14 October 2021
EMA/411659/2021
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Trodelvy

## sacituzumab govitecan

On 14 October 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Trodelvy, intended for the treatment of unresectable or metastatic triple-negative breast cancer.

Trodelvy was reviewed under EMA's accelerated assessment programme.

The applicant for this medicinal product is Gilead Sciences Ireland UC.

Trodelvy will be available as a 200 mg powder for concentrate for solution for infusion. The active substance of Trodelvy is sacituzumab govitecan, an antineoplastic agent (ATC code: L01FX17). It combines a humanised monoclonal antibody, which binds to Trop-2-expressing cancer cells, and a linked cytotoxic moiety SN-38 (govitecan), which inhibits topoisomerase I, preventing DNA repair and leading to apoptosis and cell death.

The benefits of Trodelvy are its improved progression-free survival and overall survival in patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) which had relapsed after at least two prior chemotherapies, when compared with treatment of physician's choice in a phase 3, multicentre, open-label, randomised study.

The most common side effects are diarrhoea, nausea, neutropenia, fatigue, alopecia, anaemia, vomiting, constipation, decreased appetite, cough, and abdominal pain.

The full indication is:

> Trodelvy as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, including at least one of them for advanced disease.

Trodelvy must only be prescribed to patients by healthcare professionals experienced in the use of cancer

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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therapies.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.