The first, approved TROP-2-directed antibody-drug conjugate[1,2]

TRODELVY®▼
sacituzumab govitecan
180 mg powder for concentrate for solution for infusion

Elevating the possibilities

Licensed in 2L and later mTNBC[1]

Trodelvy® is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer who have received two or more prior lines of systemic therapies, at least one of them given for unresectable locally advanced or metastatic disease[1]

This promotional material has been developed by Gilead Sciences Ltd. and is intended for GB HCPs only.
Prescribing information and adverse event reporting can be found on the last page of this brochure.

GILEAD
Oncology

GB

In your adult patients with unresectable locally advanced or metastatic TNBC (not including *de novo* diagnoses):

Early stage TNBC

Any systemic neoadjuvant and/or adjuvant therapy

Locally advanced unresectable or metastatic TNBC

1st line	**Any systemic therapy**
2nd line	**Trodelvy®▼ (sacituzumab govitecan) from 2nd line onwards for mTNBC, irrespective of time to progression or disease-free period following neoadjuvant/adjuvant therapy**
3rd line and later	

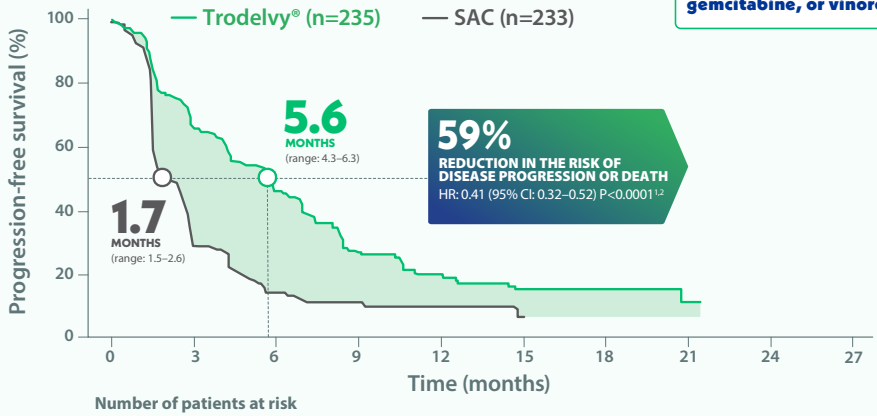
For *de novo* locally advanced unresectable or metastatic TNBC patients, 2 prior lines of therapy must be given in this setting before Trodelvy®.

The Phase 3 ASCENT trial was a multicentre, open-label, randomised study which evaluated Trodelvy® as compared with single-agent chemotherapy treatment of physician's choice (conducted in 529 patients with unresectable locally advanced or mTNBC who had relapsed after 2 prior lines of chemotherapies).[2]

Median PFS with Trodelvy® was 3X longer than with SAC[1,2]

Primary endpoint: PFS in patients without known brain metastases[2]

Patients in the SAC arm were randomised to capecitabine, eribulin, gemcitabine, or vinorelbine

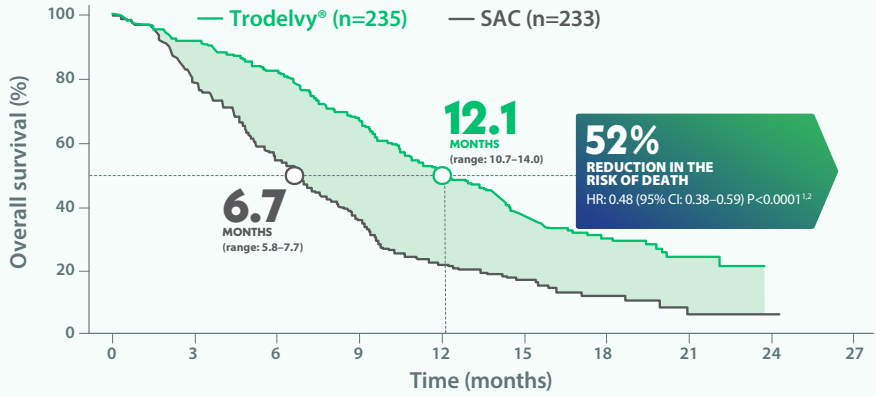


Number of patients at risk

Trodelvy®	235	154	91	49	28	15	9	1
SAC	233	39	14	5	1	1	0	0

Median OS of 1 year with Trodelvy®[1,2]

