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Enhertu® (active substance: trastuzumab deruxtecan)

Temporary authorisation in Switzerland: 29 November 2021

Medicinal product (infusion) for third-line treatment of inoperable and/or metastatic HER2-positive breast cancer

About the medicinal product

Enhertu is a cancer medicine containing the active substance trastuzumab deruxtecan and is administered as an infusion into a vein.

Enhertu is used to treat a specific type of breast cancer known as HER2-positive breast cancer in adults. HER2 is the abbreviation for human epidermal growth factor receptor 2. These receptors trigger division of cancer cells. The breast cancer to be treated is either so far advanced that it can no longer be removed (inoperable) and/or has already spread to other sites in the body (metastasised).

Before receiving treatment with Enhertu, patients must have received at least two previous drug treatments for HER2-positive breast cancer that were not sufficiently effective.

Mode of action

Enhertu contains the active substance trastuzumab deruxtecan. This active substance combines an antibody (a protein) that can recognise and bind to the HER2 receptor on breast cancer cells with a substance known as a topoisomerase I inhibitor, which is effective against malignant tumours. As a result, the DNA of the tumour cells is damaged, leading to the death of the cancer cells.

Use

Enhertu is a prescription-only medicine and is authorised as a single-dose vial containing 100 mg trastuzumab deruxtecan powder. The powder is dissolved in sterile water, diluted as required with glucose solution and administered slowly via a vein.

The recommended dose is 5.4 mg/kg body weight once every three weeks. The first dose should be administered as a 90-minute infusion. If the previous infusion was well tolerated, the duration of the infusion can be shortened to 30 minutes.

Efficacy

In a single-arm[1], multicentre study (U201), Enhertu demonstrated clinically relevant efficacy in 184 patients with inoperable or metastatic HER2-positive breast cancer who had previously received multiple treatments.

The proportion of patients with an objective tumour reduction (objective response rate, ORR) was high at 61%. This effect remained after 18 months in more than half of patients (57%).

Precautions, undesirable effects & risks

While undergoing treatment with Enhertu, there is a risk of lung disease (interstitial lung disease, ILD) that can be potentially fatal. Patients should be monitored for respiratory symptoms.

Other very common adverse reactions after administration of Enhertu are infections and diseases of the respiratory tract, changes in blood cell counts, nausea, fatigue, vomiting, hair loss, constipation, decreased appetite and headache.

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

There is a very great need for a treatment option for patients with inoperable and/or metastatic HER2-positive breast cancer who have already undergone extensive treatments. A clinically significant response rate was observed in study U201 (described above), which was greater than can be expected based on historic data with previously authorised medicinal products. A controlled study (U301) with a comparator arm is already ongoing.

Based on all the available data, the benefits of Enhertu outweigh the risks. The medicinal product Enhertu has been authorised temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials had been concluded at the time of authorisation. The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation in the event of a positive benefit-risk assessment of the results.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals, Enhertu®

Healthcare professionals can answer any further questions.

[1] single-arm = the study is performed without a comparator group (e.g. a group receiving another medicinal product or placebo).

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 Public Summary SwissPAR.

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.