

Summary report on authorisation dated 23 June 2026

Enhertu[®] (active substance: trastuzumab deruxtecan)

Temporary indication extension in Switzerland: 20 March 2026

Powder for concentrate for solution for infusion for the first-line treatment, in combination with pertuzumab, of adults with unresectable and/or metastatic HER2-positive breast cancer.

About the medicinal product

Enhertu is a cancer medicine containing the active substance trastuzumab deruxtecan. It is used in combination with pertuzumab for the first-line treatment of adult patients with HER2-positive (IHC 3+¹ or ISH+²) breast cancer. HER2 is the abbreviation for human epidermal growth factor receptor 2. These receptors trigger division of cancer cells. The breast cancer is either so far advanced that it can no longer be removed (unresectable) or has already spread to other sites in the body (metastasised).

The medicinal product Enhertu has already been authorised by Swissmedic for other indications.

This indication extension for Enhertu was authorised under "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 the FDA and other international partner authorities.

The ultimate aim of Project Orbis is to give patients faster access to innovative cancer treatments. In addition to the US regulatory authority FDA, the authorisation authorities in Australia (TGA), Brazil (ANVISA), Israel (MOH), Canada (HC), Singapore (HSA), Switzerland (Swissmedic), and the United Kingdom (MHRA) are currently represented in Project Orbis.

Further details of the international collaboration of Project Orbis are published on the

¹IHC: A laboratory test to make proteins on cancer cells visible. It uses a special dye which binds to the protein (HER2 in this case) so that the amount present on the tumour cells can be seen. The results are given as levels: 0 = almost no HER2, 1+ = little HER2, 2+ = moderate HER2, 3+ = heavy staining of the HER2 protein on the surface of the tumour cells. This means that the tumour forms particularly large amounts of HER2 proteins, which is important for the selection of specific targeted treatments.

²ISH+: In-situ-hybridisation (ISH) is a laboratory test used to determine whether cancer cells have additional copies of the HER2 gene. This involves the use of special marked DNA probes that bind to the HER2 gene and make it visible under a microscope, providing a way of determining whether the HER2 gene has reproduced (amplified). The results are generally expressed as positive or negative: ISH- = no HER2 gene amplification, ISH+ = HER2 gene amplification detected; this is regarded as HER2-positive.

Swissmedic website: Project Orbis (swissmedic.ch).

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 cancer cells with a substance known as a topoisomerase I inhibitor, which is effective against malignant tumours. As a result, the

DNA (genetic material) of the tumour cells is damaged, leading to the death of the cancer cells.

Pertuzumab is an antibody that specifically binds to the HER2 receptor at a different location, providing an additional inhibitor to cancer cell growth.

Administration

Enhertu is a prescription-only medicine and is used as a powder for solution for infusion. Before use, the powder must be dissolved and diluted by a healthcare professional according to the instructions and then administered slowly via a vein.

The recommended dose of Enhertu in combination with pertuzumab in unresectable and/or metastatic breast cancer is 5.4 mg/kg body weight. This dose is administered as an

infusion every three weeks. The first infusion of Enhertu should be administered over 90 minutes and followed by a separate intravenous infusion of 840 mg pertuzumab. If the previous infusion was well tolerated, the duration of the infusion can be shortened to 30 minutes. In addition, the pertuzumab dose should be reduced to 420 mg in all subsequent cycles. Treatment should be continued for as long as the disease does not progress and no intolerable side effects occur.

Efficacy

For this indication extension, the efficacy of Enhertu in combination with pertuzumab for the first-line treatment of adults with unresectable and/or metastatic HER2-positive breast cancer was investigated in the DESTINY-Breast09 study.

This study enrolled patients who had not previously had chemotherapy or HER2-targeted therapy for the treatment of unresectable and/or metastatic breast cancer.

A total of 1,157 patients were assigned to receive Enhertu as monotherapy, Enhertu in combination with pertuzumab, or standard chemotherapy. The primary endpoint of the

study was progression-free survival (PFS)³, which was evaluated by a blinded independent central review.

Median PFS with Enhertu in combination with pertuzumab was significantly longer than with standard chemotherapy: 40.7 months compared with 26.9 months for standard chemotherapy.

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

³ Progression-free survival (PFS): Period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

Precautions, undesirable effects, & risks

Enhertu must not be used in those who are hypersensitive to the active substance or any of the excipients.

While undergoing treatment with Enhertu in combination with pertuzumab, there is a risk of lung disease (interstitial lung disease, ILD) and neutropenia⁴ that can be potentially fatal. Patients should be monitored for symptoms such as cough, shortage of breath, fever, other respiratory symptoms, and changes in their blood counts.

The most common undesirable effects are nausea, diarrhoea, exhaustion, changes in blood counts, hair loss, vomiting, infections of the upper respiratory tract, constipation, reduced appetite, weight loss, heart disease, musculoskeletal pain and abdominal pain.

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

Why the medicinal product has been authorised

Considerable progress has been made in recent years in the treatment of unresectable and/or metastatic HER2-positive breast cancer, but a major medical need still exists nevertheless.

In the DESTINY-Breast09 study, Enhertu in combination with pertuzumab demonstrated a statistically significant and clinically meaningful improvement in PFS compared with conventional treatment.

Based on all the currently available data, the benefits of Enhertu in combination with pertuzumab in the first-line treatment of unresectable and/or metastatic HER2-positive breast cancer outweigh the risks.

This indication extension has been authorised in Switzerland on a temporary basis (in accordance with Art. 9a of the Therapeutic Products Act) since not all clinical trials data were available at the time of authorisation.

The temporary authorisation is contingent on the outstanding clinical data requested by Swissmedic being submitted on schedule. The data in question are from clinical trials that are still ongoing or have yet to be concluded. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation if the outcome of the benefit-risk assessment of the results is positive.

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 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.

⁴ Neutropenia: Reduction in certain white blood cells, which are important for fighting infection. This results in an increased risk of infections.