ELAHERE®
mirvetuximab soravtansine-gynx
injection 100 mg

NCCN CLINICAL PRACTICE GUIDELINES IN ONCOLOGY (NCCN GUIDELINES®)

The only NCCN **Category 1, Preferred** option for FRα-positive [≥75% positive tumor cells] platinum-resistant ovarian cancer[1,2]

SURVIVAL+

ELAHERE is the **first and only** treatment to show **superior efficacy** vs standard single-agent chemotherapy in FRα+ 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]

Not indicated for pediatric patients. Patient portrayal.

*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]
†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; NCCN=National Comprehensive Cancer Network® (NCCN®); 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.**

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

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

Why does FRα matter?

90%
of patients
with ovarian cancer express FRα in their cancer cells[6-8]

~35%
of patients
with advanced ovarian cancer have tumors that express FRα at a level that may make them candidates for ELAHERE monotherapy[3,5]

ADC

ELAHERE is an ADC designed to target FRα[3]

Knowing your patients' FRα status can help you be ready to treat with ELAHERE as soon as they become platinum resistant[2,3]

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

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.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

SPECIFICALLY REQUEST FRα TESTING FOR YOUR PATIENTS, AS IT MAY NOT BE AUTOMATIC[2,9]

Test for FRα with the FDA-approved VENTANA FOLR1 IHC assay[2,5,10,11]*

- **Testing can be done as early as diagnosis or any time after**
  - Formalin-fixed, paraffin-embedded archival or recently acquired tissue can be used for the test
- FRα expression is identified via IHC, not with genomic testing, so it may need to be requested as an add-on to a broad NGS panel

*VENTANA FOLR1 (FOLR1-2.1) RxDx Assay.

Activate on the results for appropriate patients[2,3]

- **Tumors with ≥75% of 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 recommend tumor molecular analysis, including FRα testing, for patients with recurrent disease to identify potential benefits from targeted therapies[1]

Test for FRα and see if your patients are eligible for treatment with ELAHERE as soon as they become platinum resistant[3,10]

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

IMPORTANT SAFETY INFORMATION (CONT'D)

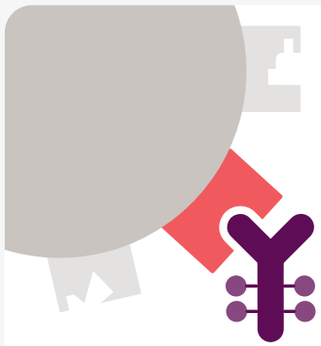
WARNINGS and PRECAUTIONS (cont'd)
Ocular Disorders (cont'd)

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%).

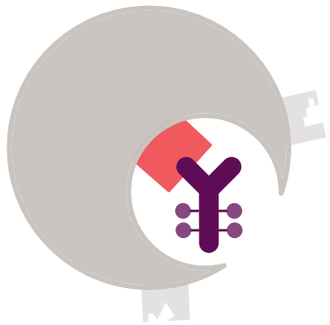
Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

ELAHERE IS DESIGNED TO TARGET FRα-EXPRESSING CELLS[3]

ELAHERE is an antibody-drug conjugate (ADC) that binds to cell surface receptor FRα[3,12-15]



ELAHERE binds to FRα on the cell surface with high affinity



Upon binding, ELAHERE is internalized by the cell and delivers a cytotoxic molecule

This prompts intracellular release of DM4, a cytotoxic microtubule inhibitor, resulting in cell cycle arrest and apoptotic cell death

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

*Via cell cycle arrest and apoptotic cell death.

The MOA of ELAHERE may affect cancer cells as well as healthy cells.[16]

NCCN Guidelines V.3.2024 recommend mirvetuximab soravtansine-gynx (ELAHERE®) as a 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]

FRα=folate receptor alpha; MOA=mechanism of action; NCCN=National Comprehensive Cancer Network® (NCCN®).

IMPORTANT SAFETY INFORMATION (CONT'D)

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

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.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

MIRASOL: THE FIRST, ONLY, AND LARGEST POSITIVE PHASE 3 STUDY SPECIFICALLY FOR PATIENTS WITH FRα+ PROC VS STANDARD CHEMOTHERAPY[3-5,17*]

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[3,4†]

Patient population[2,4] (N=453)

KEY ELIGIBILITY

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

1:1 Randomization[4]

ELAHERE[3] (n=227)
(6 mg/kg AIBW q3w)

Investigator's choice chemotherapy[4] (n=226)[‡]
- **41% paclitaxel (n=92)**
- **36% PLD (n=81)**
- **23% topotecan (n=53)**

Primary endpoint[4]

PFS by investigator

Key secondary endpoints[4§¶]

- ORR by investigator
- OS

*Versus single-agent chemotherapy.
†Includes epithelial ovarian, fallopian tube, or primary peritoneal cancer.[3]
‡Paclitaxel was administered intravenously on days 1, 8, 15, and 22 of a 4-week cycle (80 mg/m^2 of BSA); PLD was administered intravenously on day 1 of a 4-week cycle (40 mg/m^2); and topotecan was administered intravenously on days 1, 8, and 15 of a 4-week cycle (4 mg/m^2) or was administered intravenously on days 1 to 5 of a 3-week cycle (1.25 mg/m^2).[4]
§Since the primary endpoint was statistically significant, a hierarchical testing procedure was used to control the study-wise error rate for key secondary endpoints of ORR and OS, in that order.[4]
¶Due to there being no procedure in place to control the type I error on other secondary efficacy endpoints, all *P* values for treatment comparison on other secondary efficacy endpoints will be for information only and will be considered as nominal.[4,18]
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; PROC=platinum-resistant ovarian cancer; q3w=every 3 weeks.

