ELAHERE®
mirvetuximab soravtansine-gynx
injection 100 mg
SUPPORT SERVICES

Getting started: use this checklist to help enroll your patient in ELAHERE Support Services and apply to myAbbVie Assist Patient Assistance Program, if applicable

ELAHERE Support Services – access, reimbursement and patient support

- ☐ Fill out page 2 in its entirety to enroll your patient in ELAHERE Support Services
- ☐ Ensure the Provider Signature and Date are filled in
- ☐ Call 1-833-352-4373 if you have questions
- ☐ Fax completed form to 1-833-464-6329

MyAbbVie Assist

- ☐ Fill out pages 2 and 4 with your patient to apply for myAbbVie Assist Patient Assistance Program, which provides free AbbVie medicine to qualifying patients. Patients may also complete their portion electronically. Please visit **www.AbbVie.com/PAS**
- ☐ Carefully read the privacy notice on page 3 and the terms of participation, financial information and HIPAA authorization on pages 5 and 6.
- ☐ Mark the required checkbox next to "Fair Credit Reporting Act Consent" on page 4
- ☐ Complete the prescription information
- ☐ Verify all signatures are present
- ☐ Fax the completed form to 1-833-464-6329

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.**

FDA=US Food and Drug Administration; HCPCS=Healthcare Common Procedure Coding System

Please see additional Important Safety Information on pages 7-8.

Please see full Prescribing Information, including BOXED WARNING, or visit www.rxabbvie.com/pdf/elahere_pi.pdf

ELAHERE®
mirvetuximab soravtansine-gynx
injection 100 mg
SUPPORT SERVICES

ELAHERE® SUPPORT SERVICES Enrollment Form

-Fill out page 2 to enroll your patient in ELAHERE Support Services for access, reimbursement, and savings program support

-Fill out pages 2 and 4 with your patient to apply for myAbbVie Assist Patient Assistance Program. Patients may complete the patient assistance portion electronically. Please visit: **www.AbbVie.com/PAS**

Fax completed form to 1-833-464-6329.
For questions, call 1-833-352-4373.

PATIENT INFORMATION Please print clearly.

First Name _____ Last Name _____

Date of Birth _____ (MM/DD/YYYY) Sex at Birth M ☐ F ☐

Mailing Address _____ City _____ State _____ Zip Code _____

Shipping Address (no PO box) _____ City _____ State _____ Zip Code _____

Mobile Phone _____ Home Phone _____ Email Address _____

Preferred Phone: Mobile ☐ Home ☐ Preferred Language: English ☐ Spanish ☐ Other ☐ _____

☐ (Optional) I permit AbbVie to speak with the following person about this application (AbbVie reserves the right to limit some program-related communications to the patient and/or their legal representative only.)

Name _____ Relation to Patient _____ Phone _____

Privacy Notice: For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosure to third parties, visit **https://abbv.ie/PrivacyPatient**.
Consent to process my sensitive personal information: Through my submission of the ELAHERE Patient Enrollment form, I consent to the collection, use, and disclosure of my personal health data, as described in the Privacy Notice above and in AbbVie's Privacy Notice in the "How we may disclose Personal Data" section, **https://abbv.ie/PrivacyDiscloseData**. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting **https://abbviemetadata.my.site.com/AbbvieDSRM** on AbbVie's website.

INSURANCE INFORMATION

Government ☐ Commercial ☐ No Insurance ☐

Employer Name (if applicable) _____

Medical Insurance _____

Policy/Medical ID # _____

Group ID # _____

Insurance Phone Number _____

Beneficiary/Cardholder Name _____

Beneficiary/Date of Birth _____

Please Provide Your Medicare Part A ID# _____

Prescription Insurance Company _____

Rx ID # _____

Rx Group # _____

Rx Bin # _____ Rx PCN # _____

Do You Have a Medicare Supplement? Yes ☐ No ☐ Unsure ☐

Do You Have Secondary Insurance? Yes ☐ No ☐ Unsure ☐

If "Yes" was selected, please provide information on your additional plans _____

PROVIDER INFORMATION

Name _____

Address _____

City _____ State _____ Zip Code _____

Phone _____ Fax _____

Prescriber NPI # _____

Transaction ID # _____ PTAN # _____

Collaborating Physician

Name _____ NPI # _____

Insurance Contact:

