



# A Dosing and Administration Booklet

## INDICATION

ELAHERE is indicated for the treatment of adult patients with folate receptor-alpha (FR $\alpha$ ) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

## IMPORTANT SAFETY INFORMATION

### WARNING: OCULAR TOXICITY

- ELAHERE can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.
- Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of ELAHERE, every other cycle for the first 8 cycles, and as clinically indicated.
- Administer prophylactic artificial tears and ophthalmic topical steroids.
- Withhold ELAHERE for ocular toxicities until improvement and resume at the same or reduced dose.
- Discontinue ELAHERE for Grade 4 ocular toxicities.

Please see additional Important Safety Information, including **BOXED WARNING**, throughout.  
Please see [full Prescribing Information](#), including **BOXED WARNING**.

## Step 1

## ADMINISTER PROPHYLACTIC MEDICATIONS TO HELP MANAGE THE INFUSION EXPERIENCE<sup>1</sup>

Help reduce the incidence and severity of infusion-related reactions and emesis by following the ELAHERE premedication guidelines<sup>1</sup>

### Premedication prior to each ELAHERE infusion<sup>1</sup>

| Premedication  | Route of administration | Examples (or equivalent)  | Administration time prior to ELAHERE infusion |
|----------------|-------------------------|---|---|
| Corticosteroid | IV                      | Dexamethasone<br>10 mg  | At least<br>30 minutes prior                  |
| Antihistamine  | Oral or IV              | Diphenhydramine<br>25 mg to 50 mg   |   |
| Antipyretic    | Oral or IV              | Acetaminophen<br>325 mg to 650 mg   |   |
| Antiemetic     | Oral or IV              | 5-HT <sub>3</sub> serotonin receptor antagonist or appropriate alternatives | Before each dose and thereafter as needed     |

Consider additional premedications including corticosteroids the day prior to ELAHERE administration for patients who experience infusion-related reactions<sup>1</sup>

IV=intravenous.

### 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.

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## CALCULATE THEIR STARTING DOSE<sup>1\*</sup>



The recommended dosage of ELAHERE is 6 mg/kg AIBW administered once every 3 weeks (21-day cycle)<sup>1</sup>



ELAHERE is an IV infusion and is administered until disease progression or unacceptable toxicity<sup>1</sup>



Dosing based on AIBW reduces exposure variability for patients who are either underweight or overweight<sup>1</sup>

\*This was the dose calculation process used in the clinical trials.<sup>1</sup>

**The total dose of ELAHERE is calculated based on each patient's AIBW using the following formula<sup>1</sup>:**

$$\text{AIBW} = \text{IBW (kg)} + 0.4 \times (\text{actual weight (kg)} - \text{IBW (kg)})$$

**Female ideal body weight (IBW, kg) = (0.9 x height in cm) - 92**

AIBW is equivalent to adjusted body weight (AdjBW).



Scan to calculate AIBW

**Ensure all weight measurements are recorded in kilogram (kg) units and all height measurements are recorded in centimeters (cm) for ELAHERE dose calculations.**

- In the MIRASOL clinical study, the mean AIBW was 59.1 kg<sup>2</sup>
- Based on an AIBW of 59.1 kg, the dose would be 355 mg per cycle (4 vials). One vial contains 100 mg/20 mL (5 mg/mL) of mirvetuximab soravtansine-gynx<sup>1</sup>
- **Dose modifications may help manage treatment-related toxicities<sup>1</sup>**

AIBW=adjusted ideal body weight; IV=intravenous.

### 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%).

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## PREPARE ELAHERE<sup>1</sup>



**1.** Calculate the dose (mg) based on the patient's AIBW, total volume (mL) of solution required, and the number of vials of ELAHERE needed. More than 1 vial will be needed for a full dose. ELAHERE is available in 100-mg/20-mL (5-mg/mL) single-dose vials



**2.** Remove the vials of ELAHERE from the refrigerator and allow them to warm to room temperature



**3.** Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. ELAHERE is a clear to slightly opalescent, colorless solution



**4.** Gently swirl and inspect each vial prior to withdrawing the calculated dose volume of ELAHERE.  
**Do not shake the vial**



**5.** Using aseptic technique, withdraw the calculated dose volume of ELAHERE for subsequent dilution



**6.** ELAHERE contains no preservatives and is intended for a single dose only. Discard any unused drug remaining in the vial

AIBW=adjusted ideal body weight.