IMPORTANT SAFETY INFORMATION (CONT'D)

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

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.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

MIRASOL: THE FIRST, ONLY, AND LARGEST POSITIVE PHASE 3 STUDY SPECIFICALLY FOR PATIENTS WITH FRα+ PROC VS STANDARD CHEMOTHERAPY[3-5,17]* (CONT'D)

KEY ELIGIBILITY CRITERIA FOR MIRASOL

- Patients received 1 to 3 lines of prior systemic therapy; prior bevacizumab and PARPi therapy were allowed[4]
- Patients with *BRCA* mutations were allowed in the study[4]
- Patients with primary platinum-refractory disease, defined as a PFI of <3 months, were excluded[4,19]
- Patients were excluded if they had corneal disorders, ocular conditions requiring ongoing treatment, Grade >1 peripheral neuropathy, or noninfectious interstitial lung disease[3]

ELAHERE received accelerated approval based on SORAYA, a single-arm study of patients with FRα-positive PROC (N=106)[3]

See SORAYA results

*Versus single-agent chemotherapy.
BRCA=breast cancer gene; FRα=folate receptor alpha; PARPi=poly(ADP-ribose) polymerase inhibitor; PFI=platinum-free interval; PROC=platinum-resistant ovarian cancer.

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.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

453 PARTICIPANTS REPRESENTING A RANGE OF DEMOGRAPHICS[3,4]

Characteristics[4]		ELAHERE, n (%) (n=227)	Standard chemotherapy, n (%) (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% had received 2 prior lines, and 47% had received 3 prior lines. Additionally, 37% of patients had received prior systemic therapy for platinum-resistant disease, 62% had received prior bevacizumab, and 55% had received a prior PARPi.[3]
BRCA=breast cancer gene; PARPi=poly(ADP-ribose) polymerase inhibitor.

IMPORTANT SAFETY INFORMATION (CONT'D)

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

Monitor for ocular toxicity and withhold, reduce, or permanently discontinue ELAHERE based on severity and persistence of ocular adverse reactions.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

453 PARTICIPANTS REPRESENTING A RANGE OF DEMOGRAPHICS[3,4] (CONT'D)

Characteristics[4]		ELAHERE, n (%) (n=227)	Standard chemotherapy, n (%) (n=226)
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)

ECOG PS=Eastern Cooperative Oncology Group performance status.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS and PRECAUTIONS (cont'd)

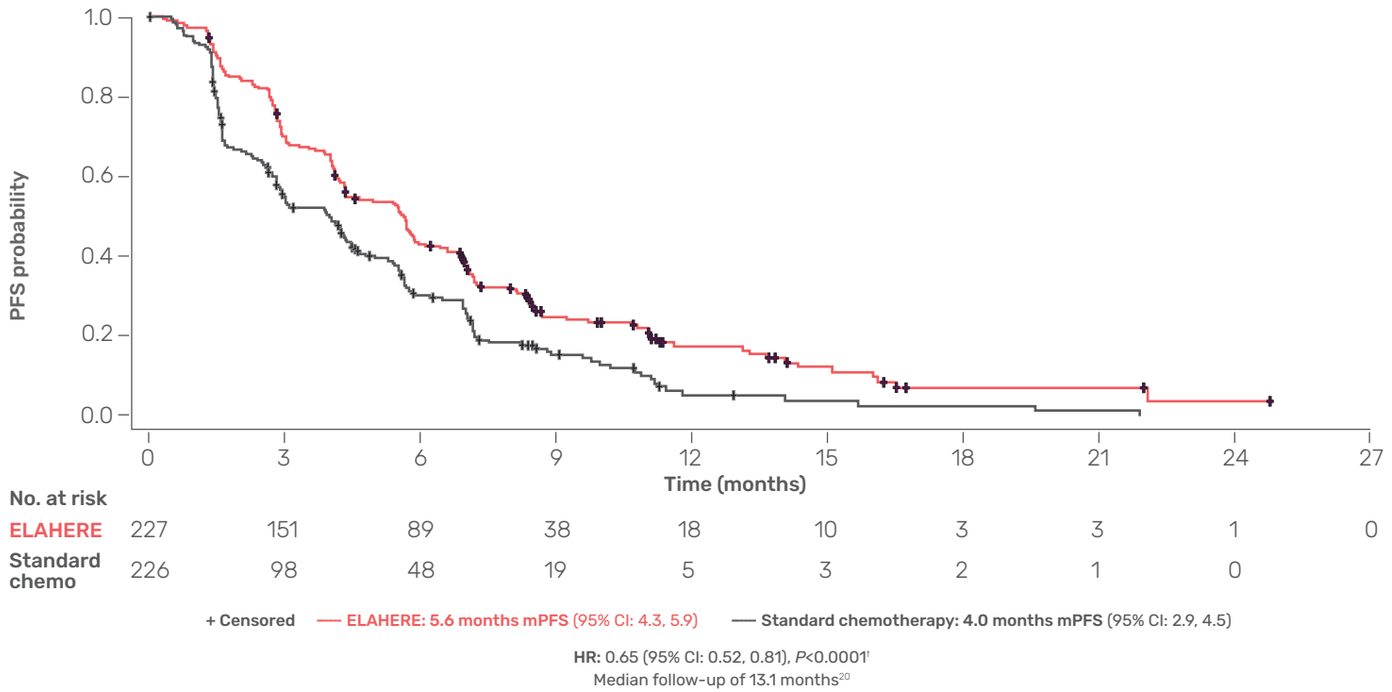
Pneumonitis

Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with ELAHERE.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

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

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



HR: 0.65 (95% CI: 0.52, 0.81), *P*<0.0001[†]
Median follow-up of 13.1 months[20]

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

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

CI=confidence interval; HR=hazard ratio; ITT=intent-to-treat; mPFS=median progression-free survival; PFS=progression-free survival.

