Elahere

Saudi Arabia · access guide

How to access Elahere for FRα-positive platinum-resistant ovarian cancer from Saudi Arabia: 2026 pathway via KFSHRC, KAMC, KFMC, PSMMC and the wider kingdom gynae-oncology and medical oncology network

By Reserve Meds clinical & regulatory team. Last reviewed 2026-05-20.

Elahere (mirvetuximab soravtansine-gynx) is the first antibody-drug conjugate approved for platinum-resistant ovarian cancer and the first folate receptor alpha (FRα)-directed therapy approved for any indication. AbbVie acquired ImmunoGen for USD 10.1 billion in February 2024 primarily to bring this drug into its oncology portfolio. The FDA converted the original November 2022 accelerated approval to full traditional approval in March 2024 based on the MIRASOL Phase 3 randomised trial, which demonstrated a statistically significant overall survival benefit (median 16.46 months vs 12.75 months on investigator-choice chemotherapy) and a 33 percent reduction in death risk. For a Saudi-resident adult woman with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer whose tumor pathology shows FRα-positive expression at the labelled threshold, Elahere is the first targeted therapy with overall survival benefit in a setting historically defined by 12 to 14 month median survival and response rates under 15 percent.

This page explains the pathway for a Saudi-resident adult woman in 2026: the load-bearing FRα biomarker test that must be cleared before eligibility, who qualifies clinically, which kingdom centres carry the gynae-oncology, medical oncology, ophthalmology, and pathology infrastructure to run Elahere, what the every-3-week IV infusion schedule and ocular boxed-warning protocol require, what realistic cost looks like in SAR under MoH and National Guard funding, and the psychosocial dimensions of treatment in a disease state where median overall survival on Elahere is 16.5 months.

Why Elahere, and why the FRα biomarker comes first

Elahere is a humanised IgG1 kappa monoclonal antibody (mirvetuximab) targeting folate receptor alpha, conjugated via a cleavable disulfide linker to the maytansinoid microtubule inhibitor payload DM4, with a drug-antibody ratio of approximately 3.4. The mechanism is FRα-mediated tumor cell internalisation, lysosomal cleavage of the linker, intracellular DM4 release, microtubule disruption, mitotic arrest, and apoptosis. The bystander effect (a lysine-DM4 metabolite diffusing into adjacent cells) extends activity to neighbouring tumor cells with lower FRα expression.

Folate receptor alpha is highly expressed on approximately 35 to 40 percent of epithelial ovarian cancers at the high-expression threshold (PS2+ staining in at least 75 percent of viable tumor cells by FDA-approved companion diagnostic) that defines Elahere eligibility. The biomarker is the gate. Without a confirmed FRα-positive tumor by the Roche VENTANA FOLR1 (FOLR1-2.1) RxDx Assay or an equivalent validated IHC method, Elahere is not indicated and the eligibility conversation does not proceed.

For a Saudi patient the operational order is: (1) the treating gynae-oncologist or medical oncologist confirms platinum-resistant disease (progression within 6 months of completing the last platinum-based regimen, per GCIG criteria) and 1 to 3 prior systemic lines; (2) the pathology service runs FOLR1 IHC on the most recent representative tumor block; (3) ONLY IF FRα-positive at the PS2+ greater-than-or-equal-to 75 percent threshold does the Elahere eligibility conversation move forward; (4) if FRα-negative or FRα-low, the pathway pivots to standard platinum-resistant chemotherapy options, bevacizumab combinations, PARP inhibitor maintenance for eligible patients, or clinical trial enrolment.

KFSHRC Riyadh runs the deepest pathology FOLR1 IHC capability in the kingdom alongside its gynae-oncology programme; KAMC Riyadh and Jeddah (National Guard Health Affairs), KFMC Riyadh, PSMMC, KFSH Dammam, and PNOC Jeddah cover the wider operational footprint. Reserve Meds organises the FOLR1 IHC referral and the slide-shipping logistics where the current pathology service does not run the assay in-house.

What Elahere is, in plain language

Elahere is an intravenous infusion every 3 weeks. The dose is 6 mg/kg of adjusted ideal body weight (a 70 kg patient at normal body composition receives approximately 420 mg per cycle). The first infusion runs over 1 hour through a 0.2 micron in-line filter; subsequent infusions run over 30 minutes if the first dose is tolerated.

