



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 May 2026
EMADOC-1700519818-3129523
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Trodelvy

sacituzumab govitecan

On 21 May 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Trodelvy. The marketing authorisation holder for this medicinal product is Gilead Sciences Ireland Unlimited Company.

The CHMP adopted a new indication as follows:

Trodelvy is indicated:

- as monotherapy for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) who have not received prior systemic therapy for metastatic disease and who are not candidates for PD-1 or PD-L1 inhibitor therapy (see section 5.1).

For information, the full indications for Trodelvy will be as follows:²

Triple-Negative Breast Cancer

Trodelvy is indicated:

- **as monotherapy for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) who have not received prior systemic therapy for metastatic disease and who are not candidates for PD-1 or PD-L1 inhibitor therapy (see section 5.1).**
- as monotherapy, ~~is indicated~~ for the treatment of adult patients with unresectable or metastatic ~~triple-negative breast cancer (TNBC)~~ who have received two or more prior systemic therapies, including at least one of them for advanced disease (see section 5.1)

HR-Positive, HER2-Negative Breast Cancer

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

² New text in bold, removed text as strikethrough.



Trodelvy as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer who have received endocrine-based therapy, and at least two additional systemic therapies in the advanced setting (see section 5.1).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.