## 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.

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## PREPARE ELAHERE<sup>1</sup> (CONT'D)

### Prior to administration<sup>1</sup>:

- ✓ Inspect the ELAHERE IV infusion bag visually for particulate matter and discoloration
- ✓ Administer premedications
- ✓ **ELAHERE must be diluted** with 5% Dextrose Injection, USP to a final concentration of 1 mg/mL to 2 mg/mL
- ✓ ELAHERE is incompatible with 0.9% Sodium Chloride Injection. ELAHERE must not be mixed with any other drugs or IV fluids
- ✓ Determine the volume of 5% Dextrose Injection, USP required to achieve the final diluted drug concentration. Either remove excess 5% Dextrose Injection, USP from a prefilled IV bag, or add the calculated volume of 5% Dextrose Injection, USP to a sterile, empty IV bag. Then add the calculated dose volume of ELAHERE to the IV bag
- ✓ Gently mix the diluted drug solution by slowly inverting the bag several times to ensure uniform mixing. **Do not shake or agitate**
- ✓ If the diluted infusion solution is not used immediately, store solution either at ambient temperature (18 °C to 25 °C [64.4 °F to 77 °F]) for no more than 8 hours (including infusion time) or under refrigeration (2 °C to 8 °C [36 °F to 46 °F]) for no more than 12 hours. If refrigerated, allow the infusion bag to reach room temperature prior to administration. After refrigeration, administer diluted infusion solution within 8 hours (including infusion time)
- ✓ **Do not freeze** prepared infusion solution

IV=intravenous.

### 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.

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ADMINISTER ELAHERE<sup>1</sup>

Administer ELAHERE as an IV infusion only, using a 0.2 or 0.22 µm PES in-line filter. Do not substitute other membrane materials



Administer the first dose at a rate of 1 mg/min

- If well tolerated after 30 minutes, the infusion rate can be increased to 3 mg/min
- If well tolerated after 30 minutes, the infusion rate can be increased to 5 mg/min

If no infusion-related reactions occur with the previous dose, subsequent infusions should be started at the maximally tolerated rate and may be increased up to a maximum infusion rate of 5 mg/min as tolerated



Following the infusion, flush the IV line with 5% Dextrose Injection, USP to ensure delivery of the full dose. **Do not use any other IV fluids for flushing**



ELAHERE is a hazardous drug. Follow applicable special handling and disposal procedures



**DO NOT** mix ELAHERE with other drugs or IV fluids



**DO NOT** mix ELAHERE with normal saline (0.9% Sodium Chloride Injection)

**STEP 4:**  
ADMINISTER  
ELAHERE

For the full Preparation and Administration Instructions, please refer to Section 2.5 of the ELAHERE Prescribing Information.

IV=intravenous; min=minute; PES=polyethersulfone.

## 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.

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IF NECESSARY, HELP PATIENTS STAY ON TREATMENT WITH DOSE MODIFICATIONS<sup>1</sup>

Dose modifications may help manage treatment-related toxicities.  
Adjust the dose while maintaining a 3-week interval between doses<sup>1</sup>

| Recommended dose reduction schedule for AEs <sup>1</sup> |                                  |
|--|----------------------------------|
|  | ELAHERE dose level               |
| Starting dose  | 6 mg/kg AIBW q3w (21-day cycle)  |
| First dose reduction                                     | 5 mg/kg AIBW q3w (21-day cycle)  |
| Second dose reduction                                    | 4 mg/kg AIBW q3w (21-day cycle)* |

\*Permanently discontinue in patients who cannot tolerate 4 mg/kg AIBW.<sup>1</sup>  
AE=adverse event; AIBW=adjusted ideal body weight; q3w=every 3 weeks.

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.

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including **BOXED WARNING**, throughout.  
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IF NECESSARY, HELP PATIENTS STAY ON TREATMENT WITH DOSE MODIFICATIONS<sup>1</sup>(CONT'D)

| Recommended dose modification guidelines for ocular AEs <sup>1</sup> |  |  |
|--|--|--|
| Adverse event  | Severity of adverse event*   | Dosage modification  |
| Keratitis/<br>keratopathy  | Nonconfluent superficial keratitis   | Monitor  |
|  | Confluent superficial keratitis, a corneal epithelial defect, or 3-line or more loss in best-corrected visual acuity | Withhold until improved or resolved, then maintain at same dose level or consider dose reduction |
|  | Corneal ulcer or stromal opacity or best-corrected distance visual acuity 20/200 or worse                            | Withhold until improved or resolved, then reduce by 1 dose level                                 |
|  | Corneal perforation  | Permanently discontinue  |
| Uveitis  | Grade 1: rare cell in anterior chamber   | Monitor  |
|  | Grade 2: 1 to 2+ cell or flare in anterior chamber   | Withhold until Grade 1 or less, then maintain dose at same dose level                            |
|  | Grade 3: 3+ cell or flare in anterior chamber  | Withhold until Grade 1 or less, then reduce dose by 1 dose level                                 |
|  | Grade 4: hypopyon  | Permanently discontinue  |

\*Unless otherwise specified, National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 5.0.<sup>1</sup>

Your patient's eye care provider will monitor for ocular AEs and should notify you if any occur

AE=adverse event.

