

For adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received 2 or more prior systemic therapies, at least one of them for metastatic disease<sup>1</sup>

# A WAY IN WITH TRODELVY

TRODELVY® (sacituzumab govitecan-hziy) attacks mTNBC with an antibody-drug conjugate (ADC) that binds to Trop-2.<sup>1</sup>

Based on pre-clinical data. May not correlate with clinical outcomes.



SEE THERAPY MANAGEMENT INFORMATION INSIDE

## DOSING & ADMINISTRATION INFORMATION

### IMPORTANT SAFETY INFORMATION

#### BOXED WARNING: NEUTROPENIA AND DIARRHEA

- Severe or life-threatening neutropenia may occur. Withhold TRODELVY for absolute neutrophil count below 1500/mm<sup>3</sup> or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.
- Severe diarrhea may occur. Monitor patients with diarrhea and give fluid and electrolytes as needed. Administer atropine, if not contraindicated, for early diarrhea of any severity. At the onset of late diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤Grade 1 and reduce subsequent doses.

#### CONTRAINDICATIONS

- Severe hypersensitivity reaction to TRODELVY.

#### WARNINGS AND PRECAUTIONS

**Neutropenia:** Severe, life-threatening, or fatal neutropenia can occur and may require dose modification. Neutropenia occurred in 61% of patients treated with TRODELVY. Grade 3-4 neutropenia occurred in 47% of patients. Febrile neutropenia occurred in 7%. Withhold TRODELVY for absolute neutrophil count below 1500/mm<sup>3</sup> on Day 1 of any cycle or neutrophil count below 1000/mm<sup>3</sup> on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever.

Please see full Important Safety Information on pages 6-7. Please see full [Prescribing Information](#), including **BOXED WARNING**.



**TRODELVY**™  
sacituzumab govitecan-hziy  
180 mg for injection

START TRODELVY AT 10 MG/KG

The recommended dose of TRODELVY is 10 mg/kg intravenously on Days 1 and 8 of 21-day continuous treatment cycles<sup>1</sup>

- Continue treatment until disease progression or intolerance to therapy
- Do not administer TRODELVY at doses greater than 10 mg/kg
- Administration considerations:
  - Administer TRODELVY as an intravenous infusion only. Protect infusion bag from light
  - Do not administer as an intravenous push or bolus
  - An infusion pump may be used
  - 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 0.9% Sodium Chloride Injection, USP
- Do NOT substitute TRODELVY for or use with other drugs containing irinotecan or its active metabolite, SN-38

21-day treatment cycles<sup>1</sup>

10 mg/kg

10 mg/kg

Days 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21

Continue treatment until disease progression or intolerance to therapy

First infusion<sup>1</sup>

- Administer infusion over 3 hours
- Observe patients during the infusion and for at least 30 minutes following the initial dose for signs or symptoms of infusion-related reactions

Subsequent infusions<sup>1</sup>

- Administer infusion over 1 to 2 hours if prior infusions were tolerated
- Observe patients during the infusion and for at least 30 minutes after the infusion

Prior to each dose of TRODELVY<sup>1</sup>

- Premedication for prevention of infusion reactions and prevention of chemotherapy-induced nausea and vomiting (CINV) is recommended
- Premedicate with antipyretics, H1 and H2 blockers prior to infusion, and corticosteroids may be used for patients who had prior infusion reactions
- Premedicate with a 2- or 3-drug combination regimen (eg, dexamethasone with either a 5-HT3 receptor antagonist or an NK<sub>1</sub> receptor antagonist, as well as other drugs as indicated)
- Medication to treat infusion-related reactions, as well as emergency equipment, should be available for immediate use

AFTER INITIATION ON STARTING DOSE, DOSES CAN BE MODIFIED AS NEEDED TO HELP MANAGE ADVERSE REACTIONS

Withhold or discontinue TRODELVY to manage adverse reactions as described in the table below

Dose modifications for adverse reactions <sup>1</sup>		
Adverse reaction	Occurrence	Dose modification
<b>Severe neutropenia</b>		
Grade 4 neutropenia ≥7 days, OR Grade 3 febrile neutropenia (absolute neutrophil count <1000/mm <sup>3</sup> 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	First	25% dose reduction and administer granulocyte-colony stimulating factor (G-CSF)
	Second	50% dose reduction
	Third	Discontinue treatment
At time of scheduled treatment, Grade 3-4 neutropenia, which delays dosing beyond 3 weeks for recovery to ≤Grade 1	First	Discontinue treatment
<b>Severe non-neutropenic toxicity</b>		
Grade 4 non-hematologic toxicity of any duration, OR Any Grade 3-4 nausea, vomiting, or diarrhea due to treatment that is not controlled with antiemetics and antidiarrheal 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	First	25% dose reduction
	Second	50% dose reduction
	Third	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	First	Discontinue treatment


- Do not re-escalate the TRODELVY dose after a dose reduction for adverse reactions has been made
- Slow or interrupt the infusion rate of TRODELVY if the patient develops an infusion-related reaction
- Permanently discontinue TRODELVY for life-threatening infusion-related reactions

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

**Diarrhea:** Diarrhea occurred in 65% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 12% of patients. One patient had intestinal perforation following diarrhea. Neutropenic colitis occurred in 0.5% of patients. Withhold TRODELVY for Grade 3-4 diarrhea and resume when resolved to ≤Grade 1. At onset, evaluate for infectious causes and if negative, promptly initiate loperamide, 4 mg initially followed by 2 mg with every episode of diarrhea for a maximum of 16 mg daily. Discontinue loperamide 12 hours after diarrhea resolves. Additional supportive measures (e.g., fluid and electrolyte substitution) may also be employed as clinically indicated. Patients who exhibit an excessive cholinergic response to treatment can receive appropriate premedication (e.g., atropine) for subsequent treatments.