Name _____

Phone _____

Billing/Co-Pay Contact:

Name _____

Phone _____

Prescriber Privacy Notice: For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosures to third parties, visit **https://abbv.ie/PrivacyHCP**

DIAGNOSIS

ICD-10-CM Code _____ Select Patient Condition Ovarian cancer ☐ Fallopian tube cancer ☐ Primary peritoneal cancer ☐

Platinum resistant with 1 to 3 prior systemic treatment regimens Yes ☐ No ☐

Planned infusion start date _____

LAB TESTING

Patient tested positive with the FDA-approved test for folate receptor alpha (FRα)* Yes ☐ No ☐

PROVIDER CONSENT

I certify that the information provided is accurate to the best of my knowledge. I certify that I am the prescriber who has prescribed ELAHERE to the previously identified patient and that I provided the patient with a description of ELAHERE Support Services. I authorize ELAHERE Support Services to act on my behalf for the purposes of identifying the patient's insurance coverage and pursuing coverage assistance when appropriate.

Provider Signature: _____ Date: _____

*FRα positive is defined as ≥75% of viable tumor cells with moderate (2+) and/or strong (3+) membrane staining based on an IHC assay.

Please see Important Safety Information on pages 7-8.

Please see full Prescribing Information, including BOXED WARNING, or visit www.rxabbvie.com/pdf/elahere_pi.pdf

Privacy Notice

AbbVie may collect your personal data through your online and offline interactions with us, including your contact, transaction, financial, demographic, insurance, geolocation, and health-related data. We may also collect your online usage data automatically through cookies and similar technologies. We use this information for several purposes, such as to provide you with, administer, and improve our programs, services, and products, customize your experiences, and for research and analytics. We retain your personal data for as long as necessary to fulfill these purposes or to comply with our record retention obligations. We do not sell your personal data but may use and disclose your personal data with marketing and advertising partners to deliver you ads based on your interests inferred from your activity across other unaffiliated sites and services ("online targeted advertising") and for website analytics. To opt out of the use or disclosure of your personal data for online targeted advertising or for website analytics, go to Your Privacy Choices, **https://abbviemetadata.my.site.com/AbbvieDSRM** on our website. For more information on the personal data categories we collect, the purposes for their collection, disclosures to third parties, and data retention, visit our Privacy Notice at **https://abbv.ie/corpprivacy**

Consent to Use of Automated Systems

By entering a phone number, you certify that you are the subscriber/an authorized user for that number and you agree to receive recurring automated, prerecorded, and/or artificial voice calls from "AbbVie" at that phone number about Patient Access Support, such as shipment notifications.