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 full Prescribing Information, including BOXED WARNING.



STEP 5:  
MODIFY DOSE  
IF NECESSARY



IF NECESSARY, HELP PATIENTS STAY ON TREATMENT WITH DOSE MODIFICATIONS<sup>1</sup>(CONT'D)

| Recommended dose modification guidelines for other AEs <sup>1</sup> |                            |   |
|---|----------------------------|---|
| Adverse event   | Severity of adverse event* | Dosage modification   |
| Pneumonitis   | Grade 1                    | Monitor   |
|   | Grade 2                    | Withhold until Grade 1 or less, then maintain at same dose level or consider dose reduction   |
|   | Grade 3 or 4               | Permanently discontinue   |
| Peripheral neuropathy   | Grade 2                    | Withhold until Grade 1 or less, then reduce by 1 dose level   |
|   | Grade 3 or 4               | Permanently discontinue   |
| Infusion-related reactions/<br>hypersensitivity                     | Grade 1                    | Maintain infusion rate  |
|   | Grade 2                    | <ul style="list-style-type: none"><li>• Interrupt infusion and administer supportive treatment</li><li>• After recovery from symptoms, resume the infusion at 50% of the previous rate, and if no further symptoms appear, increase rate as appropriate until infusion is completed</li><li>• Administer additional premedication for future cycles</li></ul> |
|   | Grade 3 or 4               | <ul style="list-style-type: none"><li>• Immediately stop infusion and administer supportive treatment</li><li>• Advise patient to seek emergency treatment and immediately notify their healthcare provider if the infusion-related symptoms recur</li><li>• Permanently discontinue</li></ul>  |
| Hematological   | Grade 3 or 4               | Withhold until Grade 1 or less, then resume at 1 lower dose level   |
| Other adverse events  | Grade 3                    | Withhold until Grade 1 or less, then resume at 1 lower dose level   |
|   | Grade 4                    | Permanently discontinue   |

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AE=adverse event.

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.

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STEP 5:  
MODIFY DOSE  
IF NECESSARY

# PROACTIVE MANAGEMENT MAY HELP WITH POTENTIAL OCULAR EVENTS<sup>1,3</sup>

## Work with an eye care provider (optometrist or ophthalmologist)<sup>1</sup>

- Prior to treatment initiation, patients should receive a baseline ophthalmic exam, including 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<sup>1</sup>

### Schedule for eye drops<sup>1</sup>

- 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

#### STEROID EYE DROPS

Day before infusion → Day 4

**1 drop  
per eye**

**6x  
daily**

Day 5 → Day 8

**1 drop  
per eye**

**4x  
daily**

#### LUBRICATING EYE DROPS

Day 1 → treatment duration

**1 drop  
per eye**

**at least  
4x daily**

Wait at least 10 minutes after administration  
of the ophthalmic topical steroid

\*Preservative-free eye drops are not a requirement for all patients. Lubricating eye drops without preservatives are recommended for patients with sensitive eyes.<sup>4,5</sup>

- Tell your patients to avoid use of contact lenses<sup>1</sup>

## 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



Find resources to help manage ocular care at [elaherehcp.com](http://elaherehcp.com)

## 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.

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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.

## 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 ( $\geq 5\%$ ) 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.

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## 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.

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  $\leq$  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 ( $\geq 20\%$ ) 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.

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## IMPORTANT SAFETY INFORMATION (CONT'D)

### USE IN SPECIAL POPULATIONS

#### Lactation

Advise women not to breastfeed during treatment with ELAHERE and for 1 month after the last dose.

#### Hepatic Impairment

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

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## REFERENCES

1. ELAHERE. Package insert. AbbVie; 2024.
2. Data on file. AbbVie, Inc.
3. Moore KN, Angelergues A, Konecny GE, et al. *N Engl J Med*. 2023;389(23):2162-2174. Supplementary appendix. doi:10.1056/NEJMoa2309169
4. Data on file. AbbVie, Inc.
5. Moore KN, Martin LP, Matulonis UA, et al. IMGN853 (mirvetuximab soravtansine), a folate receptor alpha (FR $\alpha$ )-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.

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