OS in patients without known brain metastases



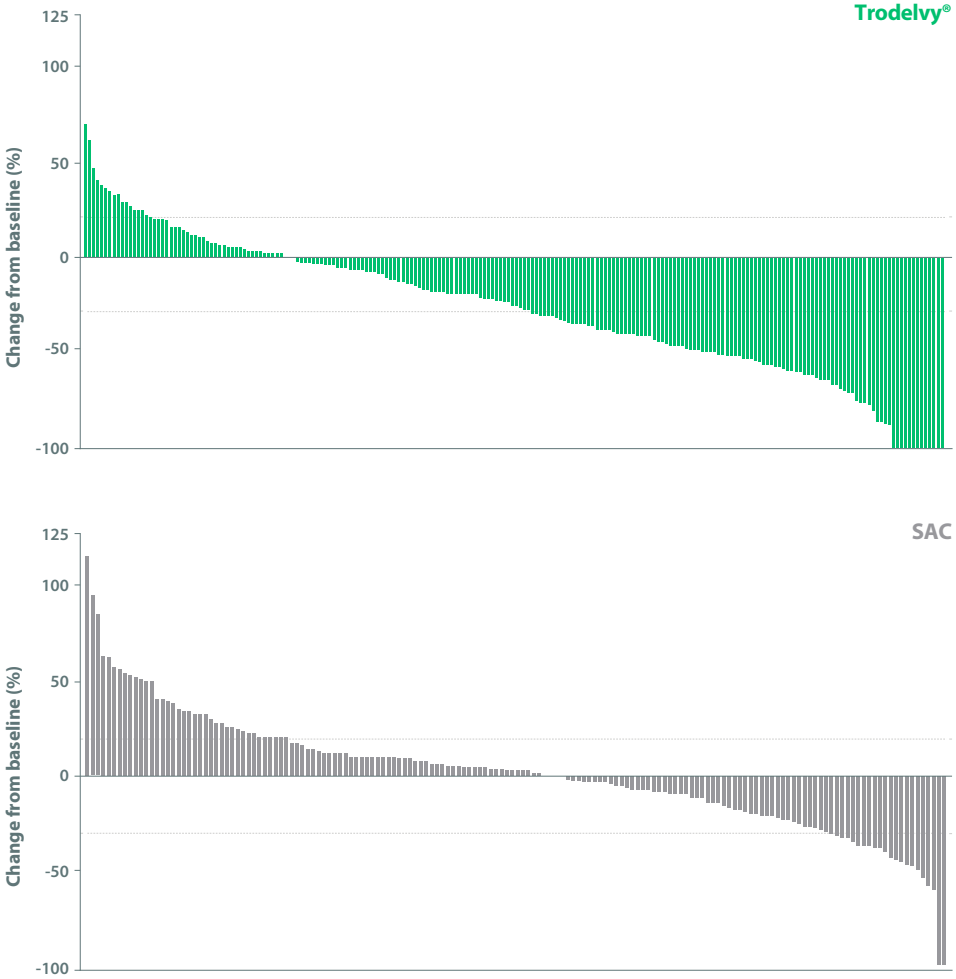
Number of patients at risk

Trodelvy®	235	214	190	153	107	70	37	13	0
SAC	233	173	117	74	45	30	11	3	1

Figures adapted from Bardia A, et al. *N Engl J Med.* 2021[2]

Trodelvy® delivered a 7x greater response rate vs SAC[1,2]

Change in tumour size in patients without brain metastases*[1-3]