ELAHERE® Co-Pay Full Terms and Conditions

Terms and Conditions apply. This benefit covers ELAHERE® (mirvetuximab soravtansine-gynx). Eligibility: Available only to patients with commercial insurance coverage for ELAHERE who meet eligibility criteria. The form of co-pay assistance, enrollment requirements, and processes may vary. Please call 1-833-ELAHERE for additional information. Co-pay assistance program is not available to patients receiving reimbursement under any federal, state, or government-funded insurance programs (for example, Medicare [including Part D], Medicare Advantage, Medigap, Medicaid, TRICARE, Department of Defense, or Veterans Affairs programs) or where prohibited by law or by the patient's health insurance provider. If you live or receive treatment in certain states, you may not be eligible. If at any time a patient begins receiving prescription drug coverage under any such federal, state, or government-funded healthcare program, patient will no longer be able to use the ELAHERE Savings Card and patient must call 1-833-ELAHERE to stop participation. Co-pay assistance provided under this program may not be transferred to or utilized for the benefit of third parties, including, without limitation, third-party insurance plans and/or pharmacy benefit managers and their agents. By enrolling in the co-pay assistance program, you agree that this program is intended solely for the benefit of you, the patient. Some health plans have established programs referred to as "accumulator adjustment" or "co-pay maximizer" programs. An accumulator adjustment program is one in which payments made by you that are subsidized by manufacturer assistance do not count toward your deductibles and other out-of-pocket cost sharing limitations. Co-pay maximizers are programs in which the amount of your out-of-pocket costs is increased to reflect the availability of support offered by a manufacturer assistance program. Except where prohibited by applicable state law, if your insurance company or health plan implements either an accumulator adjustment or co-pay maximizer program, you will not be eligible for, and agree not to use, co-pay assistance because these programs are inconsistent with our agreed intent that this program is solely for your benefit. You also agree that you are personally responsible for paying any amount of co-pay required after the savings card is applied. Any out-of-pocket costs remaining after the application of the savings card may not be paid by your health plan, pharmacy benefit programs, or any other program. If you learn your insurance company or health plan has implemented either an accumulator adjustment program or a co-pay maximizer program, you agree to inform AbbVie of this fact by calling 1-833-ELAHERE to discuss alternative options that may be available to support you. Subject to all other terms and conditions, the maximum annual benefit that may be available solely for the patient's benefit under the co-pay assistance program is $25,000 per calendar year. The actual application and use of the benefit available under the co-pay assistance program may vary on a monthly, quarterly, and/or annual basis depending on each individual patient's plan of insurance and other prescription drug costs. This co-pay assistance program is subject to change, reduction in monetary amount, or discontinuation without any notice. AbbVie in its sole discretion may unilaterally reduce or discontinue the maximum annual benefit for any reason. Patients may not seek reimbursement for value received from the ELAHERE Savings Card Program from any third-party payers, including insurance plans, flexible spending plans or health savings accounts. Co-pay support made available under this program may not be used with any other coupon, discount, prescription savings card, free trial, or other offer (including any program offered by a third-party insurance plan or pharmacy benefit manager, or an agent of either, that adjusts patient cost-sharing obligations). Restrictions, including monthly maximums, may apply. This assistance offer is not health insurance. The failure to enforce any provision of these Terms and Conditions does not constitute a waiver by AbbVie of that or any other provision. By utilizing this co-pay assistance program, you hereby accept and agree to abide by these terms and conditions. Any individual or entity who enrolls or assists in the enrollment of a patient in the co-pay assistance program represents that the patient meets the eligibility criteria and other requirements described herein. Further, you agree that you currently meet the eligibility criteria and other requirements described herein every time you use the co-pay assistance program.
To learn about AbbVie's privacy practices and your privacy choices, visit https://abbv.ie/corpprivacy.

abbvie

Fill out this page only if you are applying for myAbbVie Assist Patient Assistance Program (PAP).

Patient Name _____ Date of Birth _____

Drug Allergies _____ Patient Weight (required) _____ lb/kg

Concomitant Medications _____

Yes ☐ No ☐ Has your employer, insurance company, or another third party directed you to apply to the patient assistance program at AbbVie?

PATIENT CONSENT

Please review the Privacy Notice on page 3 and the Terms of Participation, Financial Information, and HIPAA Authorization on pages 5 and 6.

☐ **FAIR CREDIT REPORTING ACT CONSENT (REQUIRED):** I understand that I am providing written instructions to the Program under the Fair Credit Reporting Act authorizing the Program to obtain information about my credit profile from credit reporting agencies or other sources. I authorize the Program to obtain such information solely to determine PAP eligibility.

☐ **SMS TEXT CONSENT (OPTIONAL):** I consent to receive automated and recurring text messages from "AbbVie", including services updates, marketing messages, refill reminders, and Rx notifications, to the above mobile number. Message and data rates may apply. I am not required to consent as a condition of receiving goods or services. I can reply HELP for help. I can reply STOP to opt out at any time. View Privacy Notice: **https://abbv.ie/corpprivacy** and Mobile T&C: **https://privacy.abbvie/us-mobile-terms-and-conditions.html**

☐ **MARKETING CONSENT (OPTIONAL):** I consent to the collection, use, and disclosure of my health-related personal data to receive communications from AbbVie regarding its products, programs, services, scientific research and other research, opportunities, and for online targeted advertising, as further described in the "How we may use Personal Data", **https://abbv.ie/PrivacyUseData**, "How we may disclose Personal Data", **https://abbv.ie/PrivacyDiscloseData** and "Cookies and similar tracking and data collection technologies" sections, **https://abbv.ie/PrivacyTrackingCollection** of your "Privacy Notice", **https://privacy.abbvie/privacy-policies/us-privacy-policy.html**. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting **https://abbviemetadata.my.site.com/AbbvieDSRM** on AbbVie's website.