IMPORTANT SAFETY INFORMATION (CONT'D)

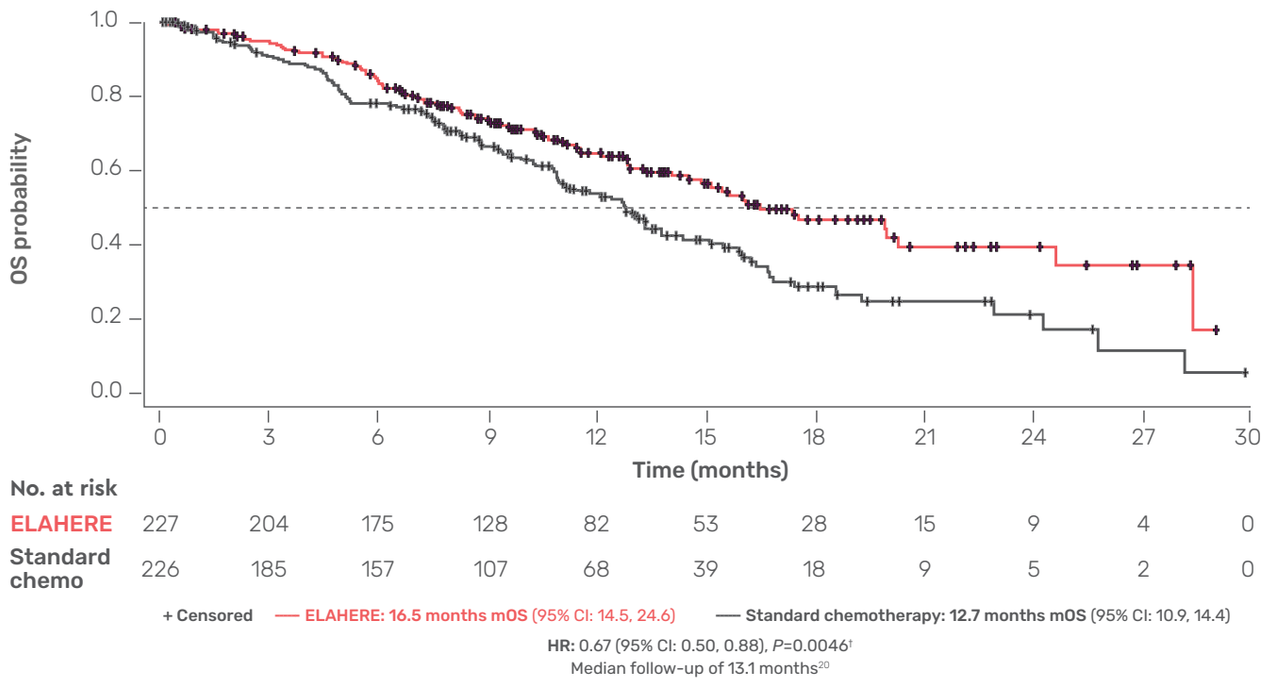
WARNINGS and PRECAUTIONS (cont'd)
Pneumonitis (cont'd)

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.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

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

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



HR: 0.67 (95% CI: 0.50, 0.88), *P*=0.0046†
Median follow-up of 13.1 months[20]

ELAHERE reduced risk of death by

33%

vs standard chemotherapy[3]*

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)

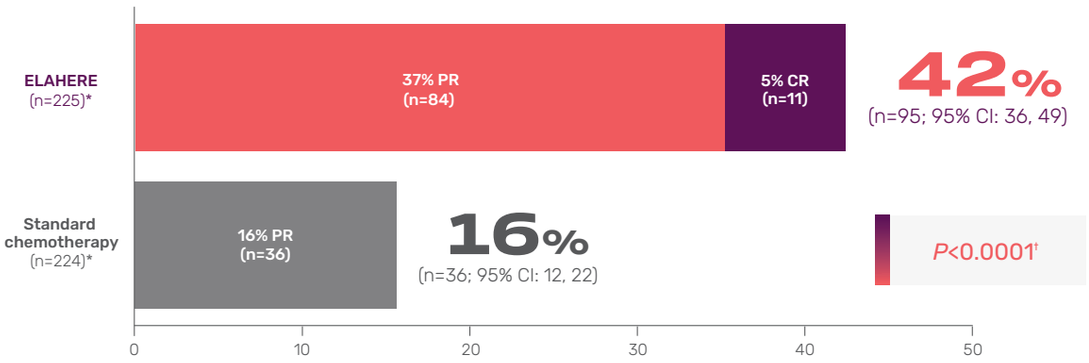
Pneumonitis (cont'd)

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.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

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

Secondary endpoint: ORR[3]



*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]

COMPLETE RESPONSE[3]

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

VS

0% of patients with **standard chemotherapy**

Other secondary endpoints

- Median DOR: 6.77 months (n=96; 95% CI: 5.62, 8.31) with ELAHERE vs 4.47 months (n=36; 95% CI: 4.17, 5.82) with standard chemotherapy; HR: 0.62 (95% CI: 0.40, 0.97)[4]
- CA-125 response: 58.0% with ELAHERE (n=105/181; 95% CI: 50.5, 65.3) vs 30.3% with standard chemotherapy (n=47/155; 95% CI: 23.2, 38.2)[4‡]

This study was not powered to evaluate other secondary endpoints. Data are exploratory and descriptive in nature. No formal inferences can be drawn.

