected prior to randomization)	Paclitaxel	93 (41)	92 (41)
	PLD	82 (36)	81 (36)
	Topotecan	52 (23)	53 (23)
ECOG PS	0	130 (57)	120 (53)
	1	97 (43)	101 (45)
	2	0	3 (1)
	Missing data	0	2 (1)
Race	White	156 (69)	145 (64)
	Black	8 (4)	5 (2)
	Asian	28 (12)	25 (11)
	Not reported	32 (14)	49 (22)
	Other	3 (1)	2 (1)
Ethnicity	Hispanic or Latino	12 (5)	15 (7)
	Not Hispanic or Latino	177 (78)	163 (72)
	Unknown	2 (1)	2 (1)
	Not reported	35 (15)	45 (20)
	Missing data	1 (<1)	1 (<1)

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

ECOG PS=Eastern Cooperative Oncology Group performance status; PLD=pegylated liposomal doxorubicin.

IMPORTANT SAFETY INFORMATION (CONT'D)

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

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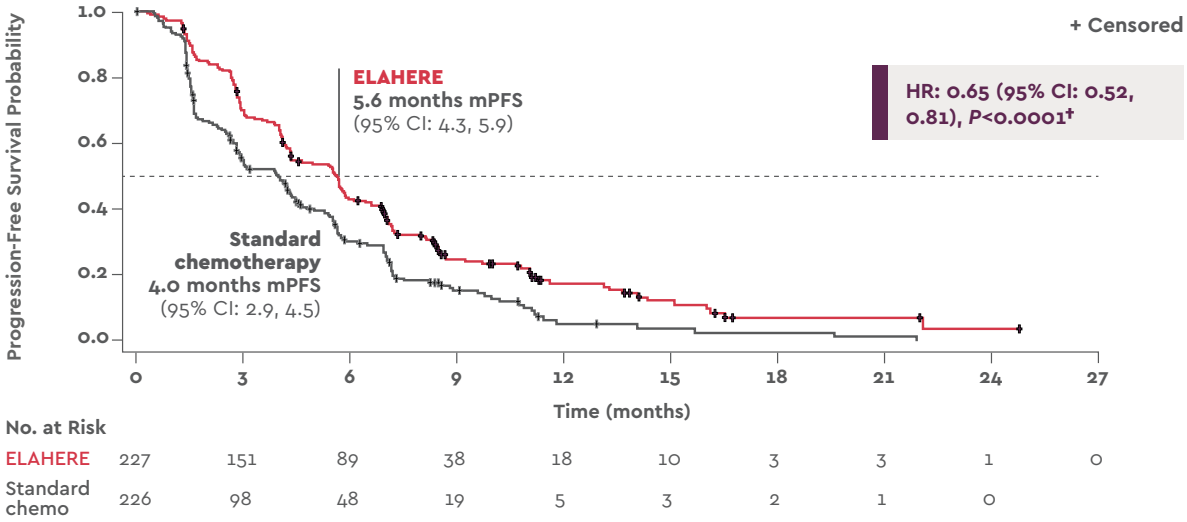
PFS: STATISTICALLY SIGNIFICANT IMPROVEMENT VS STANDARD CHEMOTHERAPY[1,2]

ELAHERE reduced risk of disease progression or death by 35% vs standard chemotherapy[1]*

Primary endpoint: Progression-free survival with ELAHERE vs standard single-agent chemotherapy (ITT population)[1]



Mirvetuximab soravtansine-gynx (ELAHERE) is recommended by the NCCN Guidelines® for Ovarian Cancer as an NCCN Category 2A preferred regimen for recurrence therapy in patients with folate receptor alpha–positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer[4]

*Risk reduction derived from the hazard ratio (HR=0.65).
†Two-sided *P* value based on stratified log-rank test.

CI=confidence interval; HR=hazard ratio; ITT=intent-to-treat; mPFS=median progression-free survival; NCCN=National Comprehensive Cancer Network® (NCCN®); PFS=progression-free survival.

