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Trodelvy® (active substance: sacituzumab govitecan)

Authorisation in Switzerland: 9 September 2021

Medicinal product (infusion) for the third-line treatment of metastatic triple-negative breast cancer (mTNBC)

About the medicinal product

Trodelvy is a cancer medicine containing the active substance sacituzumab govitecan and is administered as an infusion into a vein.

Trodelvy is used to treat adults with a type of breast cancer known as metastatic triple-negative breast cancer (mTNBC). This form of breast cancer is either so far advanced that it can no longer be removed or has already spread to other sites in the body (metastasised). The tumour cells also lack certain receptors. Receptors are very specific docking sites that exist for numerous substances. As soon as a specific substance binds to its receptor, it triggers a reaction in the cell. Triple-negative tumours have neither an oestrogen nor a progesterone receptor, nor do they possess an HER2 (human epidermal growth factor receptor 2). But these three receptors serve as possible sites of attack for other cancer medicines.

Before receiving treatment with Trodelvy, patients must have received at least two previous drug treatments for breast cancer that were not sufficiently effective. (Third-line treatment).

Mode of action

Trodelvy is a cancer medicine. The active substance sacituzumab govitecan combines an antibody (a protein) that can recognise and bind to a specific receptor (Trop-2 receptor) 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

Trodelvy is a prescription-only medicine and is authorised as a single-dose vial containing 180 mg sacituzumab govitecan powder. The powder is dissolved in saline solution and is administered slowly into a vein.

The recommended dose is 10 mg/kg body weight once weekly. Concomitant medication can also be given to prevent infusion-related adverse reactions.

Efficacy

The efficacy of Trodelvy was demonstrated in the randomised study IMMU-132-05. In this study, the administration of Trodelvy was compared with the treatment of physician's choice (TPC). The patients in the TPC group were treated with chemotherapy. The study groups were further subdivided according to the presence of brain metastases. In the group without brain metastases the median[1] progression-free survival (PFS[2]) with Trodelvy was significantly longer (by 3.9 months) compared to the TPC group (5.6 vs. 1.7 months). The overall survival[3] in the Trodelvy group was improved by 5.4 months compared to the TPC group (12.1 vs. 6.7 months). In the very small group of patients with brain metastases, no benefit over the TPC group was observed in the Trodelvy group.

Precautions, undesirable effects & risks

Trodelvy must not be used in those who are hypersensitive to the active substance or any of the excipients. Nor may Trodelvy be used in certain patients with chronic inflammatory bowel disease and/or bowel obstruction or in patients requiring dialysis.

Trodelvy can cause a life-threatening lack of certain white blood cells.

Trodelvy can also cause other undesirable effects, including diarrhoea, vomiting, nausea, abdominal pain and fatigue. Complete hair loss occurs in almost half of patients.

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

Why the medicinal product has been authorised

Metastatic triple-negative breast cancer is an aggressive condition. The overall survival in these patients is short with currently available treatments. Consequently, there is a great need for other therapeutic options.

In study IMMU 132-05, a prolongation of progression-free survival and overall survival was shown in patients who had already received previous treatments. Although, as with other cancer treatments, the side effects of the substance can be severe, these can be managed by concomitant treatment.

Based on all the available data, the benefits of Trodelvy outweigh the risks. The medicinal product Trodelvy containing the active

[1] Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always smaller than the median, the other half are always greater.

[2] 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.

[3] Overall survival: The overall survival refers to the period between the start of treatment and the death of the patient.

substance sacituzumab govitecan has been authorised in Switzerland for the treatment of adult patients with metastatic triple-negative breast cancer who have received at least two prior treatments.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Trodelvy®

Healthcare professionals (doctors, pharmacists and others) 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.

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