CONSENT TO PROCESS MY SENSITIVE PERSONAL INFORMATION: Through my submission of the AbbVie Patient Access Support enrollment form, I consent to the collection, use, and disclosure of my personal health data, as described in the Privacy Notice above and in AbbVie's Privacy Notice in the "How we may disclose Personal Data" section, **https://abbv.ie/PrivacyDiscloseData**. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting **https://abbviemetadata.my.site.com/AbbvieDSRM** on AbbVie's website.

My signature below certifies that I have provided accurate and complete information and that I have read, understood, and agreed to the Patient Terms of Participation on page 5.

REQUIRED: SIGNATURE OF PATIENT OR LEGAL REPRESENTATIVE*: _____ **DATE:** _____

LEGAL REPRESENTATIVE'S RELATIONSHIP TO PATIENT: _____

My signature certifies that I have read, understood, and agree to the release of my protected health information pursuant to the HIPAA Authorization on page 6. *Note: You have a right to receive a copy of this Authorization. You may print a copy of or save this Authorization and retain a copy for your records.*

REQUIRED: SIGNATURE OF PATIENT OR LEGAL REPRESENTATIVE*: _____ **DATE:** _____

LEGAL REPRESENTATIVE'S RELATIONSHIP TO PATIENT: _____

*Only representatives with legal authority for healthcare decisions may apply on a patient's behalf. **Indicate relationship** below signature if signing on behalf of the patient.

SITE OF INFUSION INFORMATION:

☐ Prescriber's Office (if checked, skip to next section) ☐ Other _____

Practice/Facility Name _____ Contact Person Name _____

Contact Person Title _____ Phone _____ Fax _____

Address _____ City _____ State _____ Zip Code _____

PRESCRIPTION INFORMATION Please submit prescriptions according to your specific state laws, rules, and regulations.

MEDICATION	DOSAGE FORM	QUANTITY	DIRECTIONS FOR USE	REFILLS
ELAHERE® (mirvetuximab soravtansine-gynx)	100 mg/20 mL (5 mg/mL) in single-dose vial	21-day supply ☐ Other _____	____mg IV every 3 weeks ☐ Other _____	1-year (PRN) ☐ Other _____

YES ☐ NO ☐ **Does the patient have a diagnosis consistent with the FDA-approved indication or an indication identified as medically accepted by a major drug compendium, such as the National Comprehensive Cancer Network (NCCN) Compendium?**

PRESCRIBER CERTIFICATION: See Program Terms of Participation on page 5.

I understand that this prescription may be transmitted to an AbbVie-authorized pharmacy for patient enrollment in an AbbVie-sponsored program for free product. I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. I shall not seek reimbursement for any medication dispensed hereunder from any government program or third party, including patient, nor will I sell, trade, or distribute any such medication.

myAbbVie Assist Program: myAbbVie Assist reserves the right to request additional information, if needed, and to change or discontinue the program at any time, without notice. I also understand that the applicant's acceptance into the program should not influence treatment decisions.

By signing this form, I authorize the program and its representatives to transmit this prescription form electronically, by facsimile, or by mail to a pharmacy designated by the program for the dispensing of the medication called for herein. I understand that I may not delegate signature authority.

Provider Name, Printed _____ **Phone** _____ **Fax** _____

PRESCRIBER'S SIGNATURE (REQUIRED): _____ **DATE:** _____

RUBBER STAMPS, SIGNATURE BY OTHER OFFICE PERSONNEL, OR COMPUTER-GENERATED IMAGES ARE NOT ALLOWED

Privacy Notice for Prescriber: For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosure to third parties, visit **https://abbv.ie/PrivacyHCP**

Independent Charitable Patient Assistance Programs

Please review Independent Charitable Patient Assistance Programs (ICPAPs) funding that may be available prior to applying to myAbbVie Assist Patient Assistance Program. ICPAPs are charitable organizations (often referred to as Co-Pay Foundations) that provide need-based financial assistance to help patients obtain therapies prescribed or recommended by their HCP, without regard to the manufacturer or supplier of those therapies or the patient's HCP.

Financial Information

AbbVie offers a financial assistance program that provides access and financial support to those meeting program guidelines. By signing this application form, you provide written instructions to the Program under the Fair Credit Reporting Act authorizing the Program to obtain information about your credit profile from credit reporting agencies or other sources. You authorize AbbVie to obtain such information solely to determine Patient Assistance Program (PAP) eligibility, and to perform an electronic income verification. You understand that you may be required to provide additional financial documentation for Patient Assistance consideration.