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IMPORTANT SAFETY INFORMATION (CONT'D)

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

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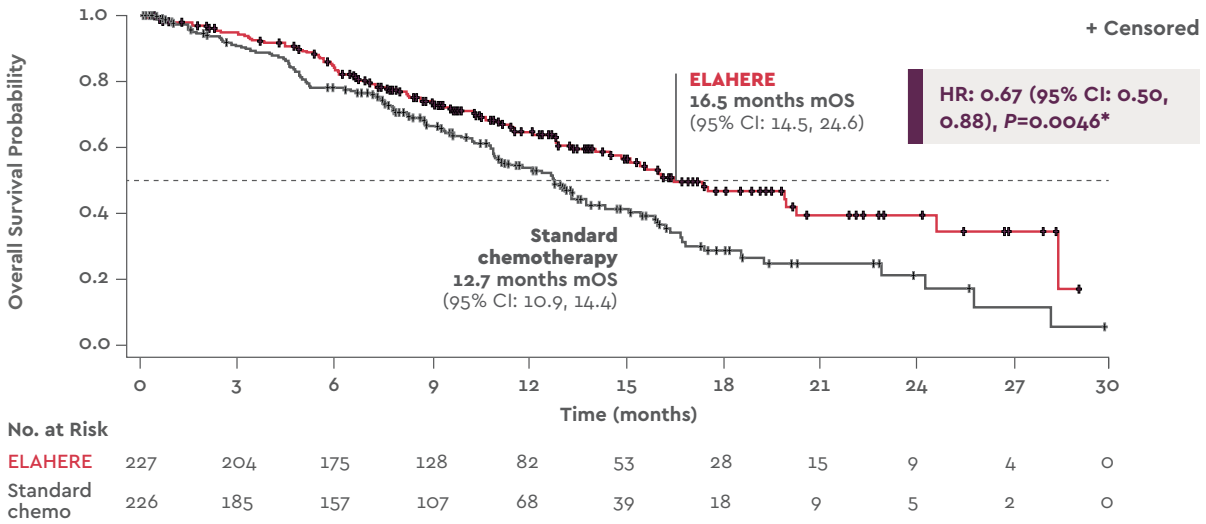
OS: FIRST AND ONLY FRα-TARGETED TREATMENT TO DELIVER A STATISTICALLY SIGNIFICANT IMPROVEMENT IN PROC[2,3]

ELAHERE delivered longer median overall survival than standard chemotherapy[1]

Secondary endpoint: Overall survival with ELAHERE vs standard chemotherapy[1]



ELAHERE reduced risk of death by 33% vs standard chemotherapy[1†]

*Two-sided *P* value based on stratified log-rank test.
†Risk reduction derived from the hazard ratio (HR=0.67).

CI=confidence interval; FRα=folate receptor alpha; HR=hazard ratio; mOS=median overall survival; OS=overall survival; PROC=platinum-resistant ovarian cancer.

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IMPORTANT SAFETY INFORMATION (CONT'D)

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.

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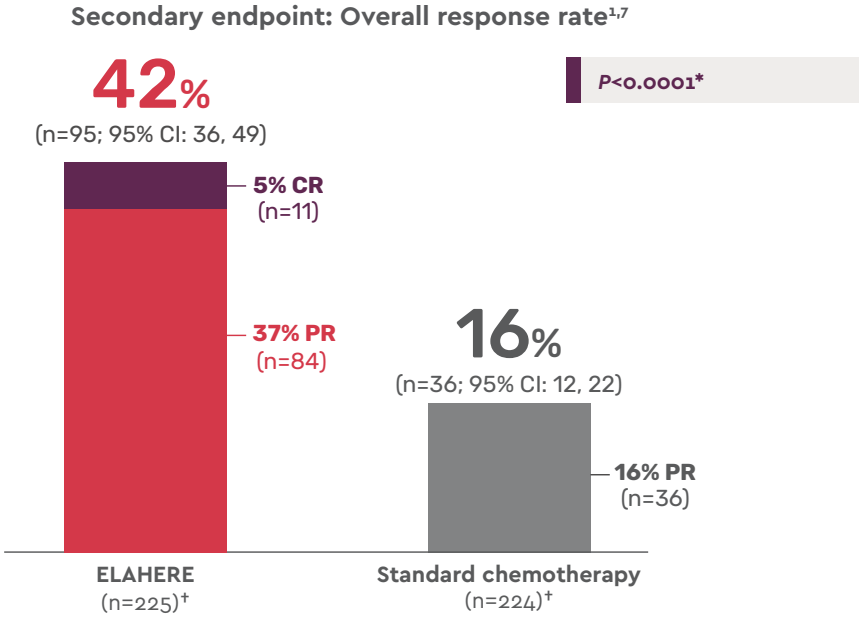
ORR: STATISTICALLY SIGNIFICANT IMPROVEMENT VS STANDARD CHEMOTHERAPY[1,2]

Complete responses: 11 patients with ELAHERE vs 0 patients with standard chemotherapy[7]



- Median duration of response: 6.77 months (n=95; 95% CI: 5.62, 7.89) with ELAHERE vs 4.47 months (n=36; 95% CI: 4.17, 5.82) with standard chemotherapy; HR: 0.64 (95% CI: 0.410, 0.993)[7]
- In the ITT population, 13.7% of patients treated with ELAHERE (n=31/227) had progressive disease vs 27.4% of patients treated with standard chemotherapy (n=62/226)[2]
- CA-125 response: 58.0% with ELAHERE (n=181; 95% CI: 50.5, 65.3) vs 30.3% with standard chemotherapy (n=155; 95% CI: 23.2, 38.2)[2]

*Two-sided *P* value based upon Cochran-Mantel-Haenszel (CMH) test.
†N values are based on the number of patients with measurable disease at baseline.