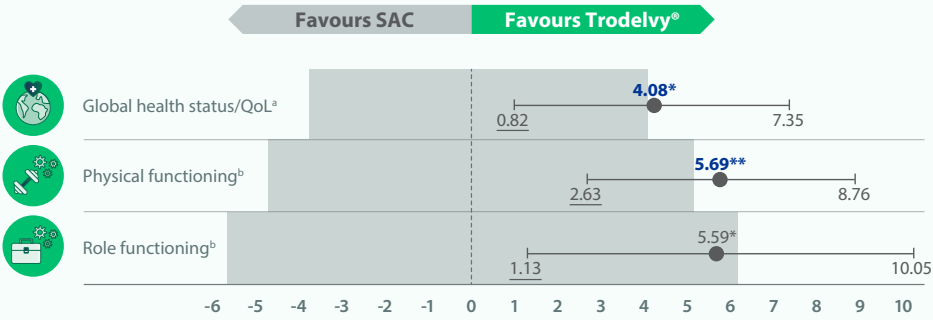
	Trodelvy® (n=235)	SAC (n=233)
Objective response rate (ORR) — n (%)	**82 (35)**	**11 (5)**
P value	**<0.001**	
Complete response	10 (4)	2 (1)
Partial response	72 (31)	9 (4)

Figure and table adapted from Bardia A, et al. *N Engl J Med.* 2021[2]

*These waterfall plots illustrate the best percentage change from baseline in the sum of the diameters of target lesions (longest diameter for non-nodal lesions and short axis for nodal lesions) in patients without brain metastases who had at least one response assessment.

Trodelvy® was superior to SAC on global health status/ QoL and physical functioning[4]

Linear MMRM analysis of overall LS mean change from baseline in scores for the primary HRQoL domains for Trodelvy® vs SAC



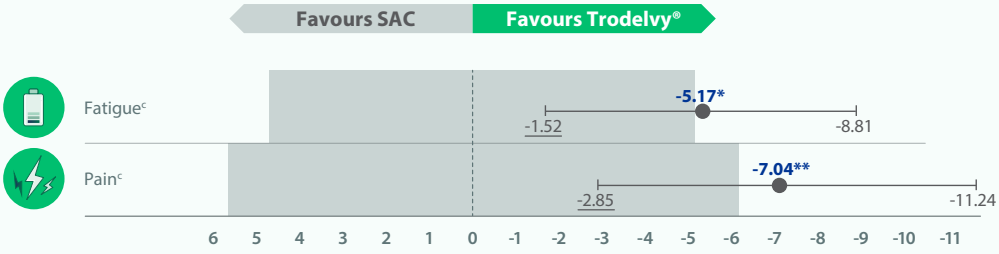
Bold blue: Trodelvy® superior to SAC (based on the MID and significance testing)

Underlined: upper or lower bound (as applicable) of the 95% CI did not exceed the noninferiority margin

Minimal important difference (MID range from zero)[5]

Trodelvy® was superior to SAC on fatigue and pain[4]

Linear MMRM analysis of overall LS mean change from baseline in scores for the primary HRQoL domains for Trodelvy® vs SAC



Bold blue: Trodelvy® superior to SAC (based on the MID and significance testing)

Underlined: upper or lower bound (as applicable) of the 95% CI did not exceed the noninferiority margin

Minimal important difference (MID range from zero)[5]

Figures adapted from Loibl S, et al. *Euro J Cancer.* 2023[4]

Trodelvy® was superior to SAC for emotional functioning, dyspnoea, and insomnia and non-inferior to SAC for all other secondary domains except diarrhoea, nausea, and vomiting[4]

Secondary HRQoL domains not presented (data on request)

*P<0.05;**P<0.01; [a]A higher score represents higher QoL; [b]A higher score represents a higher level of functioning; [c]A higher score represents a higher level of symptomatology

Trodelvy® has a well-characterised and generally manageable safety profile[1]

Adverse events of special interest in the ASCENT trial[2,6]

		Trodelvy® (n=258)			SAC (n=224)		
Treatment-emergent adverse event*		All Grades (%)	Grade 3 (%)	Grade 4 (%)	All Grades (%)	Grade 3 (%)	Grade 4 (%)
Haematologic	Neutropenia**	63	34	17	43	20	13
	Anaemia†	34	8	0	24	5	0
	Leukopenia††	16	9	1	11	4	1
	Febrile neutropenia	6	5	1	2	2	<1
Gastrointestinal	Diarrhoea	59	10	0	12	<1	0
	Nausea	57	2	<1	26	<1	0
	Vomiting	29	1	<1	10	<1	0
Other	Fatigue	45	3	0	30	5	0
	Alopecia	46	0	0	16	0	0

Table adapted from Bardia A, et al. *N Engl J Med*. 2021[2]

This is not an exhaustive list. For full details of adverse events, please refer to the Trodelvy® Summary of Product Characteristics.

