swissmedic

Summary report on authorisation dated 14 November 2025

DATROWAY® (active substance: datopotamab deruxtecan)

Authorisation in Switzerland: 28 May 2025

Powder for concentrate for solution for infusion as monotherapy for the treatment of adults with unresectable or metastatic hormone receptor-positive (HR+), HER2-negative breast cancer, who have already received an endocrine-based therapy and at least 1 line of chemotherapy, and in whom the disease has progressed on the last therapy

About the medicinal product

DATROWAY contains the active substance datopotamab deruxtecan.

It is used to treat adults with a specific form of breast cancer that is hormone receptor-positive (HR+) and HER2-negative (negative in relation to human epidermal growth factor receptor 2). DATROWAY is used in breast cancer that cannot be surgically removed (unresectable) or has already spread to other parts of the body (metastatic). The affected patients have already received an endocrine therapy and at least 1 line of chemotherapy, and the disease has progressed on the last therapy.

The medicinal product DATROWAY was authorised as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA), and Swissmedic. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least 2 of the 5 countries.

The authorisation application for DATROWAY was submitted to the drug regulatory authorities in Singapore, Australia, and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the application independently.

For the assessment of the authorisation application for DATROWAY containing the active substance datopotamab deruxtecan, Swissmedic conducted the full assessment of the preclinical data. The requirements for issuing a comprehensive SwissPAR (Swiss Public Assessment Report) and a Summary report on authorisation based on this Swis-

sPAR have not been fulfilled. Swissmedic refers to the authorisation of the foreign reference authorities.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals DATROWAY®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.