‡A reduction in CA-125 levels of ≥50% from baseline, confirmed and maintained for at least 28 days.[21]

CA-125=cancer antigen 125; CI=confidence interval; CR=complete response; DOR=duration of response; HR=hazard ratio; 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.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

PFS: EFFICACY OF ELAHERE IN SELECT EXPLORATORY SUBGROUP ANALYSES BY TREATMENT HISTORY[4]

Subgroup[4]	Hazard ratio for disease progression or death (95% CI)	No. of participants	No. of events
No. of prior lines of therapy			
1	0.44 (0.24, 0.79)	63	48
2	0.68 (0.48, 0.95)	182	138
3	0.71 (0.52, 0.98)	208	156
1 or 2	0.61 (0.45, 0.81)	245	186
Previous exposure to bevacizumab			
Yes	0.64 (0.49, 0.84)	281	220
No	0.66 (0.46, 0.94)	172	122
Previous exposure to PARPi			
Yes	0.58 (0.43, 0.78)	251	181
No	0.74 (0.54, 1.03)	191	150
Uncertain	0.98 (0.27, 3.53)	11	11
Primary platinum-free interval			
≤6 mo	0.71 (0.49, 1.03)	147	118
>6 mo	0.63 (0.48, 0.82)	305	224
Platinum-free interval			
≤3 mo	0.73 (0.52, 1.03)	187	138
>3 mo	0.61 (0.46, 0.81)	266	204

This study was not powered to evaluate these prespecified subgroups. Data are exploratory and descriptive in nature. No formal inferences can be drawn.[4]

CI=confidence interval; PARPi=poly(ADP-ribose) polymerase inhibitor; PFS=progression-free survival.

IMPORTANT SAFETY INFORMATION (CONT'D)

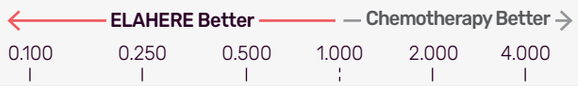
WARNINGS and PRECAUTIONS (cont'd)

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.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

OS: EFFICACY OF ELAHERE IN SELECT EXPLORATORY SUBGROUP ANALYSES BY TREATMENT HISTORY[4]



Subgroup[4]	Hazard ratio for death (95% CI)	No. of participants	No. of events
No. of prior lines of therapy			
1	0.51 (0.24, 1.10)	63	28
2	0.76 (0.48, 1.19)	182	77
3	0.65 (0.43, 0.96)	208	99
1 or 2	0.66 (0.45, 0.98)	245	105
Previous exposure to bevacizumab			
Yes	0.74 (0.54, 1.04)	281	142
No	0.51 (0.31, 0.86)	172	62
Previous exposure to PARPi			
Yes	0.48 (0.33, 0.71)	251	109
No	0.90 (0.59, 1.38)	191	87
Uncertain	0.51 (0.10, 2.59)	11	8
Primary platinum-free interval			
≤6 mo	1.02 (0.64, 1.62)	147	73
>6 mo	0.50 (0.35, 0.72)	305	131
Platinum-free interval			
≤3 mo	0.52 (0.33, 0.80)	187	88
>3 mo	0.79 (0.55, 1.14)	266	116

This study was not powered to evaluate these prespecified subgroups. Data are exploratory and descriptive in nature. No formal inferences can be drawn.[4]

CI=confidence interval; OS=overall survival; PARPi=poly(ADP-ribose) polymerase inhibitor.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS and PRECAUTIONS (cont'd)
Embryo-Fetal Toxicity (cont'd)

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.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

ORR: EFFICACY OF ELAHERE IN SELECT EXPLORATORY SUBGROUP ANALYSES BY TREATMENT HISTORY[22]

Subgroup[22]	Difference in ORR, % (95% CI)	No. of participants
No. of prior lines of therapy		
1	39.0 (18.7, 59.3)	63
2	28.6 (15.8, 41.3)	182
3	20.6 (8.8, 32.5)	208
1 or 2	31.3 (20.4, 42.1)	245
Previous exposure to bevacizumab		
Yes	26.6 (16.7, 36.5)	281
No	25.6 (12.1, 39.1)	172
Previous exposure to PARPi		
Yes	27.8 (16.9, 38.8)	251
No	26.4 (14.4, 38.4)	191
Uncertain	-3.3 (-49.4, 42.7)	11
Primary platinum-free interval		
≤6 mo	26.8 (13.6, 40.0)	147
>6 mo	26.2 (16.2, 36.2)	305
Platinum-free interval		
≤3 mo	23.6 (11.1, 36.1)	187
>3 mo	28.1 (17.7, 38.5)	266

This study was not powered to evaluate these prespecified subgroups. Data are exploratory and descriptive in nature. No formal inferences can be drawn.[4]

ORR population includes 2 patients from each arm that do not appear in the Prescribing Information analysis (patients removed had a CR and PD in the ELAHERE arm and an SD and NE in the investigator's choice arm).

CI=confidence interval; CR=complete response; NE=not evaluable; ORR=overall response rate; PARPi=poly(ADP-ribose) polymerase inhibitor; PD=progressive disease; SD=stable disease.