There was a low rate of discontinuation and no deaths with Trodelvy® in the ASCENT trial‡[2,6]

5%

of patients discontinued Trodelvy® for any adverse reaction[2]

NO

patients discontinued Trodelvy® due to treatment-related neutropenia or diarrhoea[1,6]

NO

drug-related deaths[2]

*Patients may report more than 1 event per preferred term. Adverse events were classified according to the MedDRA systems of preferred terms and system organ class and according to severity by NCI CTCAE v4.03.[6]
**Combined preferred terms of "neutropenia" and "decreased neutrophil count". Due to overlapping reporting of events for these combined terms, all grades reported are not shown for the Trodelvy® arm: grade 1: 19%; grade 2: 37%; grade ≥3: 51%.[6]
†Combined preferred terms of "anaemia", "decreased haemoglobin" and "decreased red-cell count"[6]
††Combined preferred terms of "leukopenia" and "decreased white blood cell count"[6]
‡Of the 529 patients enrolled in ASCENT, 482 patients (Trodelvy®, n=258; SAC, n=224) were included in the safety population (all patients who received ≥1 dose of study treatment).

Consider Trodelvy®

for your patients with unresectable locally advanced or 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[1]

In patients without known brain metastases in the ASCENT trial:*

3X LONGER
median PFS vs SAC

Median PFS: 5.6 months with Trodelvy® (95% CI, 4.3–6.3) vs 1.7 months with SAC (95% CI: 1.5–2.6); HR: 0.41(95% CI: 0.32–0.52) P<0.0001**[1,2]

1 YEAR
median OS

Median OS: 12.1 months with Trodelvy® (95% CI: 10.7–14.0) vs 6.7 months with SAC (95% CI, 5.8–7.7); HR: 0.48 (95% CI: 0.38–0.59) P<0.0001**[1,2]

SAFETY PROFILE
well-characterised

5% (n=12) of patients in both arms discontinued for any adverse reaction.[2]

The most common treatment-related adverse events of any grade in the ASCENT study were neutropenia (63% with Trodelvy® and 43% with SAC), diarrhoea (59% and 12%), nausea (57% and 26%), alopecia (46% and 16%), fatigue (45% and 30%), and anaemia (34% and 24%).[2] Refer to SmPC for full safety information.

In HRQoL-evaluable patients in the ASCENT trial:*

HRQoL
clinically meaningful improvements vs SAC

Trodelvy® was noninferior to SAC on all primary HRQoL domains and superior on global health status/QoL, physical functioning, fatigue, and pain†[4]

*The ASCENT trial was an international, multicentre, open-label, randomised phase 3 clinical trial which evaluated Trodelvy® as compared with treatment of single-agent chemotherapy of the physician's choice (eribulin, vinorelbine, gemcitabine, or capecitabine) in 529 patients with 2L+ mTNBC.[2]

**The efficacy results in all patients (n=529) were consistent with the population without known brain metastases (median PFS: 4.8 months vs 1.7 months; HR: 0.43 (95% CI: 0.35–0.54); P<0.001; median OS: 11.8 months vs 6.9 months; HR: 0.51 (95% CI:0.41–0.62)).[1,2]

†Primary HRQoL domains: Global health status/QoL, Physical functioning, Role functioning, Pain and Fatigue. Selected as clinically relevant in the target population and used as primary HRQoL in other published studies.[4]

Abbreviations. 1L, first line, **2L**, second line; **3L**, third line; **BMNeg**, without known brain metastases; **CBR**, clinical benefit rate; **CI**, confidence interval; **CTCAE**, Common Terminology Criteria for Adverse Events; **DOR**, duration of response; **GB**, Great Britain; **HCP**, healthcare professional; **HR**, hazard ratio; **(HR)QoL**, (health-related) quality of life; **LS**, least square; **MedDRA**, Medical Dictionary for Regulatory Activities; **MID**, minimal important difference; **MMRM**, mixed-effect model for repeated measures; **mo,** months; **(m)TNBC,** (metastatic) triple-negative breast cancer; **n,** number of participants; **NCI**, National Cancer Institute; **ORR**, objective response rate; **OS,** overall survival; **PFS,** progression-free survival; **SAC**, single-agent chemotherapy of physician's choice; **TROP-2**, trophoblast cell-surface antigen-2.