Terms of Participation

Patient Assistance Program: myAbbVie Assist provides free medicine to qualifying patients.

Participation in our program is free; we do not collect any fees from people seeking our assistance. Medication assistance is dependent on your ability to meet the eligibility criteria for our program as determined by myAbbVie Assist. myAbbVie Assist does not have any obligation to provide the program services to you and is not liable in the provision of these services. Patients with insurance plans or employers participating in an alternate funding program (also sometimes referred to as patient advocacy programs, specialty networks, SHARx, Paydhealth, or Payer Matrix, among other names) requiring them to apply to a manufacturer's patient assistance program or otherwise pursue specialty drug prescription coverage through an alternate funding vendor as a condition of, requirement for, or prerequisite to coverage of relevant AbbVie products, or that otherwise denies, restricts, eliminates, delays, alters, or withholds any insurance benefits or coverage contingent upon application to, or denial of eligibility for, specialty drug prescription coverage through the alternate funding program are not eligible for myAbbVie Assist program. You agree to inform myAbbVie Assist if you are a member of such an insurance plan or if you are applying to myAbbVie Assist on behalf of a patient who is a member of such an insurance plan. The program may be changed or discontinued without notice. You will not seek reimbursement for any products dispensed under the program. You will notify the program if your insurance or financial situation changes. If this application has been completed by a personal representative, the personal representative will provide a copy of this completed application to you.

If you are a member of a Medicare plan, including a Medicare Prescription Drug Plan, and are qualified for program assistance:

(i) You will be eligible to obtain the medication from the program for a calendar year term;

(ii) You will not purchase this medication under your Medicare plan while enrolled in the program;

(iii) You will not submit claims nor seek true out-of-pocket (TrOOP) credit for the medication provided during your enrollment;

(iv) myAbbVie Assist will inform your Medicare Prescription Drug Plan, if applicable, that you are receiving your medication at no cost outside of the Medicare Part D benefit.

If you have questions, want to update your information, or want to terminate your enrollment, please call 1-844-900-2228 or write to us at D-617927, AP5 NE; 1 N. Waukegan Rd, North Chicago, IL 60064.

HIPAA Authorization

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION:
I authorize my health care providers and staff, health plan, and pharmacies (collectively, my "Healthcare Providers") to disclose individually identifiable information about me, my health or condition(s), treatment and care that I have received, my insurance coverage, my payment information, and my medication history and prescriptions (collectively, "Protected Health Information") to AbbVie Inc. and/or its designated affiliates, agents, representatives, and service providers (collectively, "AbbVie") in order for AbbVie to (i) enroll me in, provide, operate, and administer the AbbVie Financial Support Program ("Program"); (ii) provide me with information concerning the Program; and (iii) develop, evaluate, and improve products, services, materials, and programs related to my condition or treatment. I understand that Protected Health Information disclosed to AbbVie under this Authorization will no longer be protected by HIPAA and may be subject to redisclosure by AbbVie. I understand that I am not required to sign this Authorization and that my Healthcare Providers will not otherwise condition my treatment, payment, health insurance enrollment, or eligibility for health care benefits to which I am otherwise entitled on whether I sign this Authorization. However, I understand that if I do not sign this Authorization, I cannot take part in the Program. I understand that this Authorization will expire once I am no longer participating in the Program, unless I cancel it sooner. I understand that I may cancel this Authorization at any time by making a data subject rights request at **https://abbv.force.com/AbbvieDSRM** or by writing to **privacydsr@abbvie.com**. However, I understand that if I cancel this Authorization, it will end my enrollment in the Program. I understand that cancelling this Authorization will not affect any use or disclosure of my Protected Health Information that has already taken place in reliance on this Authorization.

INDICATION AND IMPORTANT SAFETY INFORMATION

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg
SUPPORT SERVICES

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.

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.

Please see additional Important Safety Information on the following page.

Please see full Prescribing Information, including BOXED WARNING, or visit www.rxabbvie.com/pdf/elahere_pi.pdf

IMPORTANT SAFETY INFORMATION (cont'd)

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg
SUPPORT SERVICES

WARNINGS and PRECAUTIONS (cont'd)

Pneumonitis (cont'd)

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 full Prescribing Information, including BOXED WARNING, or visit www.rxabbvie.com/pdf/elahere_pi.pdf

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US-EPROC-250858 February 2026 033151