The first and only approved **TROP-2**-directed ADC[1,2,3]

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

mTNBC

Survival Elevated

TRODELVY significantly improved survival vs single-agent chemotherapy in 2L and later mTNBC in the Phase 3 ASCENT trial*[4]

TRODELVY dosing, preparation and management

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.[4]

TRODELVY special warnings and precautions include traceability, severe or life-threatening neutropenia, severe diarrhoea, hypersensitivity, nausea and vomiting, use in patients with reduced UGT1A1 activity, embryo-foetal toxicity, and sodium.

Please see Package Insert for full details on managing adverse reactions.

*ASCENT was an international, Phase 3, multicentre, open-label, randomised trial of patients with unresectable locally advanced or metastatic TNBC (N=529). Patients were randomised 1:1 to receive TRODELVY 10 mg/kg IV on Days 1 and 8 every 21 days, or single-agent chemotherapy of the physician's choice (eribulin, vinorelbine, gemcitabine, or capecitabine). The primary endpoint was PFS in patients without present or prior history of brain metastases at baseline (88% of the overall study population), as measured by BICR based on RECIST v1.1 criteria. Median PFS in the primary analysis population was 5.6 months with TRODELVY vs 1.7 months with single-agent chemotherapy (HR: 0.41; *P*<.0001). Median OS was 12.1 months with TRODELVY vs 6.7 months with single-agent chemotherapy (HR: 0.48; *P*<.0001).[4]

2L, second line; ADC, antibody-drug conjugate; BICR, blinded independent central review; HR, hazard ratio; IV, intravenous; mTNBC, metastatic triple-negative breast cancer; OS, overall survival; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumours; TNBC, triple-negative breast cancer; TROP-2, trophoblast cell surface antigen 2.

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References: 1. Health Sciences Authority. TRODELVY Product License (sacituzumab govitecan). **2.** Food & Drug Administration. TRODELVY. Available at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-regular-approval-sacituzumab-govitecan-triple-negativebreast-cancer. **3.** European Medicines Agency. TRODELVY (sacituzumab govitecan). Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/ trodelvy#authorisation-details-section. **4.** TRODELVY (sacituzumab govitecan) Singapore Package Insert. **5.** Data on file. Gilead Sciences, Inc. 2021. **6.** Rugo H, et al. Poster. SABCS [virtual meeting]. 2020 (abstr PS11- 09). **7.** Bardia A, et al. N Engl J Med. 2021;384(16):1529-1541.

Please scan the QR code for full prescribing information

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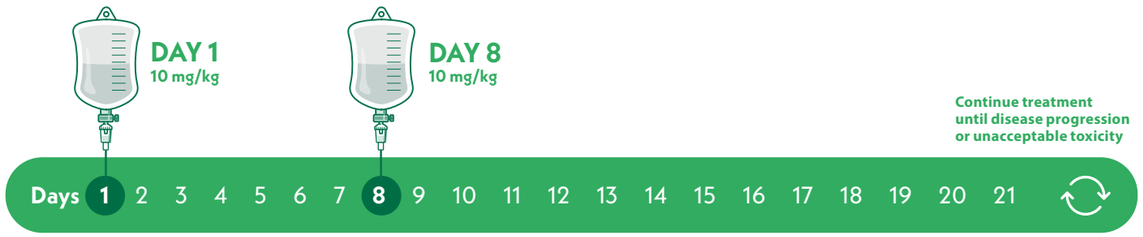
TRODELVY dosing and administration[4]

The recommended dose of TRODELVY is 10 mg/kg body weight administered as an IV infusion once weekly on Day 1 and Day 8 of 21-day treatment cycles.



Pre-infusion medication

Consider antiemetic preventive treatment with 2 or 3 medicinal products to prevent and treat chemotherapy-induced nausea and vomiting, e.g.:

- Dexamethasone with either a 5-HT3 receptor antagonist or NK-1 receptor antagonist
- Other drugs as indicated

Pre-infusion medication is recommended to prevent infusion reactions, e.g.:

- Antipyretics
- H1 and H2 blockers
- Corticosteroids

Method of administration

	First infusion	Subsequent infusions
Infusion period	3 hours	1–2 hours (if prior infusions were tolerated)
Observation period	Observe patients during the infusion and for ≥30 min after	

The infusion rate of TRODELVY should be slowed down or infusion interrupted if the patient develops an infusion-related reaction. Grade ≥3 infusion reactions occurred in 1.9% of patients receiving TRODELVY (n=7/366).

Administer TRODELVY as an IV infusion*

Protect the infusion bag from light†

Do not mix TRODELVY, or administer as an infusion, with other medicinal products

Upon completion of the infusion, flush the intravenous line with 20 mL sodium chloride 0.9% solution for injection

*Do not administer as an IV push or bolus. An infusion pump may be used.
†The infusion bag should be covered during administration to the patient until dosing is complete. It is not necessary to cover the infusion tubing or to use light-protective tubing during the infusion.

IV, intravenous.

Dose modifications can be made as needed to help manage adverse reactions[4]

TRODELVY dose should be held if:

- The absolute neutrophil count is below 1500/mm^3 on Day 1 of any cycle, the neutrophil count is below 1000/mm^3 on Day 8 of any cycle, or in case of neutropenic fever. Hold treatment until improved
- Grade 3–4 diarrhoea occurs at the time of scheduled treatment. Hold treatment until resolved to ≤Grade 1
- Grade 3 nausea or Grade 3–4 vomiting occurs at the time of scheduled treatment. Hold treatment until resolved to ≤Grade 1

Dose modifications for severe neutropenia

ADVERSE REACTION	FIRST OCCURRENCE	SECOND OCCURRENCE	THIRD OCCURRENCE
Grade 4 neutropenia ≥7 days, or **Grade 3 febrile neutropenia (absolute neutrophil count <1000/mm^3 and fever ≥38.5°C),** or **At time of scheduled treatment, Grade 3–4 neutropenia which delays dosing by 2 or 3 weeks for recovery to ≤Grade 1**	Administer reactive G-CSF **25%** dose reduction (7.5 mg/kg)	**50%** dose reduction (5 mg/kg)	Discontinue treatment
At time of scheduled treatment, Grade 3–4 neutropenia which delays dosing beyond 3 weeks for recovery to ≤Grade 1	Discontinue treatment		

Dose modifications for severe non-neutropenic toxicity

ADVERSE REACTION	FIRST OCCURRENCE	SECOND OCCURRENCE	THIRD OCCURRENCE
Grade 4 non-hematologic toxicity of any duration, or **Any Grade 3–4 nausea, vomiting, or diarrhoea due to treatment that is not controlled with antiemetics and anti-diarrhoeal agents,** or **Other Grade 3–4 non-hematologic toxicity persisting >48 hours despite optimal medical management,** or **At time of scheduled treatment, Grade 3–4 non-neutropenic hematologic or non-hematologic toxicity, which delays dose by 2 or 3 weeks for recovery to ≤Grade 1**	**25%** dose reduction (7.5 mg/kg)	**50%** dose reduction (5 mg/kg)	Discontinue treatment
In the event of Grade 3–4 non-neutropenic hematologic or non-hematologic toxicity, which does not recover to ≤Grade 1 within 3 weeks	Discontinue treatment		

G-CSF, granulocyte-colony stimulating factor.

TRODELVY has a well-characterised safety profile[4]

In the Phase 3 ASCENT trial:

<5% (n=10/258) of patients discontinued TRODELVY for any adverse reaction[6]

NO drug-related deaths in the TRODELVY group[7]

- No patients in the TRODELVY group discontinued treatment due to treatment-related neutropenia or diarrhoea[6]

Adverse events of special interest in the ASCENT trial[7]

		TRODELVY (n=258)			Single-agent chemotherapy (n=224)		
		All Grades n (%)	Grade 3 n (%)	Grade 4 n (%)	All Grades n (%)	Grade 3 n (%)	Grade 4 n (%)
	Neutropenia*	163 (63)	88 (34)	44 (17)	96 (43)	45 (20)	29 (13)
Hematologic	Anaemia†	89 (34)	20 (8)	0	54 (24)	11 (5)	0
	Leukopenia‡	41 (16)	23 (9)	3 (1)	25 (11)	10 (4)	2 (1)
	Febrile neutropenia	15 (6)	12 (5)	3 (1)	5 (2)	4 (2)	1 (<1)
Gastrointestinal	Diarrhoea	153 (59)	27 (10)	0	27 (12)	1 (<1)	0
	Nausea	147 (57)	6 (2)	1 (<1)	59 (26)	1 (<1)	0
	Vomiting	75 (29)	2 (1)	1 (<1)	23 (10)	1 (<1)	0
Other	Fatigue	115 (45)	8 (3)	0	68 (30)	12 (5)	0
	Alopecia	119 (46)	0	0	35 (16)	0	0

In ASCENT, approximately 80% of patients stayed on the full TRODELVY dose without the need for a dose reduction[§7]

There are minor differences in the adverse event rates shown above compared with those reported in the package insert, which uses pooled data from 2 clinical trials (ASCENT and IMMU-132-01).

*The neutropenia category included neutropenia and decreased neutrophil count.
†The anaemia category included anaemia, decreased hemoglobin level, and decreased red cell count.
‡The leukopenia category included leukopenia and decreased white cell count.
§Dose reductions due to adverse events occurred with similar frequency in the two groups (22% of the patients who received TRODELVY and 26% of those who received chemotherapy).

Practical AE management with TRODELVY[4]

Management of neutropenia

Talk to patients about the possibility of experiencing neutropenia while on TRODELVY 1

Encourage patients to notify their healthcare team if they experience fever, chills, or other signs of infection 2

Consider use of reactive G-CSF to manage neutropenia[4] 3

Dose modifications or interruptions may be required to manage severe neutropenia[4]

TRODELVY should not be administered if the absolute neutrophil count is below 1500/mm^3 on Day 1 of any cycle or if the neutrophil count is below 1000/mm^3 on Day 8 of any cycle. TRODELVY should not be administered in case of neutropenic fever.[4] 4

Management of diarrhoea

Talk to patients about the possibility of experiencing diarrhoea while on TRODELVY

Encourage patients to notify their healthcare team at the first signs or symptoms of severe or persistent diarrhoea. 1

Initiate loperamide at the onset of diarrhoea unless an infectious cause is identified[4]

Per ASCENT study: Consider initiating loperamide 4 mg, then 2 mg with every diarrhoea episode, max of 16 mg/day. Discontinue loperamide 12 hours after diarrhoea resolves.[7] 2

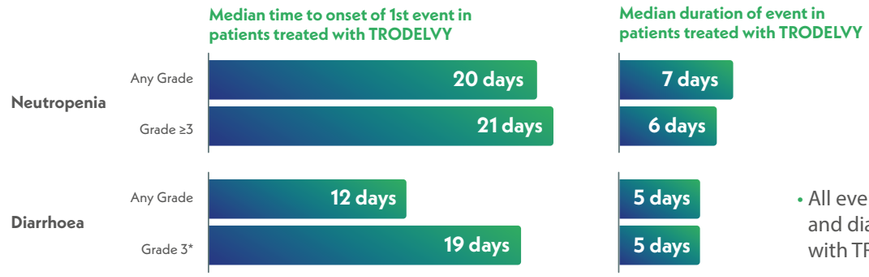
Initiate other supportive measures such as administration of fluids or electrolytes as clinically appropriate[4] 3

Dose modifications or interruptions may be required to manage persistent Grade ≥3 diarrhoea[4]

If a patient is experiencing Grade ≥3 diarrhoea at the time of scheduled treatment, TRODELVY should not be administered. When resolved to ≤Grade 1, TRODELVY should be continued.[4] 4

Patients who exhibit an excessive cholinergic response to treatment with TRODELVY (e.g. abdominal cramping, diarrhoea, salivation, etc.) can receive appropriate treatment (e.g. atropine) for subsequent treatments with TRODELVY.[4]

Most instances of neutropenia and diarrhoea occurred within the first 2 cycles and lasted about 1 week[6]



- All events of Grade ≥3 neutropenia and diarrhoea in patients treated with TRODELVY resolved[6]

*No events of Grade 4 diarrhoea were reported.

AE, adverse event; G-CSF, granulocyte-colony stimulating factor.

TRODELVY reconstitution and dilution[4]

TRODELVY is a cytotoxic medicinal product. Applicable special handling and disposal procedures have to be followed.

mTNBC

TRODELVY®
sacituzumab govitecan
200 mg powder for concentrate for solution for infusion

Reconstitution

1. Calculate the required dose (mg) of TRODELVY based on the patient's body weight at the beginning of each treatment cycle (or more frequently if the patient's body weight changed by more than 10% since the previous administration).

   Required TRODELVY dose (mg) = Patient's body weight (kg) x 10 mg/kg

2. Allow the required number of vials to warm to room temperature (20°C to 25°C).

3. Using a sterile syringe, slowly inject 20 mL of sodium chloride 9 mg/mL (0.9%) solution for injection into each TRODELVY vial. The resulting concentration will be 10 mg/mL.

   PLEASE NOTE: The target fill amount of drug product is 200 mg per each TRODELVY vial. The amount of drug indicated on the label (180 mg/vial) represents the minimum amount of drug possibly contained in the vial based on filling and extraction variability. Based on the target fill amount of 200 mg per vial, upon reconstitution with 20 mL of sodium chloride 9 mg/mL (0.9%) solution for injection following labelled instructions contained in the TRODELVY package insert, the resulting target concentration will be 10 mg/mL.[2]

4. Gently swirl vials and allow to dissolve for up to 15 minutes. Do not shake. The product should be inspected visually for particulate matter and discoloration prior to administration. The solution should be free of visible particulates, clear and yellow. Do not use the reconstituted solution if it is cloudy or discoloured.

5. Use immediately to prepare a diluted TRODELVY solution for infusion.

Dilution

6. Calculate the required volume of the reconstituted TRODELVY solution needed to obtain the appropriate dose according to the patient's body weight.

   Required volume of reconstituted TRODELVY solution (mL) = Patient's required TRODELVY dose (mg) ÷ 10

7. Determine the final volume of the infusion solution to deliver the appropriate dose at a TRODELVY concentration range of 1.1 mg/mL to 3.4 mg/mL.

8. Withdraw and discard a volume of 9 mg/mL (0.9%) sodium chloride from the final infusion bag that is necessary to achieve the indicated TRODELVY concentration following addition of the pre-determined volume of reconstituted TRODELVY solution.

9. Withdraw the calculated amount of the reconstituted TRODELVY solution from the vial(s) using a syringe. Discard any unused portion remaining in the vial(s).

10. Slowly inject the required volume of reconstituted TRODELVY solution into a polyvinyl chloride, polypropylene or ethylene/propylene copolymer infusion bag to minimise foaming. Do not shake the contents.

    For patients whose body weight exceeds 170 kg, divide the total dose of TRODELVY equally between two 500 mL infusion bags and infuse sequentially over 3 hours for the first infusion and over 1–2 hours for subsequent infusions.

11. If necessary, adjust the volume in the infusion bag as needed with sodium chloride 9 mg/mL (0.9%) solution for injection, to obtain a concentration of 1.1 mg/mL to 3.4 mg/mL (the total volume should not exceed 500 mL). Only 9 mg/mL (0.9%) sodium chloride injection should be used since the stability of the reconstituted product has not been determined with other infusion-based solutions.

If not used immediately:

The infusion bag containing TRODELVY solution can be stored refrigerated 2°C to 8°C for up to 24 hours

After refrigeration, administer diluted solution at room temperature up to 25°C within 8 hours (including infusion time).

Do not freeze or shake

Protect from light

Notes

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200 mg powder for concentrate for solution for infusion