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.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

A DETAILED SAFETY PROFILE TO HELP YOU 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.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

A DETAILED SAFETY PROFILE TO HELP YOU 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 accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

A DETAILED SAFETY PROFILE TO HELP YOU 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.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

A DETAILED SAFETY PROFILE TO HELP YOU SUPPORT YOUR PATIENTS THROUGH TREATMENT[3] (CONT'D)

Adverse events seen in MIRASOL

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

- 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 that required dose reductions in ≥3% of patients included[3]:

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

Clinically relevant AEs that occurred in <10% of patients who received ELAHERE included infusion-related reactions/hypersensitivity (8%)[3]

The median duration of ELAHERE treatment was 5 months (range: 0.69 to 27.4)[3]

AE=adverse event.

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.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

ADDITIONAL ADVERSE EVENTS OF INTEREST[22,23]

Events reported in MIRASOL, in addition to safety data from the ELAHERE Prescribing Information

Adverse event		ELAHERE[22,23] (n=218)	Standard chemotherapy[22,23] (n=207)
		All Grades (%)	All Grades (%)
General	Alopecia	1	14
Gastrointestinal	Stomatitis	3	11
Hematologic	Anemia	10	34
	Neutropenia	11	29
	Thrombocytopenia	7	16

This analysis was not powered to demonstrate a difference in adverse events between ELAHERE and traditional chemotherapy.

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.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

OCULAR EVENTS SEEN AND MANAGED ACROSS CLINICAL TRIALS[4,22]*

Ocular events were mostly Grade 1 or 2[4,22]

59% of patients treated with ELAHERE had an ocular event; 11% of patients experienced Grade 3 ocular events[3]

Ocular events completely or partially resolved for most patients[3]

Of the patients treated with ELAHERE who had an ocular event, 53% had complete resolution and 38% had partial improvement†

1% of patients discontinued ELAHERE due to ocular events[3]

Median time to onset of the first ocular event was 5.1 weeks (range: 0.1 to 68.6)[3]

This pooled safety population reflects exposure to ELAHERE in 682 patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer at 6 mg/kg AIBW administered intravenously once every 3 weeks until disease progression or unacceptable toxicity in 4 clinical trials: MIRASOL, SORAYA, NCT02631876, and NCT01609556. The median duration of treatment was 4.4 months (range: 1.0 to 30.0). The most common (≥5%) ocular adverse reactions were blurred vision (48%), keratopathy (36%), dry eye (27%), cataract (16%), photophobia (14%), and eye pain (10%).[3]

*In Study 0416, Study 0417, Study 0403 (NCT02631876), and Study 0401 (NCT01609556).[3]
†Partial improvement was defined as improvement by ≥1 grade from the worst grade at last follow-up.[22]

Ocular events seen in MIRASOL[4,24]

56% (n=122) of patients treated with ELAHERE experienced an ocular event vs 9% of patients receiving standard chemotherapy.

- Of the patients treated with ELAHERE who had an ocular event, 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

This analysis was not powered to demonstrate a difference in adverse events between ELAHERE and traditional chemotherapy.

AIBW=adjusted ideal body weight.

IMPORTANT SAFETY INFORMATION (CONT'D)
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 accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

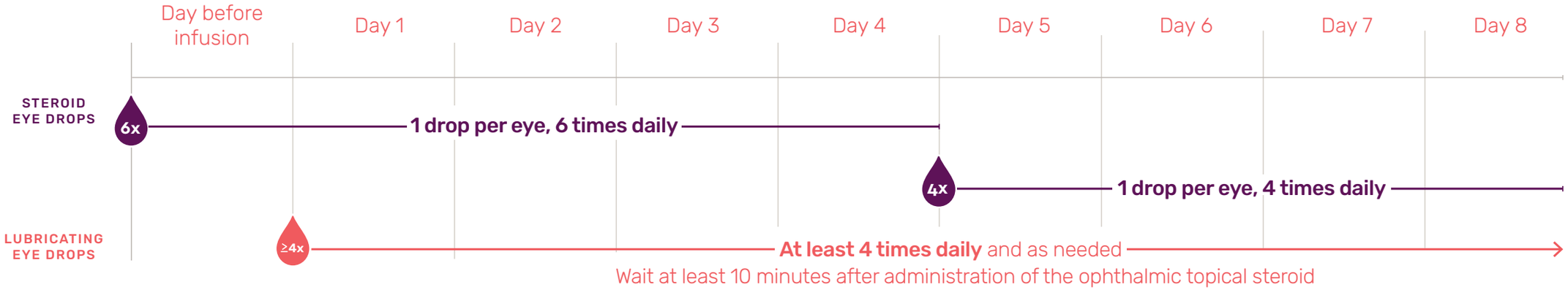
PROACTIVE MANAGEMENT MAY HELP WITH POTENTIAL OCULAR EVENTS[3,22]

Work with an eye care provider (optometrist or ophthalmologist)[3]

- Prior to treatment initiation, patients should receive a baseline ophthalmic exam, including a visual acuity and slit lamp exam
- Patients should have follow-up exams during every other cycle for the first 8 cycles and as clinically indicated

Schedule for eye drops[3]

- 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 a slit lamp exam



*Preservative-free eye drops are not a requirement for all patients. Lubricating eye drops without preservatives are recommended for patients with sensitive eyes.[25,26]

- Tell your patients to avoid the use of contact lenses[3]

Resources are available to help you and your patients manage their eye care:

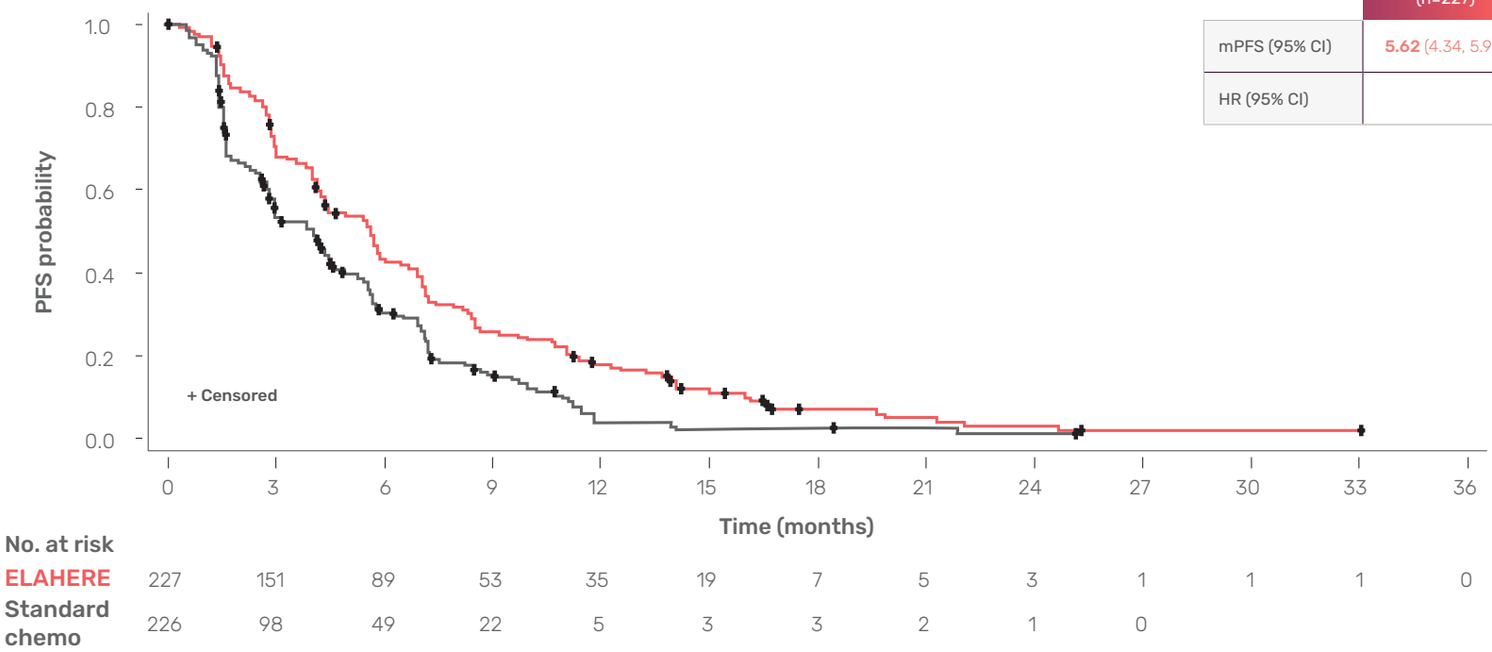
- ✓ **Ocular Assessment Form** for optometrists and ophthalmologists
- ✓ Informational **videos and brochures**
- ✓ **Patient Starter Kit** with lubricating eye drops

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

PFS: RESULTS IN A LONGER-TERM FOLLOW-UP[20]*

After the primary analysis data cutoff of March 6, 2023, ELAHERE continued to be studied in patients until October 27, 2023, with a median follow-up of 20.3 months. This represents the updated nonanalytical results from the extended data cutoff[20]

Post hoc PFS by investigator (ITT population)[20]



	ELAHERE (n=227)	Standard chemotherapy (n=226)
mPFS (95% CI)	**5.62** (4.34, 5.95)	**3.98** (2.86, 4.47)
HR (95% CI)	**0.64** (0.52, 0.80)	

*Through day 120 after the primary analysis.[20]

No inference can be drawn for this data set. Follow-up analysis is exploratory and data are descriptive in nature.

CI=confidence interval; HR=hazard ratio; ITT=intent-to-treat; mPFS=median progression-free survival; PFS=progression-free survival.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS and PRECAUTIONS

Ocular Disorders

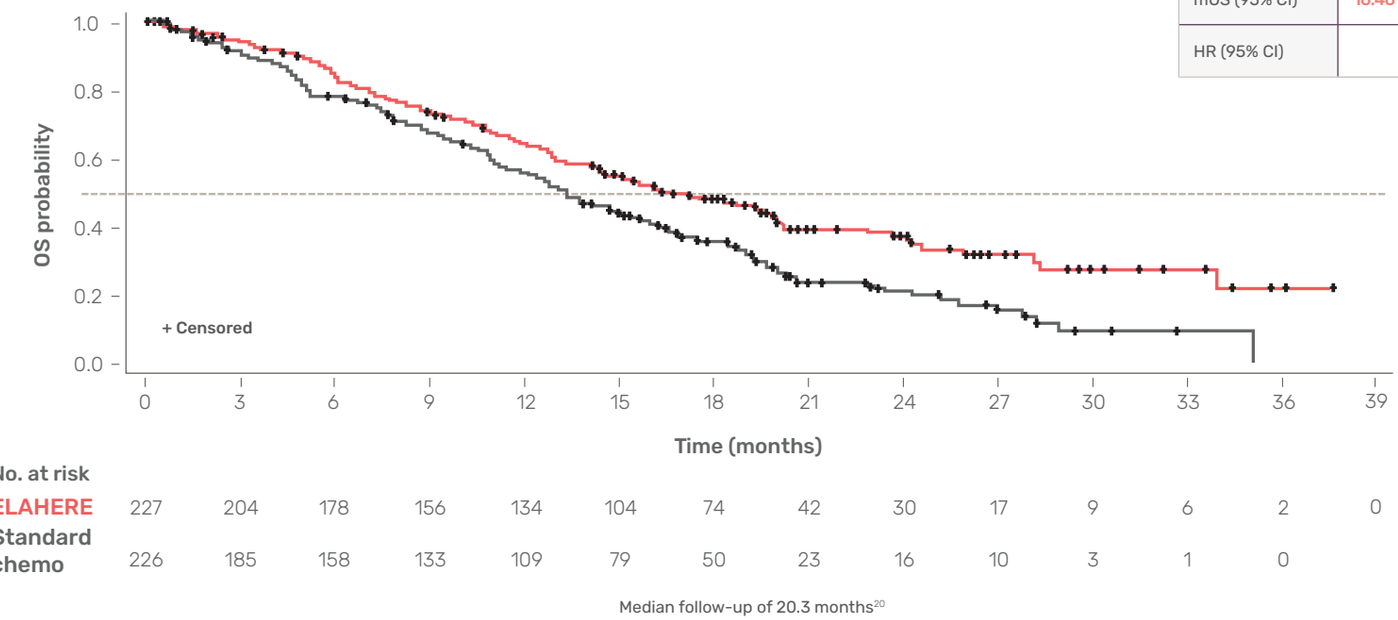
ELAHERE can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