CA-125=cancer antigen 125; CI=confidence interval; CR=complete response; HR=hazard ratio; ITT=intent-to-treat; ORR=overall response rate; PR=partial response.

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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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MIRASOL STUDY SAFETY PROFILE

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

Adverse event	ELAHERE (n=218)		Standard chemotherapy (n=207)	
	All Grades (%)	Grades 3–4 (%)	All Grades (%)	Grades 3–4 (%)
GASTROINTESTINAL DISORDERS[1]				
Abdominal pain[a]	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[1]				
Blurred vision[b]	45	9	3	0
Keratopathy[c]	37	11	0	0
Dry eye[d]	29	3	5	0
Photophobia	18	0.5	0.5	0
Cataract[e]	16	3	0.5	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS[1]				
Fatigue[f]	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[1]				
Peripheral neuropathy[g]	37	4	23	4
Headache	14	0	10	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS[1]				
Musculoskeletal pain[h]	31	1	21	2
METABOLISM AND NUTRITION DISORDERS[1]				
Decreased appetite	18	1	14	1
RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS[1]				
Pneumonitis[i]	10	0.5	0.5	0
BLOOD AND LYMPHATIC SYSTEM DISORDERS[2]				
Neutropenia	11	0.9	29	17
Anemia	10	0.9	34	10

[a] Abdominal pain includes abdominal pain, abdominal pain upper, abdominal pain lower, and abdominal discomfort.
[b] Blurred vision includes vision blurred, vitreous floaters, visual acuity reduced, diplopia, accommodation disorder, and visual impairment.
[c] Keratopathy includes corneal disorder, corneal epithelial microcysts, keratitis, keratopathy, corneal deposits, punctate keratitis, and corneal opacity.
[d] Dry eye includes dry eye and lacrimation increased.
[e] Cataract includes cataract and cataract nuclear.
[f] Fatigue includes fatigue and asthenia.
[g] Peripheral neuropathy includes neuropathy peripheral, peripheral sensory neuropathy, peripheral motor neuropathy, paresthesia, hypoesthesia, polyneuropathy, neurotoxicity, and peripheral sensorimotor neuropathy.
[h] Musculoskeletal pain includes back pain, myalgia, neck pain, arthralgia, musculoskeletal pain, non-cardiac chest pain, bone pain, pain in extremity, musculoskeletal stiffness, musculoskeletal chest pain, and musculoskeletal discomfort.
[i] Pneumonitis includes pneumonitis, interstitial lung disease, respiratory failure, and organizing pneumonia.

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MIRASOL STUDY SAFETY PROFILE

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	ELAHERE (n=218)[1,2]	Standard chemotherapy (n=207)[2]
Grade ≥3 AEs (%)	**42** (n=91)	**54** (n=112)
Serious AEs (%)	**24** (n=52)	**33** (n=68)
Discontinuations due to AEs (%)	**9** (n=20)	**16** (n=33)
Common reasons for discontinuation (≥1%)	Pneumonitis (2%), blurred vision (1%), and peripheral neuropathy (1%)	Peripheral neuropathy (2%), thrombocytopenia (1%), and fatigue (1%)

The most common (≥2%) serious AEs were intestinal obstruction (5%), abdominal pain (3%), and pleural effusion (3%). Fatal AEs occurred in 3% of patients, including intestinal obstruction, dyspnea in the setting of subileus, neutropenic sepsis, cardiopulmonary failure, respiratory failure, ischemic stroke, and pulmonary embolus[1]

Dosage delays of ELAHERE due to an AE occurred in 54% of patients treated with ELAHERE. AEs which required dosage delays in ≥3% of patients included[1]:

- Blurred vision (22%)
- Keratopathy (19%)
- Dry eye (7%)
- Neutropenia (6%)
- Pneumonitis (6%)
- Photophobia (5%)
- Cataract (4%)
- Peripheral neuropathy (4%)