References. **1.** Trodelvy® Summary of Product Characteristics for GB. Gilead Sciences Ltd. Available at: https://www.medicines.org.uk/emc product/12880. Accessed: December 2023; **2.** Bardia A, et al. *N Engl J Med*. 2021;384(16):1529–1541; **3.** Bardia A, et al. Poster (LBA17). ESMO [virtual meeting]. 2021; **4.** Loibl S et al. *Euro J Cancer*. 2023;178:23–33; **5.** Cocks K, et al. *J Clin Oncol*. 2011;29:89–96; **6.** Rugo H, et al. Poster. San Antonio Breast Cancer Symposium (virtual meeting). 2020 (poster PS11–09).

PRESCRIBING INFORMATION: Consult Summary of Product Characteristics (SmPC) before prescribing.

Trodelvy® ▼(sacituzumab govitecan) 180 mg powder for concentrate for solution for infusion. **INDICATION:** 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. **DOSAGE/ADMINISTRATION:** Intravenous infusion only. Should be administered in an environment where resuscitation facilities are available. Premedication for prevention of infusion reactions and chemotherapy-induced nausea and vomiting (CINV) is recommended. Initial infusion administered over 3 hours, patients should be observed for at least 30 minutes after initial dose for signs/symptoms of infusion-related reactions. Subsequent infusions administered over 1 to 2 hours, if prior infusions were tolerated. Adults: 10 mg/kg administered once weekly on Days 1 and 8 of 21-day treatment cycles. Elderly: No overall differences in safety and effectiveness observed between patients ≥ 65 years old and younger patients. Hepatic impairment: Mild - No adjustment to starting dose required. Safety not established in moderate/severe- not recommended. Renal impairment: Mild - No adjustment to starting dose required. Moderate, severe, or end-stage renal impairment - not studied. Paediatric (< 18 years): Safety and efficacy not established. **CONTRAINDICATIONS:** Hypersensitivity to active substance or any excipients or to previous irinotecan therapy. **WARNINGS/PRECAUTIONS:** Refer to SmPC. Hypersensitivity: Trodelvy can cause anaphylactic reactions and severe and life-threatening hypersensitivity. Inform patients of the risk of serious infusion reactions and anaphylaxis. Instruct patients to report signs or symptoms of hypersensitivity to their medical team. Neutropenia: Can cause severe or life-threatening neutropenia. Should not be administered in case of neutropenic fever. Administration of granulocyte colony-stimulating factor (G-CSF) and dose reduction are required for severe neutropenia or febrile neutropenia. Consider G-CSF for secondary prophylaxis. Diarrhoea: Can cause severe diarrhoea. Grade 3-4 diarrhoea must resolve to </=Grade 1 before treatment, dose reduction is required. Infusion-related reactions: Pre-infusion medication for patients receiving Trodelvy is recommended. Patients should be closely observed for infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. Infusion should be slowed down or interrupted, if patient develops infusion-related reaction. Should be permanently discontinued if life-threatening, infusion-related reactions occur. Nausea and vomiting: Emetogenic. Premedication with a two or three drug combination regimen (e.g., dexamethasone with either a 5-HT3 receptor antagonist or an NK-1 receptor antagonist) is recommended for prevention of CINV. In case of Grade 3 nausea or Grade 3-4 vomiting treatment should only be continued with additional supportive measures when resolved to ≤ Grade 1. All patients should be given take-home medications with clear instructions for prevention and treatment of nausea and vomiting. Increased risk of adverse reactions in patients with reduced UGT1A1 activity: Individuals who are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk of severe neutropenia, severe diarrhoea, febrile neutropenia, and anaemia and may be at increased risk for other adverse reactions following initiation of treatment. Patients