Before each infusion the patient receives standard ADC premedications: corticosteroid (dexamethasone 10 mg IV or equivalent oral), antihistamine (diphenhydramine 25 to 50 mg IV or equivalent oral), antipyretic (acetaminophen / paracetamol 650 to 1000 mg orally), anti-emetic per institutional protocol.

The layer that distinguishes Elahere from most other ADCs is the ophthalmic supportive regimen around every infusion: corticosteroid ophthalmic drops (prednisolone acetate 1 percent) one drop in each eye 6 times daily for the day before infusion, the day of infusion, and 4 days after the infusion; lubricating preservative-free artificial tears at least 4 times daily, continuous throughout the treatment course and for 1 month after the last dose; cycloplegic drops if pre-existing dry eye is present.

Infusion-day chair time runs approximately 2 hours including premed observation, infusion, and post-infusion observation. Treatment continues until disease progression or unacceptable toxicity; median time on treatment in MIRASOL was approximately 6 months, with a meaningful minority of patients beyond 12 months.

Eligibility at a Saudi gynae-oncologist or medical oncologist clinic

1. Confirmed platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer (progression within 6 months of completing the last platinum-based regimen, per GCIG criteria). 2. One to three prior systemic therapy regimens. 3. FRα-positive tumor: at least 75 percent of viable tumor cells with PS2+ staining intensity on FOLR1 IHC. Load-bearing gate. 4. ECOG performance status 0 or 1 (ECOG 2 case by case). 5. Adequate marrow: ANC at least 1.5 x 10^9/L, platelets at least 100 x 10^9/L, haemoglobin at least 9.0 g/dL. 6. Adequate liver: AST and ALT no more than 3 x ULN (no more than 5 x ULN with liver metastases); total bilirubin no more than 1.5 x ULN. 7. Adequate renal: creatinine clearance at least 30 mL/min. 8. No active ocular disease; pre-existing dry eye or mild prior keratopathy does not exclude but requires baseline ophthalmology and a tailored regimen. 9. No grade 3 or higher peripheral neuropathy at baseline. 10. Pregnancy excluded; effective contraception during treatment and for 7 months after the last dose for patients of reproductive potential. 11. Stable CNS metastases acceptable if asymptomatic and off corticosteroids for at least 4 weeks.

A Saudi patient should arrive with the original pathology report, current imaging, CA-125 trend, complete prior treatment history with response durations and toxicity profile, current laboratory panels, baseline ophthalmology examination where available, and a representative tumor block released for FOLR1 IHC. Reserve Meds assembles this documentation pack so the pathway opens efficiently rather than stalling on missing pieces.

The Saudi administration picture, plainly

The kingdom adult gynae-oncology and medical oncology network covering Elahere in 2026 includes:

- KFSHRC Riyadh and Jeddah, with the deepest adult gynae-oncology and medical oncology programmes in the kingdom; pathology FOLR1 IHC capability established at Riyadh, VERIFY at intake. ADC administration well established. Likely first kingdom centre for Elahere. - KAMC Riyadh and Jeddah (National Guard Health Affairs), with comprehensive adult oncology including gynae-oncology. - KFMC Riyadh, with adult medical oncology. - Prince Sultan Military Medical City (PSMMC) Riyadh, with adult medical oncology. - Princess Noorah Oncology Center (PNOC) Jeddah, with comprehensive oncology including gynae-oncology. - KFSH Dammam, with adult medical oncology. - King Abdulaziz University Hospital (KAUH) Jeddah, with adult medical oncology. - Specialised Medical Center Hospital, Riyadh, with adult medical oncology. - Dr Sulaiman Al-Habib Medical Group hospitals, with adult medical oncology services across the kingdom.

The Saudi Food and Drug Authority is the regulator. AbbVie Saudi holds the regional commercial responsibility. Elahere is within the 24-month post-FDA-full-approval window; SFDA registration status VERIFY at intake. Where domestic registration is in progress, the named-patient programme is the operational supply pathway and Reserve Meds coordinates the import-licence application alongside the clinical workflow. The named-patient pathway in Saudi Arabia is well established for high-cost oncology therapies through the SFDA Compassionate Use programme.

