Datroway access in Saudi Arabia

A TROP2-directed antibody-drug conjugate for HR+/HER2-negative metastatic breast cancer, reached through the SFDA Personal Importation Program.

Quick orientation

Datroway (datopotamab deruxtecan-dlnk) is a TROP2-directed antibody-drug conjugate from the Daiichi Sankyo and AstraZeneca DXd platform partnership. The US FDA approved Datroway on January 17, 2025 for adults with unresectable or metastatic hormone receptor-positive (HR+), HER2-negative (IHC 0, IHC 1+, or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy in the advanced setting, with a second 2025 accelerated approval in EGFR-mutated non-small cell lung cancer (NSCLC) after progression on EGFR-targeted therapy and platinum-based chemotherapy. The European Commission granted marketing authorization in the breast cancer indication on April 4, 2025. In Saudi Arabia, Datroway is not yet registered with the SFDA. The lawful route for KSA patients whose oncologist has identified Datroway as the right next step is the SFDA Personal Importation Program (PIP). Reserve Meds coordinates US specialty wholesale procurement, the SFDA documentation kit, and the validated 2 to 8 degrees Celsius cold-chain shipment to the treating oncology center. Reserved for you.

Why patients in Saudi Arabia need Datroway via the named-patient pathway

HR+, HER2-negative metastatic breast cancer is the largest molecular subtype of advanced breast cancer worldwide. The standard treatment sequence (endocrine therapy plus a CDK4/6 inhibitor, then later-line endocrine maneuvers and chemotherapy) leaves a meaningful gap when patients exhaust endocrine and chemotherapy options. Datroway adds a TROP2-directed ADC option in that gap. TROPION-Breast01, the pivotal trial supporting the FDA approval, demonstrated a progression-free survival benefit over investigator's choice chemotherapy (median PFS 6.9 months versus 4.9 months, hazard ratio 0.63) with a confirmed objective response rate of 36 percent versus 23 percent.

As of this page's review date, Datroway is not on the SFDA register. The Daiichi Sankyo and AstraZeneca commercial filings outside the US are advancing through the EU (approved April 2025), the UK MHRA (post-EMA pipeline), and other regulators, but Kingdom-level registration has not landed. For Saudi oncology patients with HR+/HER2-negative metastatic breast cancer who have exhausted endocrine and chemotherapy lines and whose oncologist has identified Datroway as the next step, or in the labeled NSCLC EGFR-mutated subset after progression on EGFR-targeted therapy and platinum-based chemotherapy, the only legal access route is the SFDA Personal Importation Program.

The SFDA Personal Importation Program for Datroway

The SFDA Personal Importation Program allows a KSA-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognized reference authority and a clinically equivalent locally registered alternative is not suitable.

Applications are filed through the dispensing institution's import pharmacy and reviewed by SFDA's Drug Sector, with named-patient transactions increasingly routed through the agency's Ghad digital platform.

For a Datroway case, the application package contains the clinical justification letter from the treating medical oncologist (diagnosis with ICD-10 coding, molecular profile including HR and HER2 status confirmed on tumor tissue, full prior-line documentation including endocrine therapy, CDK4/6 inhibitor exposure, and prior chemotherapy lines, the dosing plan, and the monitoring plan), SCFHS license verification, an SFDA-format anonymized patient identifier, product details (Datroway 100 mg single-dose vials, Daiichi Sankyo Inc. as license holder of record with AstraZeneca as co-commercial partner, country of origin, requested quantity, lot, expiry), the destination dispensing facility license, and a chain-of-custody plan covering 2 to 8 degrees Celsius cold-chain handling from US release through international air freight, customs, and final delivery to the treating hospital pharmacy or oncology day unit. Continuous temperature monitoring with validated qualified shippers and IATA-compliant cold-chain documentation is required.

The clinical-justification angle specific to Datroway is the documented prior-line failure across endocrine and chemotherapy options in the HR+/HER2-negative indication, with specific reference to lines exhausted and disease progression. The treating oncologist's letter typically names the prior endocrine agents (including aromatase inhibitor, fulvestrant, the CDK4/6 inhibitor used), prior chemotherapy lines, and the rationale for moving to a TROP2-directed ADC over alternatives. The dosing plan (6 mg/kg administered as an intravenous infusion once every 3 weeks, with a 540 mg cap for patients 90 kg or heavier, the first infusion over 90 minutes and subsequent infusions over 30 minutes if tolerated, with mandatory antiemetic premedication and prophylactic steroid eye drops) belongs in the same letter. The Warning and Precaution for interstitial lung disease and pneumonitis (a recognized class effect of the deruxtecan payload, also seen with Enhertu where it carries a Boxed Warning) is acknowledged in the patient intake.

Approval timelines for routine cases at established tertiary cancer centers typically run 10 to 21 business days. Cold-chain biologic cases sometimes attract closer scrutiny on the chain-of-custody plan and can extend to four to eight weeks for a first-time importer.

Where Datroway gets dispensed in Saudi Arabia

Datroway is a temperature-sensitive biologic that requires 2 to 8 degrees Celsius storage in the unreconstituted vial state, protected from light in the original carton, and must not be frozen or shaken. Reconstitution is performed at the infusion site with sterile water for injection, followed by dilution in 5 percent dextrose IV bag (the product is incompatible with sodium chloride solutions during preparation). Administration is intravenous infusion in a qualified setting with infusion-reaction management and the ability to escalate care if respiratory or ocular symptoms emerge. Home administration is not an option.

The dispensing-facility shortlist for Datroway in the Kingdom is therefore the subset of SFDA-licensed institutions with established medical oncology day units, infusion pharmacy capability, validated 2 to 8 degrees Celsius storage, and named-patient import pharmacy infrastructure. The operative institutions are King Faisal Specialist Hospital and Research Centre (KFSH&RC), the comprehensive cancer center of choice for many tertiary oncology cases in the Kingdom with operations in Riyadh, Jeddah, and Madinah; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs network (MNGHA) oncology services in Riyadh and Jeddah; King Saud University Medical City (KSUMC) oncology service; Dr. Sulaiman Al Habib Medical Group (HMG) oncology centers in Riyadh and Jeddah; Saudi German Health oncology;

and Dr. Soliman Fakeeh Hospital oncology day unit in Jeddah. For patients outside Riyadh and Jeddah, partnering with an SFDA-licensed specialty importer in one of those two cities and routing the infusion through one of the named institutions is the practical model.

Real cost picture for Datroway in Saudi Arabia

The transparent cost build for a Datroway case has three line items. First, the underlying US drug cost. Per-vial pricing references in the public domain indicate approximately USD 4,800 to 5,000 per 100 mg vial. At 6 mg/kg dosing, a typical 70 to 80 kg patient requires roughly four to five vials per infusion, putting per-infusion drug cost in the approximate range of USD 20,000 to 25,000 (roughly SAR 75,000 to SAR 93,750 at the 3.75 SAR per 1 USD currency peg) at US WAC, with a six-cycle course landing in the approximate range of USD 120,000 to 150,000 (roughly SAR 450,000 to SAR 562,500) before international logistics or coordination. Course duration is open-ended (t