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Trodelvy (*sacituzumab govitecan*)

An overview of Trodelvy and why it is authorised in the EU

What is Trodelvy and what is it used for?

Trodelvy is a cancer medicine used to treat adults with a type of breast cancer known as triple-negative breast cancer. In triple-negative breast cancer, the cancer cells do not have receptors (targets) for certain hormones on their surface and do not make abnormally high levels of a protein called HER2 (HER2-negative). In these patients, the medicine is used when it is not possible to remove the cancer with surgery because the cancer has spread to areas outside the breast (locally advanced) or to other parts of the body (metastatic). It is used in patients who have had two or more prior systemic (whole body) treatments, including at least one of them for advanced disease.

Trodelvy is also used for treating breast cancer when the cancer cells have receptors for certain hormones on their surface (HR-positive) and are HER2-negative. It is used in patients who have had endocrine-based therapy (hormone treatment) as well as two or more prior systemic treatments when their cancer cannot be removed by surgery or is metastatic.

Trodelvy contains the active substance sacituzumab govitecan.

How is Trodelvy used?

The medicine can only be obtained with a prescription. It should be prescribed and given by a healthcare professional who has experience in the use of cancer medicines. It should be given in a setting where resuscitation equipment is available if patients develop severe allergic reactions.

Trodelvy is given by infusion (drip) into a vein on day 1 and day 8 of a repeating 3-week cycle. Treatment may be continued for as long as it remains effective and the patient does not have unacceptable side effects.

All patients are monitored for any reactions during the infusion and for at least 30 minutes afterwards. Infusion-related reactions can be severe and, to reduce their risk, patients should be given other medicines before treatment with Trodelvy. If the patient develops infusion-related reactions, the doctor may slow down or interrupt the infusion.

For more information about using Trodelvy, see the package leaflet or contact your doctor or pharmacist.

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How does Trodelvy work?

The active substance in Trodelvy, sacituzumab govitecan, consists of two active components: a monoclonal antibody (a type of protein) that has been linked to a small molecule, SN-38. The monoclonal antibody has been designed to recognise and attach to Trop-2, a protein found on many breast cancer cells.

Once attached, the medicine is taken up by the cell where SN-38 becomes active. SN-38 blocks an enzyme called topoisomerase I, which is involved in copying cell DNA needed to make new cells. By blocking the enzyme, cancer cells are prevented from multiplying and eventually die.

What benefits of Trodelvy have been shown in studies?

Trodelvy has been compared with standard treatment in one main study involving 529 patients with metastatic or locally advanced triple-negative breast cancer who received two or more prior systemic (whole body) treatments, including at least one of them for advanced disease. Patients who took Trodelvy lived for an average of 4.8 months without their disease worsening, compared with 1.7 months for the patients who took standard treatment. Patients on Trodelvy lived for an average of 11.8 months compared with 6.9 months for patients on standard treatment.

Another main study compared Trodelvy to one of four commonly used chemotherapy treatments as chosen by the doctor in 543 patients with HR-positive HER2-negative metastatic breast cancer who had received endocrine-based therapy and at least two systemic chemotherapy treatments before. Patients who received Trodelvy lived for an average of 5.5 months before their disease got worse, compared with 4.0 months for patients who were given another treatment. Patients on Trodelvy lived for an average of 14.4 months compared with 11.2 months for the other group of patients.

What are the risks associated with Trodelvy?

For the full list of side effects and restrictions with Trodelvy, see the package leaflet.

The most common side effects with Trodelvy (which may affect more than 1 in 5 people) include neutropenia (low levels of neutrophils, a type of white blood cell that fights infection), nausea, diarrhoea, tiredness, alopecia (hair loss), anaemia (low levels of haemoglobin which can cause tiredness and pale skin), constipation, vomiting, decreased appetite, dyspnoea (difficulty breathing) and abdominal (belly) pain.

The most common serious side effects include febrile neutropenia (low white blood cell counts with fever due to infection), diarrhoea, neutropenia and pneumonia (infection of the lungs).

Why is Trodelvy authorised in the EU?

The European Medicines Agency decided that Trodelvy's benefits are greater than its risks and it can be authorised for use in the EU.

Trodelvy has shown meaningful improvements in overall survival in patients with metastatic triple-negative breast cancer who received two or more prior systemic treatments, including at least one of them for advanced disease. Similar improvements were seen in how long patients lived without their disease worsening. Trodelvy has also shown meaningful improvements in heavily pre-treated patients with HR-positive HER2-negative metastatic breast cancer. Most patients in the main studies had metastatic cancer, but the Agency considered that similar benefits could be expected in patients with locally advanced cancer that cannot be removed by surgery.

In terms of safety, although Trodelvy has important side effects compared with standard treatments, such as severe neutropenia and diarrhoea, they are considered manageable with medications and dose modifications.

What measures are being taken to ensure the safe and effective use of Trodelvy?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Trodelvy have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Trodelvy are continuously monitored. Suspected side effects reported with Trodelvy are carefully evaluated and any necessary action taken to protect patients.

Other information about Trodelvy

Trodelvy received a marketing authorisation valid throughout the EU on 22 November 2021.

Further information on Trodelvy can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/trodelvy

This overview was last updated in 07-2023.