Dose reductions of ELAHERE due to an AE occurred in 34% of patients. AEs which required dose reductions in ≥3% of patients included[1]:

- Blurred vision (14%)
- Keratopathy (10%)
- Peripheral neuropathy (6%)
- Dry eye (5%)

Clinically relevant AEs that occurred in <10% of patients who received ELAHERE in the MIRASOL study included infusion-related reactions/hypersensitivity (8%)[1]

1% of patients treated with ELAHERE reported alopecia (Grade 1) vs 14% of patients treated with standard chemotherapy (7% Grade 1 and 7% Grade 2)[7]

In the MIRASOL study, the median duration of ELAHERE treatment was 5 months (range: 0.69 to 27.4)[1]

AE=adverse event.

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OCULAR EVENTS WITH ELAHERE FROM MIRASOL (N=218)[2,11]*

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Ocular events were mostly Grade 1 or 2[2,11]

- 56% of patients treated with ELAHERE had an ocular AE (n=122); of those who had an ocular AE, 14% were Grade ≥3 (n=30)[11]
- Of the patients treated with ELAHERE who had an ocular event (n=122), 51% had complete resolution and 42% had partial improvement.† Of the remaining 7% who had no documented improvement, 5% were at Grade 1 and 2% were at Grade 2[7,11]
- 1.8% of patients treated with ELAHERE discontinued due to ocular-related events[2]
- Median time to onset of first ocular AE was 5.4 weeks (range: 0.1 to 68.6)[2]

No corneal ulcerations or perforations have been reported[2]

*Data cutoff was March 6, 2023.[2]
†Partial improvement was defined as improvement by ≥1 grade from the worst grade at last follow-up.[11]
AE=adverse event.

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LABORATORY ABNORMALITIES[1]

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

IMPORTANT SAFETY INFORMATION (CONT'D)

Hepatic Impairment

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

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

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

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PROACTIVE MANAGEMENT OF OCULAR EVENTS

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Work with an eye care provider (optometrist or ophthalmologist) to manage ocular events that may occur.

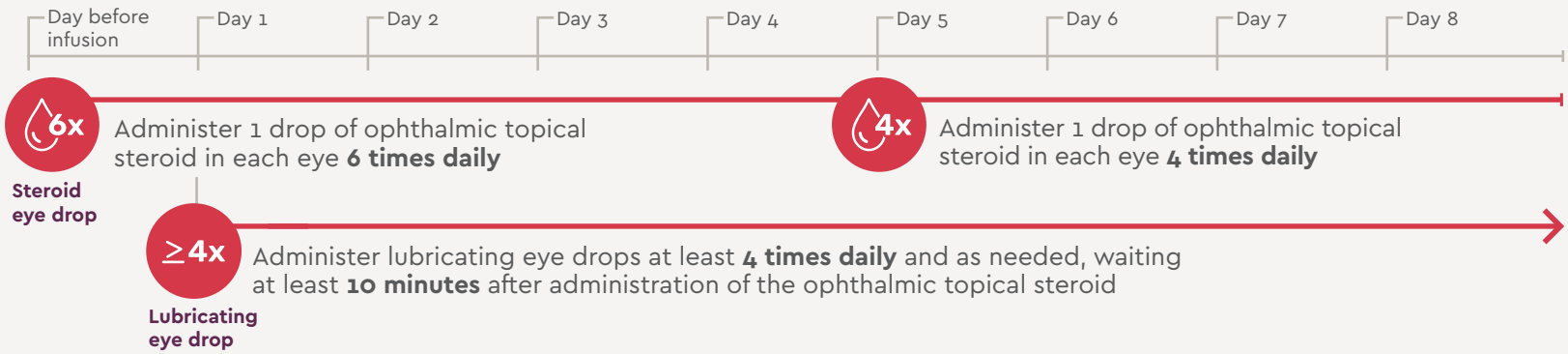
Patients should receive a baseline ophthalmic exam from an eye care provider, including visual acuity and slit-lamp exam, prior to treatment initiation, and follow-up exams during every other cycle for the first 8 cycles and as clinically indicated[1]

Tell your patients to avoid use of contact lenses[1]

Schedule for ophthalmic topical steroids and lubricating eye drops[1,7,12,13]

The use of ophthalmic topical steroids and preservative-free lubricating eye drops* is recommended

- The initial prescription and renewals of any corticosteroid medication should be made only after examination with a slit lamp



There are several resources available to help you and your patients manage their eye care:

Ocular assessment form for optometrists and ophthalmologists

Patient starter kit with lubricating eye drops, eye drop reminder checklist, and informational brochures

*Preservative-free is not a requirement for all patients. Lubricating eye drops without preservatives are recommended for patients with sensitive eyes.

