EMA/598134/2021
EMEA/H/C/005182

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. It 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 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. The dose depends on the patient's weight. Treatment may be continued for as long as it remains effective.

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. Patients are also given medicines to reduce any risk of nausea (sickness) and vomiting. In case the patient develops infusion-related reactions, the doctor may slow down or interrupt the infusion. The doctor may reduce the dose or stop treatment in case the patient develops certain side effects.

For more information about using Trodelvy, see the package leaflet or contact your healthcare provider.

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 on many breast cancer cells. Once attached, the medicine is taken up by the cell wherein SN-38 becomes active. SN-38

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

is a cancer medicine that belongs to the group 'topoisomerase inhibitors'. It 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.

What are the risks associated with Trodelvy?

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

The most common serious side effects are febrile neutropenia (low white blood cell counts with fever due to infection) and diarrhoea.

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

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 clinically meaningful improvements in overall survival in patients with metastatic triple-negative breast cancer who received two or more prior systemic (whole body) treatments, including at least one of them for advanced disease. Similar improvements were seen in the duration patients lived without their disease worsening. Most patients in the main study 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, they are considered manageable.

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 Trodelvycan be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/trodelvy

This overview was last updated in 11-2021.