OS: CONSISTENT RESULTS IN A LONGER-TERM FOLLOW-UP[20]*

Post hoc OS (ITT population)[20]

	ELAHERE (n=227)	Standard chemotherapy (n=226)
mOS (95% CI)	**16.46** (14.36, 19.88)	**13.34** (11.37, 15.44)
HR (95% CI)	**0.67** (0.53, 0.86)	



Median follow-up of 20.3 months[20]

*Through day 120 after the primary analysis.[20]

No inference can be drawn from this data set. Follow-up analysis is exploratory and data are descriptive in nature.

CI=confidence interval; HR=hazard ratio; ITT=intent-to-treat; mOS=median overall survival; OS=overall survival.

IMPORTANT SAFETY INFORMATION (CONT'D)

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

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%).

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

NO NEW SAFETY SIGNALS IDENTIFIED IN THE LONGER-TERM FOLLOW-UP[20]

Updated safety by treatment cohort in MIRASOL[20]*

Adverse event		ELAHERE (n=218)		Standard chemotherapy† (n=207)	
		All Grades (%)	Grades 3-4 (%)	All Grades (%)	Grades 3-4 (%)
Gastrointestinal disorders	Diarrhea	29	1	17	<1
	Nausea	27	2	29	2
	Abdominal pain	31	3	15	1
	Stomatitis	4	0	11	<1
	Constipation	27	<1	19	1
Ocular	Blurred vision	43	8	2	0
	Keratopathy	33	9	0	0
	Dry eye	29	4	2	0
Hematologic	Neutropenia	11	<1	29	17
	Anemia	10	<1	34	10
	Thrombocytopenia	8	<1	16	6
Miscellaneous	Fatigue	30	2	25	5
	Dyspnea	8	1	13	3
	Alopecia‡	1	0	14	0
	Peripheral neuropathy	22	1	14	2

Updated safety overview in MIRASOL[20]*

Events, n (%)	ELAHERE (n=218)	Standard chemotherapy, n (%) (n=207)
Any TEAE	210 (96)	194 (94)
Grade ≥3 TEAE	93 (43)	112 (54)
Serious AEs	55 (25)	68 (33)
Treatment-related serious AEs	21 (10)	16 (8)
Dose reductions due to TEAEs	75 (34)	50 (24)
Dose delays/holds due to TEAEs	121 (56)	111 (54)
Discontinuations due to TEAEs	22 (10)	33 (16)
Deaths on study drug or within 30 days of last dose	9 (4)	11 (5)

*Safety population.[20]
†Paclitaxel, n=82; PLD, n=76; topotecan, n=49.[20]
‡Grade 3 events not applicable for alopecia.[20]

Long-term safety adverse events are preferred terms and not grouped terms.[20]

Additional data from the ELAHERE Prescribing Information include[3]:

- Fatigue
  - ELAHERE: 47% (all grades), 3% (Grades 3-4)
  - Standard chemotherapy: 41% (all grades), 7% (Grades 3-4)
- Peripheral neuropathy
  - ELAHERE: 37% (all grades), 4% (Grades 3-4)
  - Standard chemotherapy: 23% (all grades), 4% (Grades 3-4)

No inference can be drawn from this data set. Follow-up analysis is exploratory and data are descriptive in nature.

AE=adverse event; PLD=pegylated liposomal doxorubicin; TEAE=treatment-emergent adverse event.

IMPORTANT SAFETY INFORMATION (CONT'D)

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

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.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

ACCESS, ASSISTANCE, AND MORE WITH ELAHERE SUPPORT SERVICES (ESS)

What ESS offers

Once enrolled, ESS offers the following services and programs for patients:

ACCESS & REIMBURSEMENT

- Benefits investigation
- Prior authorization assistance
- Appeals assistance

COPAY ASSISTANCE*

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

PATIENT ASSISTANCE

- Support for uninsured or underinsured patients who meet eligibility requirements to access medication at no charge†

NURSE NAVIGATORS

- A resource available to patients and their caregivers to answer questions about their treatment based on the Prescribing Information

ELAHERE® SUPPORT SERVICES

Get in touch with ELAHERE Support Services

For questions, connect with an ELAHERE Support Services program specialist by calling 1-833-ELAHERE (1-833-352-4373), Monday to Friday, 8 AM to 8 PM ET, or emailing ELAHERESupport@cardinalhealth.com

1-833-ELAHERE (1-833-352-4373)

1-833-464-6329

elaherehcp.com

ELAHERESupport @cardinalhealth.com

830 Winter Street
Waltham, MA 02451

*Terms and conditions apply. Patients are eligible for copay 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.

