swissmedic

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Enhertu® (active substance: trastuzumab deruxtecan)

Indication extension in Switzerland: 30 June 2022

Medicinal product (infusion) for second-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).

Enhertu was granted a temporary authorisation by Swissmedic on 29 November 2021 for the treatment of HER2-positive breast cancer in patients who have received at least two previous drug treatments that were not sufficiently effective (third-line treatment).

With the current indication extension, Enhertu can also be used as second-line treatment after at least one insufficiently effective previous drug treatment.

The indication extension for Enhertu was authorised in connection with "Project Orbis". Project Orbis is a programme for promising cancer treatments coordinated by the FDA, the US regulatory authority. It provides a framework for the concurrent submission and review of cancer medicines by several international partner authorities in various countries. The ultimate aim is to give patients faster access to innovative cancer treatments. Currently, the authorisation authorities in Australia (TGA), Brazil (ANVISA), Canada (HC), Israel (MOH), Singapore (HSA), Switzerland (Swissmedic) and the United Kingdom (MHRA) are represented in Project Orbis.

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 genetic material 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

The efficacy of Enhertu as second-line treatment for inoperable and/or metastatic HER2-positive breast cancer was demonstrated in study U302 (DESTINY-Breast03).

The 524 female and male patients in the DESTINY-Breast03 study had previously received at least one treatment with trastuzumab (antibody against HER2) plus a taxane (chemotherapy) for the treatment of breast cancer. Patients had either responded inadequately to this treatment, or further tumour growth had occurred during the treatment. Patients who had received postoperative therapy with trastuzumab plus a taxane with the aim of a cure (adjuvant), were also eligible to take part in the study if further tumour growth occurred within 6 months of completing the treatment.

The efficacy of Enhertu in this study was compared with the standard treatment (trastuzumab emtansine).

At the time of the interim analysis of the study, a statistically significant improvement in progression-free survival (PFS[1]) was observed in the patients treated with Enhertu compared to those patients who were treated with trastuzumab emtansine.

The clinical trial had not yet been concluded at the time of authorisation, and further data, including on overall survival, will be collected and will need to be submitted to Swissmedic in due course.

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, decreased appetite, vomiting, constipation and diarrhoea.

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

[1] PFS: Progression-free survival: Period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

Why the medicinal product has been authorised

Breast cancer is the most common type of cancer in women, as well as the leading cause of death from cancer in women. HER2-positive breast cancer accounts for 15-20% of the invasive forms of the disease.

Although considerable progress has been made in recent years in the treatment of metastatic HER2-positive breast cancer, a great medical need still exists.

The above-mentioned study U302 demonstrated a statistically significant and clinically relevant improvement in progression-free survival (PFS) in patients treated with Enhertu.

Based on all the available data, the benefits of Enhertu in the second-line treatment of inoperable and/or metastatic HER2-positive breast cancer outweigh the risks.

Further information on the medicinal product

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

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 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.