For pathology FOLR1 IHC where the local centre does not run the assay, KFSHRC Riyadh is the operational regional reference; tumor blocks ship in via the standard inter-hospital pathology referral pathway.

The 2026 pathway, step by step

Week 0 to 2: Reserve Meds assembles the document pack with the treating gynae-oncologist or medical oncologist and requests release of the most recent representative tumor block.

Week 2 to 3: FOLR1 IHC. In-house turnaround at KFSHRC Riyadh or comparable kingdom reference laboratory typically 5 to 7 working days. THIS IS THE GATE. If FRα-positive at the labelled threshold the pathway proceeds. If FRα-negative or FRα-low the conversation pivots to non-Elahere options.

Week 3 to 4: Baseline ophthalmology examination at a Saudi ophthalmology service willing to partner on the every-2-cycle ocular monitoring schedule. Financial pre-authorisation conversation in parallel. MoH coverage and CCHI-regulated commercial cover are reviewed against the FDA labelled indication and the FRα-positive pathology report. National Guard Health Affairs cover for KAMC patients; Aramco cover for Aramco-network patients; commercial coverage for private-network patients. AbbVie patient-access programmes explored where insurance coverage is partial.

Week 4 to 5: First infusion at the chosen kingdom centre. Day 0 of the Elahere clock. Premedications, 1-hour first infusion, observation period for infusion reactions. Ophthalmic drop protocol begins.

Cycles 2 through 4 and beyond: every-3-week infusion (30 minutes from cycle 2 if first dose tolerated). Ophthalmology examination every 2 cycles for the first 8 cycles, then per institutional protocol. CA-125 every cycle. Imaging response assessment every 6 to 9 weeks. Treatment continues until disease progression, unacceptable toxicity, or patient decision to discontinue.

Boxed warning ocular toxicity protocol (load-bearing operational fact)

Elahere carries an FDA boxed warning for ocular toxicity. The DM4 payload concentrates in corneal epithelium, producing a characteristic ADC-class keratopathy. Approximately 50 percent of patients develop some grade of visual symptom (blurred vision, dry eye, photophobia, keratopathy, cataract, keratitis); approximately 9 percent develop grade 3 to 4 ocular AEs. Onset is typically within the first 2 to 4 cycles. The toxicity is usually reversible with dose interruption, dose reduction, or treatment discontinuation if grade 3 or higher.

The operational discipline is non-negotiable:

- Baseline ophthalmology examination before first dose. - Ophthalmology examination every 2 cycles for the first 8 cycles, then per protocol. - Any patient-reported visual change between scheduled examinations triggers urgent ophthalmology review. - Ophthalmic drop schedule is part of treatment, not optional supportive care. - Dose modification per CTCAE grade: delay for grade 2; dose reduce for recurrent grade 2 or first grade 3; permanently discontinue for grade 4 or persistent grade 3.

Not every Saudi ophthalmologist has prior experience with chemotherapy-class keratopathy. The MDT includes an ophthalmologist familiar with ADC-class ocular AEs or willing to develop the protocol in partnership with the treating oncologist.

Cost expectation in SAR

US wholesale acquisition cost is approximately USD 28,000 per 100 mg vial. A patient at 70 kg adjusted ideal body weight at 6 mg/kg uses approximately 4 vials per cycle, approximately USD 112,000 per cycle. With median time-on-treatment around 6 months in MIRASOL (approximately 8 to 10 cycles), treatment course cost is approximately USD 950,000 to USD 1.2 million. At 2026 indicative cross rates the SAR-equivalent treatment course cost is approximately SAR 3.6 to 4.5 million. Outliers run higher when treatment extends beyond 12 months in patients with durable response.

For Saudi nationals receiving care at MoH-funded or NGHA-funded centres, the standard funding pathway for high-cost oncology biologics applies; pre-authorisation against the FDA labelled indication and the FRα-positive pathology report is the gating step. For CCHI-regulated commercial insurance, pre-authorisation against the labelled indication is standard; oncology annual benefit ceilings can apply. AbbVie patient-access programmes for the GCC are an active operational pathway where insurance coverage is partial or where the case sits in the named-patient supply window.