Enroll your patients in ELAHERE Support Services

Visit elaherehcp.com to download and complete the enrollment form

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

HELPFUL RESOURCES

Patient resources

PATIENT EYE DROP TRACKER

Also available in Spanish and Mandarin

- Includes useful tips for helping patients manage their eye care
- Patients can track eye drops, take notes to share with their doctor, and record upcoming appointments

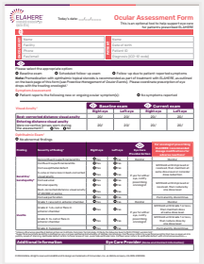
PATIENT STARTER KIT

- Tools to help patients get started on ELAHERE
- Includes welcome card, dry erase magnet and marker, ocular brochure, eye drops, and wallet card

PATIENT WELCOME KIT

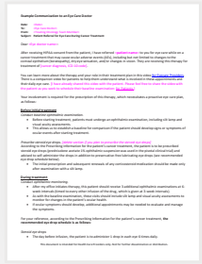
- ESS can provide Welcome Kits for new patients
- Includes welcome card, blanket, lotion, eye drops, and lip balm

HCP resources



OCULAR ASSESSMENT FORM

- Designed to facilitate the management of eye care among healthcare professionals
- Aids in reporting of exam findings to the treating oncologist and helps determine if dose modifications may be needed



ECP REFERRAL TEMPLATE

- Provides an example of an eye care provider (ECP) referral letter
- Includes detailed information about managing eye care during treatment with ELAHERE

Find even more support at elaherehcp.com

ESS=ELAHERE Support Services; HCP=healthcare professional.

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

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

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[‡]

33%
reduction
in the 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[§]

More than 2.5x
as many patients responded with ELAHERE[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]
†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]

Test appropriate patients with ovarian cancer for FRα as early as diagnosis to determine eligibility for ELAHERE monotherapy as soon as they become platinum resistant[3,10]

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; ORR=overall response rate; OS=overall survival; PFS=progression-free survival; PROC=platinum-resistant ovarian cancer.

IMPORTANT SAFETY INFORMATION (CONT'D)
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 accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

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.

INDICATION AND IMPORTANT SAFETY INFORMATION (CONT'D)

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.

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).

Please see additional Important Safety Information, including Boxed WARNING, throughout.
Please see accompanying Full Prescribing Information or visit rxabbvie.com/pdf/elahere_pi.pdf.

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.3.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed February 25, 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. 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
7. Markert S, Lassmann S, Gabriel B, et al. *Anticancer Res*. 2008;28(6A):3567-3572.
8. 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
9. Provider FAQs. Foundation Medicine. Accessed February 25, 2025. https://www.foundationmedicine.com/faq/provider-faqs
10. Despierre E, Lambrechts S, Leunen K, et al. *Gynecol Oncol*. 2013;130(1):192-199. doi:10.1016/j.ygyno.2013.03.024
11. US Food and Drug Administration. Premarket approval letter for VENTANA FOLR1 (FOLR-2.1) RxDx Assay. November 14, 2022. Accessed February 25, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf22/P220006A.pdf
12. Kovtun YV, Audette CA, Ye Y, et al. *Cancer Res*. 2006;66(6):3214-3221. doi:10.1158/0008-5472.CAN-05-3973
13. Erickson HK, Park PU, Widdison WC, et al. *Cancer Res*. 2006;66(8):4426-4433. doi:10.1158/0008-5472.CAN-05-4489
14. Tsumura R, Manabe S, Takashima H, Koga Y, Yasunaga M, Matsumura Y. *J Control Release*. 2018;284:49-56. doi:10.1016/j.jconrel.2018.06.016
15. Miotti S, Canevari S, Ménard S, et al. *Int J Cancer*. 1987;39(3):297-303. doi:10.1002/ijc.2910390306
16. Nguyen TD, Bordeau BM, Balthasar JP. *Cancers (Basel)*. 2023;15(3):713. doi:10.3390/cancers15030713
17. ClinicalTrials.gov. Accessed February 25, 2025. https://clinicaltrials.gov/search?cond=Platinum-resistant%20Ovarian%20Cancer&term=Folate%20Receptor%20Alpha%20Positive&aggFilters=phase:3,results:with,status:com
18. Data on file. AbbVie, Inc.
19. Data on file. AbbVie, Inc.
20. 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.
21. Data on file. AbbVie, Inc.
22. Moore KN, Angelergues A, Konecny GE, et al. *N Engl J Med*. 2023;389(23):2162-2174. Supplementary appendix. doi:10.1056/NEJMoa2309169
23. Data on file. AbbVie, Inc.
24 Data on file. AbbVie, Inc.
25. Data on file. AbbVie, Inc.
26. Moore KN, Martin LP, Matulonis UA, et al. IMGN853 (mirvetuximab soravtansine), a folate receptor alpha (FRα)-targeting antibody-drug conjugate (ADC): single agent activity in platinum-resistant epithelial ovarian cancer (EOC) patients. Poster presented at: American Society of Clinical Oncology Annual Meeting; June 3-7, 2016; Chicago, IL.