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 efficacy and safety

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 Singapore Package Insert. **5.** Gennari A, et al. Ann Oncol. 2021;32(12):1475–1495. **6.** Bardia A, et al. N Engl J Med. 2021;384(16):1529-1541. **7.** Eisenhauer EA, et al. Eur J Cancer. 2009;45(2):228-247; **8.** O'Shaughnessy J, et al. Poster. ASCO [virtual meeting]. 2021 (Poster 1077). **9.** Carey, L.A., Loirat, D., Punie, K. et al. Sacituzumab govitecan as second-line treatment for metastatic triple-negative breast cancer—phase 3 ASCENT study subanalysis. npj Breast Cancer 8, 72 (2022). https://doi.org/10.1038/s41523-022-00439-5. **10.** Hurvitz SA, et al. Poster. ESMO BC. 2022 (Poster 168P). **11.** Rugo H, et al. Poster. SABCS [virtual meeting]. 2020 (abstr PS11- 09).

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SG-TRO-0001 V1.0 29Nov2022

TRODELVY is indicated for use as early as 2L mTNBC[4]

TRODELVY is indicated for the treatment of adult patients with unresectable or metastatic TNBC who have received two or more prior systemic therapies, including at least one of them for advanced disease.[4]

STAGE I/II/III (TNBC)

Standard therapy including systemic chemotherapy (neoadjuvant or adjuvant)

STAGE IV (mTNBC)

Systemic therapy — **1L**

TRODELVY (preferred) (or chemotherapy of physician's choice) — **2L**

ESMO recommended
ESMO guidelines recommend TRODELVY as a preferred treatment option for 2L mTNBC[5]

Chemotherapy of physician's choice — **3L**

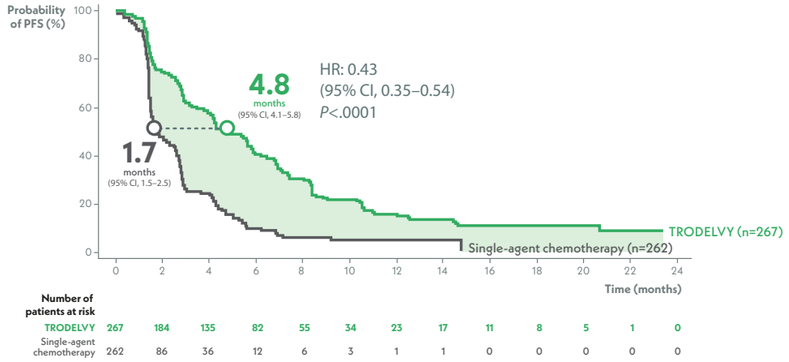
Chemotherapy of physician's choice — **4L**

1L, first line; 2L, second line; 3L, third line; 4L, fourth line; ESMO, European Society for Medical Oncology; mTNBC, metastatic triple-negative breast cancer; TNBC, triple-negative breast cancer.

TRODELVY significantly improved survival vs chemotherapy for patients with 2L and later mTNBC[4]

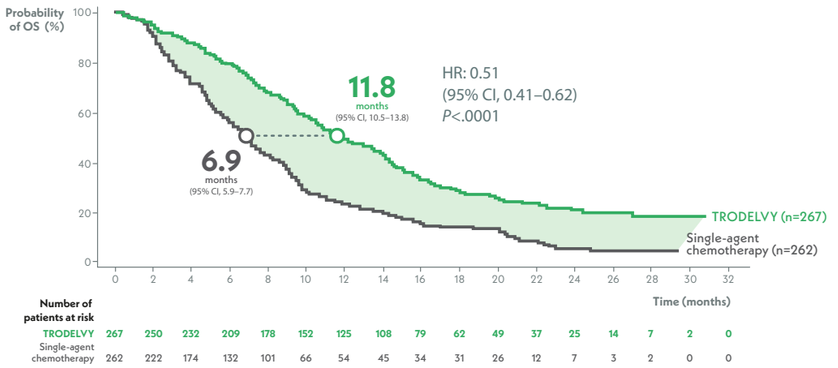
In the Phase 3 ASCENT trial ITT population:

Median PFS with TRODELVY was nearly 3X LONGER than chemotherapy*†[4]



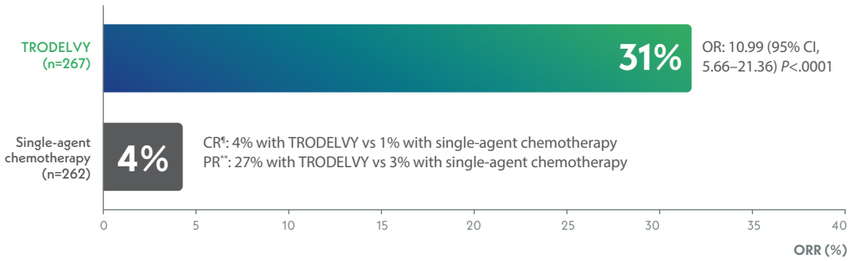
*Assessed by independent central review in the ITT population. The PFS improvement in the primary analysis population (median PFS: 5.6 months vs 1.7 months; HR: 0.41; *P*<.0001) was consistent with the ITT population. The primary analysis population consisted of patients without present or prior history of brain metastases at baseline (n=468). The ITT population consisted of patients with or without brain metastases at baseline (N=529).[4]
†Single-agent chemotherapy of physician's choice (eribulin, vinorelbine, gemcitabine, or capecitabine).[4]

Median OS of 1 YEAR with TRODELVY‡[4]



‡Assessed by independent central review in the ITT population. The OS improvement in the primary analysis population (median OS: 12.1 months vs 6.7 months; HR: 0.48; *P*<.0001) was consistent with the ITT population. The primary analysis population consisted of patients without present or prior history of brain metastases at baseline (n=468). The ITT population consisted of patients with or without brain metastases at baseline (N=529). ITT population final database lock 25 February 2021.[4]

TRODELVY delivered more than 7X GREATER objective response rate than chemotherapy§‖[6]



§Based on objective response rates for TRODELVY and single-agent chemotherapy of physician's choice (eribulin, vinorelbine, gemcitabine, or capecitabine).[4]
‖Assessed by independent central review in the ITT population.[4] The ORR results in the primary analysis population (ORR: 35% vs 5%; OR: 10.8; 95% CI, 5.6–21.0) were consistent with the ITT population. The primary analysis population consisted of patients without present or prior history of brain metastases at baseline (n=468). The ITT population consisted of patients with or without brain metastases at baseline (N=529).[6]
¶Assessed by independent central review in the ITT population.[6] CR defined as disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm.[7]
**Assessed by independent central review in the ITT population.[6] PR defined as at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.[7]

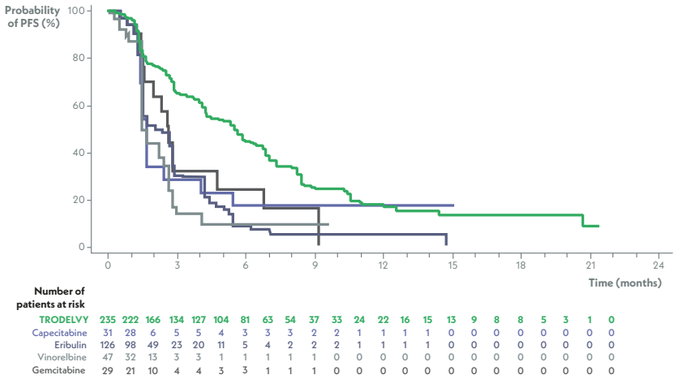
2L, second line; CI, confidence interval; CR, complete response; HR, hazard ratio; ITT, intent-to-treat; mTNBC, metastatic triple-negative breast cancer; OR, odds ratio; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PR, partial response.

TRODELVY demonstrated consistent outcomes in post hoc subgroup analyses[8-10]

In subgroup analyses of ASCENT, TRODELVY helped patients experience:

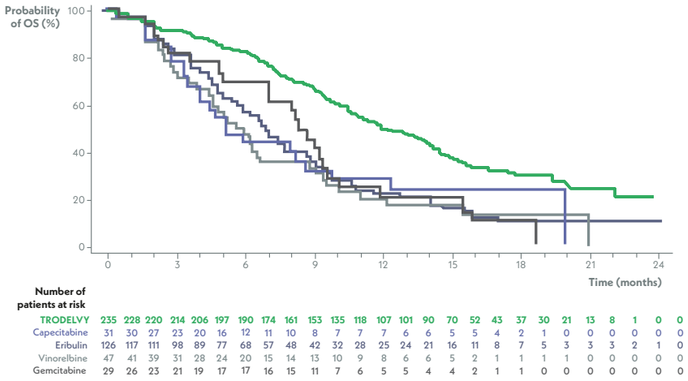
Improved outcomes vs chemotherapy, regardless of chemotherapy used[*8]

PFS by individual chemotherapy[8]



Median PFS (95% CI)	
TRODELVY (n=235)	**5.6 months** (2.6–8.1)
Capecitabine (n=31)	**1.6 months** (1.4–2.4)
Eribulin (n=126)	**2.1 months** (1.5–2.8)
Vinorelbine (n=47)	**1.6 months** (1.4–2.7)
Gemcitabine (n=29)	**2.7 months** (1.6–4.8)

OS by individual chemotherapy[8]



Median OS (95% CI)	
TRODELVY (n=235)	**12.1 months** (10.7–14.0)
Capecitabine (n=31)	**5.2 months** (3.5–8.6)
Eribulin (n=126)	**6.9 months** (5.8–7.8)
Vinorelbine (n=47)	**5.9 months** (4.5–6.7)
Gemcitabine (n=29)	**8.4 months** (5.0–9.6)

Response rates by individual chemotherapy[8]

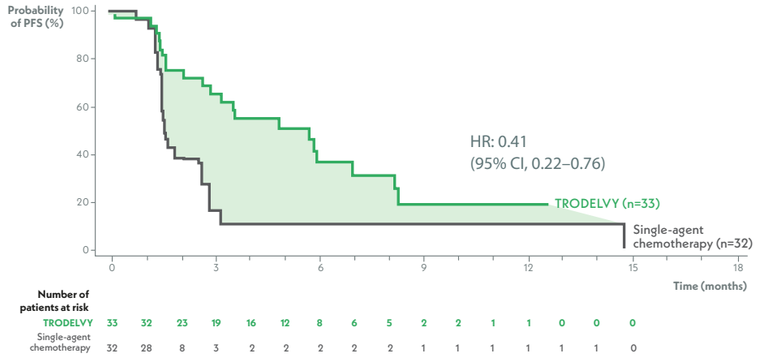
	TRODELVY (n=235)	**Capecitabine** (n=31)	**Eribulin** (n=126)	**Vinorelbine** (n=47)	**Gemcitabine** (n=29)
ORR	35%	6%	5%	4%	3%
CR	4%	0%	2%	0%	0%
PR	31%	6%	3%	4%	3%
CBR	45%	10%	8%	6%	14%
Median DOR (95% CI)	6.3 months (5.5–9.0)	NE	3.6 months (2.9–4.2)	2.8 months (NE)	2.9 months (NE)

Figures adapted from O'Shaughnessy J, et al. 2021.
*Assessed by independent central review in the brain metastases negative population.

CBR, clinical benefit rate; CI, confidence interval; CR, complete response; DOR, duration of response; HR, hazard ratio; NE, not estimable; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PR, partial response.

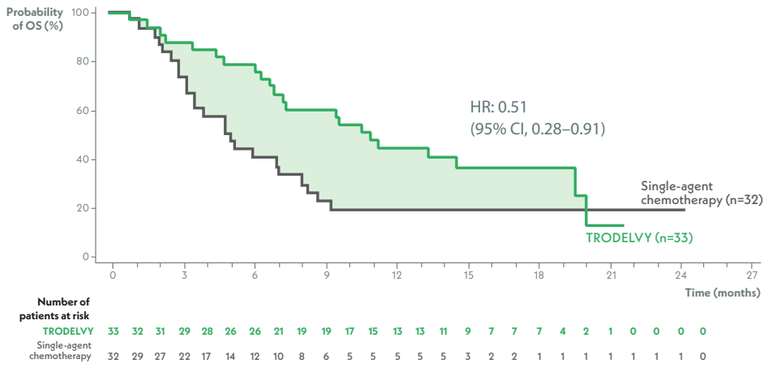
Improved outcomes vs chemotherapy in the 2L patient population[*9]

PFS in 2L population[9]



Median PFS (95% CI)	
TRODELVY (n=33)	**5.7 months** (2.6–8.1)
Single-agent chemotherapy (n=32)	**1.5 months** (1.4–-2.6)

OS in 2L population[9]



Median OS (95% CI)	
TRODELVY (n=33)	**10.9 months** (6.9–19.5)
Single-agent chemotherapy (n=32)	**4.9 months** (3.1–7.1)

Response rates in 2L population[9]

	TRODELVY (n=33)	**Single-agent chemotherapy** (n=32)
ORR	30%	3%
CR	3%	0%
PR	27%	3%
CBR	42%	6%
Median DOR (95% CI)	6.7 months (2.9–NE)	NE

Figures adapted from Carey A, et al. 2021.
*Assessed by independent central review in the brain metastases negative population. This ASCENT subanalysis of patients with mTNBC who recurred ≤12 months after (neo)adjuvant chemotherapy and then only received 1 line of therapy in the metastatic setting assessed the benefit of TRODELVY in this subgroup vs the overall trial population.[4]

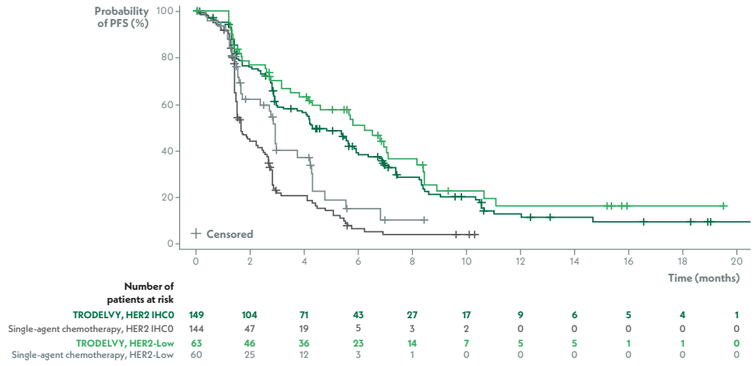
CBR, clinical benefit rate; CI, confidence interval; CR, complete response; DOR, duration of response; HR, hazard ratio; NE, not evaluable; ORR, objective response rate; OS, overall survival; PFS, progression-free survival.

TRODELVY demonstrated consistent outcomes in post hoc subgroup analyses[8-10]

In subgroup analyses of ASCENT, TRODELVY helped patients experience:

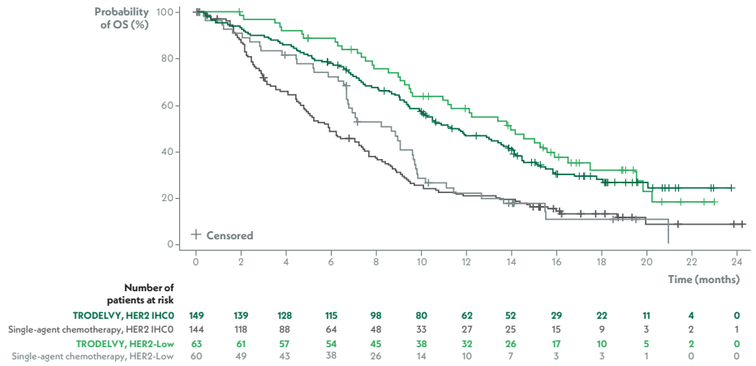
Improved outcomes vs chemotherapy, regardless of HER2 status*[10]

PFS by HER2 status[10]



		Median PFS
HER2 IHC0	TRODELVY (n=149)	4.3 months
	Single-agent chemotherapy (n=144)	1.6 months
HER2 IHC1+ or HER2 IHC2+ with ISH-negative	TRODELVY (n=63)	6.2 months
	Single-agent chemotherapy (n=60)	2.9 months

OS by HER2 status[10]



		Median OS
HER2 IHC0	TRODELVY (n=149)	11.3 months
	Single-agent chemotherapy (n=144)	5.9 months
HER2 IHC1+ or HER2 IHC2+ with ISH-negative	TRODELVY (n=63)	14.0 months
	Single-agent chemotherapy (n=60)	8.7 months

Response rates by HER2 status[10]

	HER2 IHC0		HER2 IHC1+ or HER2 IHC2+ with ISH-negative	
	TRODELVY (n=149)	Single-agent chemotherapy (n=144)	TRODELVY (n=63)	Single-agent chemotherapy (n=60)
ORR	31%	3%	32%	8%
CR	2%	0%	5%	2%
PR	29%	3%	27%	7%
CBR	68%	26%	68%	45%
Median DOR (95% CI)	6.9 months (5.4–9.0)	2.9 months (2.8–NE)	5.6 months (4.3–NE)	3.6 months (2.9–NE)

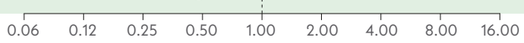
Figures adapted from Hervitz SA, et al. 2022.
*Assessed in patients with and without brain metastases.

CBR, clinical benefit rate; CR, complete response; DOR, duration of response; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ISH, in-situ hybridisation; NE, not estimable; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PR, partial response.

PFS benefit vs chemotherapy was consistently demonstrated across all patient subgroups[4,6]

Median PFS by subgroup*[6]

Subgroup	Progression-free survival, months: No. of patients	TRODELVY	Chemotherapy	HR for disease progression or death
All patients	468	5.6	1.7	0.41
Age				
<65 yr	378	4.6	1.7	0.46
≥65 yr	90	7.1	2.4	0.22
Race				
White	369	5.7	1.7	0.39
Black	56	5.4	2.2	0.45
Asian	18	NE	1.5	0.40
Previous therapies				
2 or 3	330	5.8	1.6	0.39
>3	138	5.6	2.5	0.48
Geographic region				
North America	298	4.9	2.0	0.44
Rest of the world	170	5.9	1.6	0.36
Previous use of PD-1 or PD-L1 inhibitors				
Yes	127	4.2	1.6	0.37
No	341	6.2	2.1	0.42
Liver metastasis				
Yes	199	4.2	1.5	0.48
No	269	6.8	2.3	0.36
Initial diagnosis of TNBC				
Yes	322	5.7	1.6	0.38
No	146	4.6	2.3	0.48



Adapted from Bardia A, et al. 2021.
*Assessed by independent central review in the brain metastases negative population.

HR, hazard ratio; NE, not estimable; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand 1; PFS, progression-free survival; TNBC, triple-negative breast cancer.

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[11]

NO drug-related deaths in the TRODELVY group[6]

- No patients in the TRODELVY group discontinued treatment due to treatment-related neutropenia or diarrhoea[11]

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

		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 (%)
Hematologic	Neutropenia*	163 (63)	88 (34)	44 (17)	96 (43)	45 (20)	29 (13)
	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§6

*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] 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]

Management of diarrhoea

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

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

Initiate loperamide at the onset of diarrhoea unless an infectious cause is identified[4] 2

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.[3]

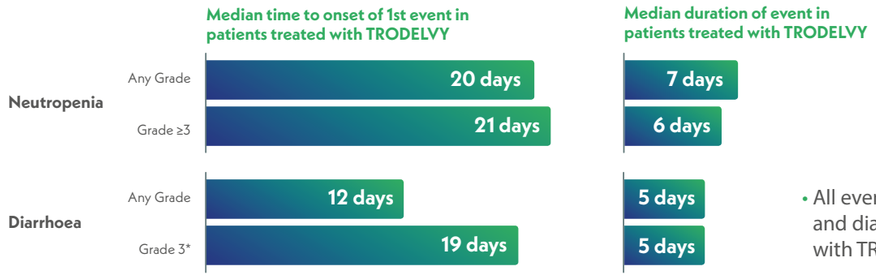
Initiate other supportive measures such as administration of fluids or electrolytes as clinically appropriate[4] 3

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

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[11]



- All events of Grade ≥3 neutropenia and diarrhoea in patients treated with TRODELVY resolved[11]

*No events of Grade 4 diarrhoea were reported.

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

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).

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

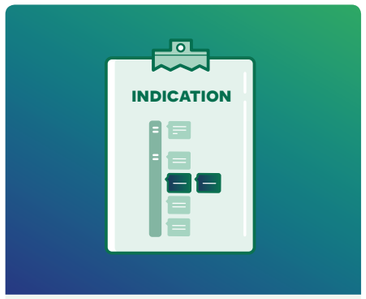
ADVERSE REACTION	FIRST OCCURRENCE	SECOND OCCURRENCE	THIRD OCCURRENCE
Grade 4 neutropenia ≥7 days, or Grade 3 febrile neutropenia (absolute neutrophil count <1000/mm^3 and fever ≥38.5°C), or At time of scheduled treatment, Grade 3–4 neutropenia which delays dosing by 2 or 3 weeks for recovery to ≤Grade 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.

Elevate outcomes for your patients with 2L and later mTNBC WITH TRODELVY



For use as early as
2L mTNBC

ESMO guidelines recommend TRODELVY as a preferred treatment option for 2L mTNBC[5]

Median OS
1 YEAR

Median OS:
11.8 months with TRODELVY
(95% CI,10.5–13.8
vs 6.9 months
with single-agent
chemotherapy
(95% CI, 5.9–7.7); *P*<.0001*[4]

Well-characterised
SAFETY

<5% of patients on TRODELVY discontinued due to adverse reactions[10]

NO drug-related deaths in the TRODELVY group[6]

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.

*Assessed by independent central review in the ITT population. The OS improvement in the primary analysis population was consistent with the ITT population (median OS: 12.1 months vs 6.7 months; HR: 0.48; *P*<.0001). The primary analysis population consisted of patients without present or a prior history of brain metastases at baseline (n=468). The ITT population consisted of patients with or without brain metastases at baseline (N=529). ITT population final database lock 25 February 2021.[4]

2L, second line; CI, confidence interval; ESMO, European Society for Medical Oncology; HR, hazard ratio; ITT, intent-to-treat; mTNBC, metastatic triple-negative breast cancer; OS, overall survival.

Notes