with known reduced UGT1A1 activity should be closely monitored for adverse reactions. Withhold or permanently discontinue based on clinical assessment of onset, duration and severity of observed adverse reactions in patients with evidence of acute early-onset or unusually severe adverse reactions, which may indicate reduced UGT1A1 activity. **INTERACTIONS:** See SmPC for full list. UGT1A1 inhibitors: Concomitant administration with inhibitors of UGT1A1 may increase incidence of adverse reactions due to potential increase in systemic exposure to SN-38 (the small molecule moiety of sacituzumab govitecan) primarily metabolised via UGT1A1; UGT1A1 inducers: Exposure to SN-38 may be substantially reduced in patients concomitantly receiving UGT1A1 enzyme inducers. CYP3A: SN-38 is primarily metabolised via UGT1A1. Inhibitors or inducers of CYP3A are not anticipated to impact SN-38 exposure. **PREGNANCY/LACTATION/FERTILITY:** See SmPC for full details. Pregnancy: Trodelvy can cause teratogenicity and/or embryo-foetal lethality during pregnancy. Trodelvy is not recommended during pregnancy. Women of Childbearing Potential (WOCBP)/ Contraception in Males and Females: WOCBP have to use effective contraception during treatment and for 6 months after the last dose. Male patients with female partners of childbearing potential have to use effective contraception during treatment and for 3 months after the last dose. The pregnancy status of women of childbearing potential should be verified prior to the initiation of Trodelvy. Breast-feeding: Should be discontinued during treatment and for 1 month after the last dose. Fertility: may be impaired in females of reproductive potential. **DRIVING/USING MACHINERY:** Minor influence on ability to drive and use machines. Dizziness reported as "very common" side effect. **SIDE EFFECTS:** Refer to SmPC for full list of side effects. Very common (≥ 1/10): Urinary tract infection, Upper respiratory tract infection; Neutropenia, Anaemia, Leukopenia, Lymphopenia, Decreased appetite, Hypokalaemia, Hypomagnesaemia, Hyperglycaemia, Insomnia, Hypersensitivity, Headache, Dizziness, Cough, Dyspnoea, Nausea, Diarrhoea, Vomiting, Constipation, Abdominal pain, Alopecia, Rash, Pruritus, Back pain, Arthralgia, Fatigue, Pyrexia, Aspartate aminotransferase increased, Weight decreased,; Common (≥1/100 to <1/10): Pneumonia, Bronchitis, Febrile neutropenia, Thrombocytopenia, Hypophosphataemia, Dehydration, Hyponatraemia, Hypocalcaemia, Dysgeusia, Hypotension, Epistaxis, Rhinorrhoea, Nasal congestion, Stomatitis, Abdominal pain upper, Dyspepsia, Abdominal distension, Gastrooesophageal reflux disease, Colitis, Dry skin, Skin hyperpigmentation, Rash maculo-papular, Dermatitis acneiform, Proteinuria, Oedema, Chills, Pain, ALP increased, LDH increased, aPTT prolonged,; Serious: Neutropenia, Febrile neutropenia, Diarrhoea, Pneumonia, Anaphylactic reactions, Hypersensitivity, Respiratory failure, Sepsis, Neutropenic colitis. **LEGAL CATEGORY:** POM. **PACK:** Type 1 clear glass single-dose 50 mL vials, dark grey rubber stopper, crimp-sealed with aluminum flip-off cap. One vial per pack. **PRICE:** UK NHS List Price – Pack of 1 x 50mL vial = £793.00 **MARKETING AUTHORISATION NUMBER:** PLGB 11972/0050 **FURTHER INFORMATION:** Gilead Sciences Ltd, 280 High Holborn, London, WC1V 7EE, UK; +44 (0) 8000 113700. ukmedinfo@gilead.com. Trodelvy is a trademark. **DATE OF PREPARATION:** October 2023; UK-TRO-1351.

▼**Additional monitoring required**

Adverse events should be reported.

For UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard or via the Yellow Card app (download from the Apple App Store or Google Play Store).

Adverse events should also be reported to Gilead to safety_FC@gilead.com or +44 (0) 1223 897500. Trodelvy is a biological medicine, healthcare professionals should report adverse reactions by brand name and batch number.