Datroway access in Egypt

A TROP2-directed antibody-drug conjugate for HR-positive, HER2-negative metastatic breast cancer, reached through the Egyptian Drug Authority Personal Importation pathway.

Quick orientation

Datroway (datopotamab deruxtecan-dlnk) is an intravenous TROP2-directed antibody-drug conjugate (ADC) co-developed by Daiichi Sankyo and AstraZeneca. The US FDA approved Datroway on January 17, 2025 for adult patients with unresectable or metastatic hormone receptor-positive (HR+), HER2-negative breast cancer who have received prior endocrine-based therapy and chemotherapy in the advanced setting, with a second 2025 accelerated approval for EGFR-mutated non-small cell lung cancer after progression on EGFR-targeted therapy and platinum chemotherapy. In Egypt, where breast cancer carries a high national burden, Datroway is not yet locally registered. For Egyptian patients whose oncologist has exhausted endocrine and chemotherapy options in the HR+/HER2- metastatic setting, the lawful route is the EDA Personal Importation pathway, supported by a DSCSA-compliant US specialty wholesale chain and named-patient documentation prepared in coordination with the dispensing institution. Reserve Meds coordinates the US sourcing, the cold-chain logistics to Cairo International Airport, and the documentation kit your oncologist will need, while clinical decisions stay with your treating oncologist. Reserved for you.

Why patients in Egypt need Datroway via the named-patient pathway

Breast cancer is the most commonly diagnosed cancer among Egyptian women, and HR+/HER2- disease is the largest molecular subtype of advanced breast cancer worldwide. The standard treatment sequence in Egypt (endocrine therapy plus a CDK4/6 inhibitor, then later-line endocrine maneuvers and chemotherapy) leaves a real gap once endocrine and chemotherapy options are exhausted. In international markets, ADC access typically lags US and EU approval timelines by 12 to 36 months or longer.

The Egyptian Drug Authority has not yet listed Datroway on the national registration list. The two routes a patient might otherwise consider are not viable for an in-country case: Trodelvy (sacituzumab govitecan), the other TROP2-ADC, has its own evidence base but is also not consistently stocked in Egyptian hospital pharmacies; and Enhertu (trastuzumab deruxtecan) targets HER2 (not TROP2) and is positioned for HER2-low and HER2-ultralow disease, which is a different patient profile. Datroway therefore enters the named-patient channel as a specific on-label option for HR+/HER2- patients (IHC 0, IHC 1+, or IHC 2+/ISH-) whose oncologist has prescribed it after prior endocrine therapy and chemotherapy in the advanced setting. The EDA Personal Importation framework, codified by Law No. 151 of 2019, is the lawful route when a recognised reference authority has approved a medicine and no clinically equivalent locally registered alternative is suitable.

The EDA named-patient pathway for Datroway

The Egyptian Drug Authority (EDA) was created by Law No. 151 of 2019, with executive regulations issued under Prime Minister Decision No. 777 of 2020. EDA permits importation of

unregistered medicines for a specific named patient where no equivalent registered product is available locally or where the available quantity of an equivalent locally registered product cannot meet the patient's clinical need. The pathway is commonly referred to as Personal Importation and described in EDA correspondence as Special Access or Compassionate Use for novel agents.

For a Datroway case, applications are filed through the dispensing institution's import pharmacy. The standard package includes the clinical justification letter from the treating medical oncologist on hospital letterhead (the HR+/HER2- metastatic breast cancer diagnosis with documented receptor status by IHC and ISH where indicated, the staging workup, prior lines of therapy with named medicines and documented outcomes, the clinical rationale for a TROP2-ADC, the requested dose, planned cycle schedule, and projected duration), a recent prescription specifying brand name (Datroway), generic name (datopotamab deruxtecan-dlnk), strength (100 mg single-dose vial), and the per-cycle quantity calculated from the patient's body weight, the patient identifier copy (national ID card or passport), the treating oncologist's Egyptian Medical Syndicate membership number and Ministry of Health licence reference, product details (Daiichi Sankyo and AstraZeneca as co-commercial partners, with Daiichi Sankyo Inc. as US license holder of record on the FDA approval; country of origin; FDA approval reference; shelf life; cold-chain storage at 2 to 8 degrees Celsius), the destination dispensing facility licence (specifically the receiving infusion facility's licence to handle 2 to 8 degree Celsius cytotoxic biologics), and a chain-of-custody plan with continuous temperature monitoring through Cairo International Airport.

The clinical-justification angle specific to Datroway is documented prior-line therapy in the metastatic setting and an explicit acknowledgment of the FDA-labeled Warning for interstitial lung disease (ILD) and pneumonitis. The ILD warning is not a Boxed Warning on the Datroway label (in contrast to its sister DXd-platform compound Enhertu, where it carries a Boxed Warning), but severe, life-threatening, or fatal ILD/pneumonitis has been reported with Datroway, and the EDA reviewer will look for the treating oncologist's monitoring plan: surveillance for new or worsening pulmonary symptoms (cough, dyspnea, fever), the practical plan to hold Datroway for any suspected ILD pending workup, and permanent discontinuation for any Grade 2 or higher ILD/pneumonitis. The dose is 6 mg/kg every three weeks, capped at 540 mg for patients 90 kg or more, administered over 90 minutes for cycle 1 and over 30 minutes thereafter if well tolerated. Premedication for nausea (corticosteroid plus 5-HT3 antagonist plus or minus NK1 antagonist) and prophylactic steroid eye drops for ocular surface toxicity belong in the same plan.

Routine EDA personal-import authorisations for well-documented oncology biologics typically process in a 3 to 6 week window once a complete package is submitted. Complex cases involving cold-chain ADCs can extend to 6 to 10 weeks, particularly for a first-time case at a given institution. EDA reserves discretion at every step. Reserve Meds does not promise EDA timelines and is not the filer.

Where Datroway gets dispensed in Egypt

Datroway is a 2 to 8 degree Celsius cold-chain biologic that must be administered in a qualified infusion setting with the ability to manage infusion reactions and escalate respiratory or ocular care. The dispensing-facility shortlist is therefore narrower than for an ambient-temperature oral. The institutions that handle EDA named-patient imports as routine workflow and have established oncology infusion capability with cold-chain ADC handling experience include Cairo University Hospitals (Kasr Al Ainy) with its dedicated oncology unit and Drug Information Center, Ain Shams University Hospitals with its strong oncology service, Children's Cancer Hospital

Egypt 57357 for the limited adult breast cancer cases routed through its specialty programs, Dar Al Fouad Hospital in 6th of October City (JCI-accredited, with active oncology services as part of the Alameda Healthcare Group), As-Salam International Hospital in Cairo, and the Cleopatra Hospitals Group with its multi-site oncology infrastructure.

For patients whose treating oncologist is at a regional hospital outside Cairo, Giza, or Alexandria, the practical route is to partner with a Cairo-based licensed specialty importer that handles the EDA filing, cold-chain customs clearance through Cairo International Airport, and delivery