2 Please see full Important Safety Information on pages 6-7. Please see full Prescribing Information, including BOXED WARNING.



TRODELVY™  
sacituzumab govitecan-hziy  
180 mg for injection

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# A WELL-CHARACTERIZED SAFETY PROFILE IN UNRESECTABLE LOCALLY ADVANCED OR mTNBC

## Adverse reactions that led to discontinuation of TRODELVY occurred in 5% of patients<sup>1</sup>

- Adverse reactions leading to permanent discontinuation in ≥1% of patients who received TRODELVY were pneumonia (1%) and fatigue (1%)

### Adverse reactions in ≥10% of patients with mTNBC in the ASCENT trial<sup>1</sup>

		TRODELVY (n=258)		Single-agent chemotherapy* (n=224)				TRODELVY (n=258)		Single-agent chemotherapy* (n=224)	
Adverse reaction		All grades (%)	Grades 3–4 (%)	All grades (%)	Grades 3–4 (%)	Adverse reaction		All grades (%)	Grades 3–4 (%)	All grades (%)	Grades 3–4 (%)
<b>Blood and lymphatic system disorders</b>						<b>Metabolism and nutrition disorders</b>					
Neutropenia <sup>†</sup>		64	52	44	34	Decreased appetite		28	2	21	1
Anemia <sup>‡</sup>		40	9	28	6	Hypokalemia		16	3	13	0.4
Leukopenia <sup>§</sup>		17	11	12	6	Hypomagnesaemia		12	0	6	0
Lymphopenia <sup>  </sup>		10	2	6	2	<b>Musculoskeletal and connective tissue disorders</b>					
<b>Gastrointestinal disorders</b>						Back pain		16	1	14	2
Diarrhea		59	11	17	1	Arthralgia		12	0.4	7	0
Nausea		57	3	26	0.4	<b>Nervous system disorders</b>					
Vomiting		33	2	16	1	Headache		18	0.8	13	0.4
Constipation		37	0.4	23	0	Dizziness		10	0	7	0
Abdominal pain		30	3	12	1	<b>Psychiatric disorders</b>					
Stomatitis <sup>¶</sup>		17	2	13	1	Insomnia		11	0	5	0
<b>General disorders and administration site conditions</b>						<b>Respiratory, thoracic, and mediastinal disorders</b>					
Fatigue <sup>#</sup>		65	6	50	9	Cough		24	0	18	0.4
Pyrexia		15	0.4	14	2	<b>Skin and subcutaneous tissue disorders</b>					
<b>Infections and infestation</b>						Alopecia		47	0	16	0
Urinary tract infection		13	0.4	8	0.4	Rash		12	0.4	5	0.4
Upper respiratory tract infection		12	0	3	0	Pruritus		10	0	3	0
<b>Investigations</b>											
Alanine aminotransferase increased		11	1	10	1						

\*Single-agent chemotherapy included one of the following single agents: eribulin (n=139), capecitabine (n=33), gemcitabine (n=38), or vinorelbine (except if patient had ≥Grade 2 neuropathy, n=52). Graded per NCI CTCAE v.5.0.

<sup>†</sup>Including neutropenia and neutrophil count decreased. <sup>‡</sup>Including anemia, hemoglobin decreased, and red blood cell count decreased.

<sup>§</sup>Including leukopenia and white blood cell count decreased. <sup>||</sup>Including lymphopenia and lymphocyte count decreased. <sup>¶</sup>Including stomatitis, glossitis, mouth ulceration, and mucosal inflammation. <sup>#</sup>Including fatigue and asthenia.

# ADDITIONAL SAFETY INFORMATION

## Serious adverse reactions<sup>1</sup>

- Serious adverse reactions occurred in 27% of patients receiving TRODELVY
- Serious adverse reactions in >1% of patients receiving TRODELVY included neutropenia (7%), diarrhea (4%), and pneumonia (3%)
- Fatal adverse reactions occurred in 1.2% of patients who received TRODELVY, including respiratory failure (0.8%) and pneumonia (0.4%)

## Most common adverse reactions<sup>1</sup>

- The most common adverse reactions in ASCENT (≥25%) were fatigue (65%), neutropenia (64%), diarrhea (59%), nausea (57%), alopecia (47%), anemia (40%), constipation (37%), vomiting (33%), abdominal pain (30%), and decreased appetite (28%)
- In the pooled safety population (n=795), the most common (≥25%) adverse reactions were nausea (66%), diarrhea (65%), fatigue (62%), neutropenia (61%), alopecia (45%), anemia (42%), vomiting (39%), constipation (37%), decreased appetite (34%), rash (32%) and abdominal pain (28%)

## Treatment interruption<sup>1</sup>

- Adverse reactions leading to a treatment interruption occurred in 63% of patients
- The most frequent (≥5%) adverse reactions leading to a treatment interruption were neutropenia (47%), diarrhea (5%), respiratory infection (5%), and leukopenia (5%)

## Dose reductions<sup>1</sup>

- Adverse reactions leading to a dose reduction occurred in 22% of patients
- The most frequent (>4%) adverse reactions leading to a dose reduction were neutropenia (11%) and diarrhea (5%)
- G-CSF was used in 44% of patients who received TRODELVY

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS

**Hypersensitivity and Infusion-Related Reactions:** