July 2025

Trodelvy▼ (sacituzumab govitecan): Consider primary prophylaxis with granulocyte colony-stimulating factor (G-CSF) in patients at increased risk of febrile neutropenia

Dear Healthcare Professional,

Gilead, in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), would like to inform you of the following:

Summary

- Trodelvy can cause severe or life-threatening neutropenia and fatal infections have been observed.
- Neutropenia and febrile neutropenia are some of the most common serious side effects of Trodelvy.
- An update has been made to the Summary of Product Characteristics (SmPC) of Trodelvy recommending consideration of primary prophylaxis with granulocyte colony stimulating factor (G-CSF) in patients at increased risk of febrile neutropenia.

Background

Therapeutic indications for Trodelvy:

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

You are reminded that Trodelvy can cause severe or life-threatening neutropenia. Fatal infections in the setting of neutropenia have been observed in clinical studies with Trodelvy, primarily in the first two cycles of treatment.

Neutropenia and febrile neutropenia are some of the most common serious side effects of Trodelvy. Neutropenia is listed with frequency very common (≥ 1/10) and febrile neutropenia is listed with frequency common (≥ 1/100 to < 1/10). Please see SmPC for full details.

The SmPC of Trodelvy was recently updated, recommending consideration of primary prophylaxis with G-CSF in patients at increased risk of febrile neutropenia.

New evidence

In patients treated with Trodelvy, prophylaxis with G-CSF has been shown to reduce the risk of neutropenia and complications from neutropenia. In patients who received primary prophylaxis compared to those who did not, any Grade and Grade 3 and higher neutropenia was reduced by approximately half (31% vs 65% and 26% vs 50%, respectively). Primary prophylaxis with G-CSF should now be considered (UK SmPC Section 4.2 Posology and Method of Administration, Section 4.4 Special warnings and Precautions for Use, Section 4.8 Undesirable effects), starting in the first cycle of treatment with Trodelvy in patients at increased risk of febrile neutropenia.

Prescriber Action

- Primary prophylaxis with G-CSF should be considered starting with the first cycle of treatment in patients at increased risk of febrile neutropenia, for example older patients, patients with previous neutropenia, poor performance status, organ dysfunction, or multiple comorbidities.
- Consider treating neutropenia with G-CSF and consider prophylaxis in subsequent cycles as clinically indicated.
- Monitor absolute neutrophil count (ANC) during treatment. Trodelvy should not be administered if ANC is below 1500/mm^3 on Day 1 of any cycle or below 1000/mm^3 on Day 8 of any cycle. Withhold Trodelvy for neutropenic fever.
- Dose reductions for Trodelvy are required due to neutropenia or febrile neutropenia.
- After the first instance, for subsequent Grade 3-4 febrile neutropenia events or subsequent prolonged Grade 3-4 neutropenia events, reduce one dose level with each recurrence or discontinue according to Table 1 (SmPC Section 4.2).

Healthcare providers are advised to take this information into consideration when prescribing Trodelvy and discuss these risks with their patients and caregivers. Patients should be reminded that Trodelvy increases the risk of neutropenia and infections and to seek urgent medical attention at the first signs of fever or infection. Provide patients with a copy of the Patient Information Leaflet (PIL), which provides information about the medicine and explains the symptoms that patients should be aware. The PIL can be found here. This letter is not intended to be a complete description of the benefits and risks related to the use of Trodelvy. Please refer to the accompanying full SmPC for more information. The SmPC can be found here.

Call for reporting

Trodelvy ▼ (sacituzumab govitecan) is subject to additional monitoring. This will allow quick identification of new safety information.

Healthcare professionals should report any suspected adverse reactions associated with the use of these products to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼
- all suspected adverse drug reactions (ADRs) that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason

Please include in your report the product name and batch details.

You can report via:

- the Yellow Card website: www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Company contact point:

If you have any questions, or if you require any further information, please contact the medical information service at Gilead Sciences Ltd:

E-mail: ukmedinfo@gilead.com

Telephone: 08000 113 700 (UK)

Signed by Julian Cole
I approve this document
June 30, 2025 | 4:17:18 PM BST
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Dr Julian Cole MA MRCPI Dip Pharm Med FFPM GFMD
Country Medical Director UK & Ireland
Gilead Sciences, Ltd

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Trodelvy ▼/ sacituzumab govitecan
Marketing authorisation holder(s)	Gilead Sciences Ltd
DHPC recipients	Prescribing Oncologists with interest in breast cancer and Chief Pharmacists

Timetable	Date
DHPC and communication plan agreed by MHRA	25-June-2025
Dissemination of DHPC	By 25-July-2025 Dissemination via email to Prescribing Oncologists with interest in breast cancer and Chief Pharmacists. Hard copies to be sent where no email address is available