Monitoring and mental-health screening

Per-cycle laboratory monitoring: CBC with differential, comprehensive metabolic panel including AST, ALT, total bilirubin, creatinine, CA-125. Per-cycle symptom monitoring: vision (new blurred vision, photophobia, dry eye triggers ophthalmology review), peripheral neuropathy (sensory predominant, dose-modify per grade), fatigue, nausea, diarrhea, abdominal pain. Pneumonitis risk is low but present (any-grade approximately 10 percent, grade 3 to 4 approximately 2 percent); new cough, dyspnoea, or hypoxia triggers chest imaging.

Platinum-resistant ovarian cancer carries a median overall survival under 18 months on standard chemotherapy. Elahere extends survival to a median 16.5 months in MIRASOL but is not curative. The MDT integrates baseline and periodic mental-health screening from day one: PHQ-9 depression screen for the patient at baseline and every 2 to 3 cycles; caregiver-burden screening (Zarit Burden Interview short form or equivalent) at baseline and 3-month intervals; routine social work involvement for advance care planning and family-meeting facilitation; low threshold for psychiatric referral where PHQ-9 score is in the moderate range or higher, where the patient expresses thoughts of self-harm, or where the caregiver-burden screen flags severe strain. This is part of the standard of care in the platinum-resistant setting.

Religious, ethical, and family-logistics framing

Elahere is a recombinant monoclonal antibody manufactured in mammalian cell culture (CHO cells) conjugated to a small-molecule cytotoxic payload. No porcine, bovine, or human-derived component is used in the final product. The infusion is permissible across the Saudi Council of Senior Scholars framework for medical interventions on the same footing as other recombinant biologic and ADC therapies (trastuzumab, trastuzumab emtansine, trastuzumab deruxtecan, sacituzumab govitecan).

The decision to proceed with treatment, to limit treatment scope, or to transition to comfort care when response is lost or toxicity becomes intolerable is a family decision made in consultation with the treating gynae-oncologist. The spectrum of acceptable decisions in late-line ovarian cancer is broad. The MDT supports whichever direction the family chooses and re-opens the conversation as the clinical picture evolves. The every-3-week infusion schedule, the every-2-cycle ophthalmology rhythm, and the daily ophthalmic drop regimen create a sustained operational load on the patient and the primary caregiver; reliable adherence to the ophthalmic drop schedule requires family involvement for many patients.

When Elahere is NOT the right option

- FRα-negative or FRα-low tumor (PS2+ in less than 75 percent of viable tumor cells on FOLR1 IHC): Elahere is not indicated. Pathway pivots to standard platinum-resistant chemotherapy (single-agent pegylated liposomal doxorubicin, weekly paclitaxel, topotecan, gemcitabine), bevacizumab combinations, PARP inhibitor maintenance for BRCA-mutated or HRD-positive eligible patients, or clinical trial enrolment. - More than 3 prior systemic lines: outside the labelled indication. - Active grade 3 or higher peripheral neuropathy at baseline: defer. - Active corneal disease or recent ocular surgery: defer; ophthalmology clearance required first. - Pregnancy or refusal of effective contraception for a patient of reproductive potential: contraindicated. - ECOG performance status 3 or 4: not labelled; the conversation pivots to comfort care. - Platinum-sensitive disease: not yet the labelled indication; PICCOLO data support FRα-positive platinum-sensitive use as an emerging operational case at clinician discretion under the named-patient pathway.

Reserve Meds does not push a default. The page above describes the Elahere pathway because Elahere is the ADC the patient or family has asked about. If the FOLR1 IHC returns FRα-negative or FRα-low, or if the conversation with the treating physician points toward a different pathway, the operational pathway shifts accordingly and we coordinate that pathway instead.

What Reserve Meds does on this case

We are a US-based concierge coordinator. We are not the prescriber and not the dispensing pharmacy. On a Saudi Elahere case we build the document pack, arrange the FOLR1 IHC pathology referral (in-kingdom where capability exists or to KFSHRC Riyadh as the regional reference), coordinate baseline ophthalmology and the every-2-cycle monitoring rhythm, run the financial pre-authorisation conversation in parallel with the clinical workup, engage AbbVie patient-access programmes where insurance coverage is partial, support the SFDA Compassionate Use named-patient supply application where domestic registration is still in progress, and stay with the case through response assessment and progression. Clinical decisions remain with your treating gynae-oncologist and the multidisciplinary tumour board.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.
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