Please see Full Prescribing Information, including Boxed WARNING.

ELAHERE SUPPORT SERVICES

ELAHERE®
mirvetuximab soravtansine-gynx
injection 100 mg

ELAHERE Support Services: Here to help your patients navigate access to their treatment

ELAHERE Support Services is committed to helping appropriate patients **start on ELAHERE** by offering **access** and **reimbursement** support as well as **affordability** assistance.

Access & reimbursement support

- Benefits investigation
- Prior authorization (PA) assistance
- Appeals assistance

Co-pay assistance program*

To support commercially eligible patients with out-of-pocket costs. **Patients could pay as little as $0 for their medication**

Patient Assistance Program (PAP)

To support uninsured or underinsured patients who meet eligibility requirements access medication at no charge†

Sign up your patient for ELAHERE Support Services using the ELAHERE Support Services **enrollment form**

ELAHERE®
SUPPORT SERVICES

Questions? Connect with an ELAHERE Support Services Program specialist
Phone: 1-833-ELAHERE (1-833-352-4373) Monday to Friday, 8 AM to 8 PM ET
Email: ELAHERESupport@cardinalhealth.com

*Terms and conditions apply. Patients are eligible for co-pay assistance if enrolled in private commercial health insurance and are not covered by state or federal healthcare programs, and who meet the eligibility criteria. Patients will be enrolled for 12 months. There are no income requirements to participate in the program.
†Criteria include: patients who are uninsured or have insurance that excludes coverage for ELAHERE (including patients on Medicare or Medicaid), residents of the United States or Puerto Rico, and patients who meet the financial eligibility requirements. Terms and conditions apply.

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INTEGRATING ELAHERE INTO PRACTICE

Process overview[1,5]

1. Test for FRα using VENTANA FOLR1 IHC assay
2. Order ELAHERE as indicated
3. Optometrist or ophthalmologist conducts a baseline eye exam
4. Prescribe topical ophthalmic steroid drops and reinforce lubricating and steroid eye drop schedules
5. Administer premedications and infuse ELAHERE at 6 mg/kg AIBW every 3 weeks
6. Monitor for AEs and modify dose as needed
7. Optometrist or ophthalmologist conducts follow-up exams every other cycle for first 8 cycles and as clinically indicated

AE=adverse event; AIBW=adjusted ideal body weight; FOLR1=folate receptor 1; FRα=folate receptor alpha; IHC=immunohistochemistry.

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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.

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).

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information, including Boxed WARNING.

REFERENCES

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THE FIRST TREATMENT TO SHOW STATISTICALLY SIGNIFICANT IMPROVEMENTS IN FRα+ PLATINUM-RESISTANT OVARIAN CANCER[1-3]

Statistically significant improvements in PFS, OS, and ORR with ELAHERE vs standard chemotherapy[1]

Efficacy endpoint	ELAHERE (n=227)	Standard chemotherapy (n=226)
Progression-free survival[1] HR: 0.65 (95% CI: 0.52, 0.81), *P*<0.0001	**5.6 months** (95% CI: 4.3, 5.9)	**4.0 months** (95% CI: 2.9, 4.5)
Overall survival[1] HR: 0.67 (95% CI: 0.50, 0.88), *P*=0.0046	**16.5 months** (95% CI: 14.5, 24.6)	**12.7 months** (95% CI: 10.9, 14.4)
Overall response rate[1,7] *P*<0.0001	**42%** (n=95/225) (95% CI: 36, 49)	**16%** (n=36/224) (95% CI: 12, 22)
• Complete response	**5%** (n=11)	**0%**
• Partial response	**37%** (n=84)	**16%** (n=36)
Duration of response[7]	**6.77 months** (95% CI: 5.62, 7.89)	**4.47 months** (95% CI: 4.17, 5.82)

ELAHERE safety profile[1]

- Rate of serious AEs: 24% with ELAHERE vs 33% with standard chemotherapy[2]
- The most common (≥20%) AEs, 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[1]
- 1% of patients treated with ELAHERE reported alopecia (Grade 1) vs 14% of patients treated with standard chemotherapy (7% Grade 1 and 7% Grade 2)[7]

AE=adverse event; CI=confidence interval; FRα=folate receptor alpha; HR=hazard ratio; ORR=overall response rate; OS=overall survival; PFS=progression-free survival.

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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 throughout and accompanying Full Prescribing Information, including Boxed WARNING.

immunogen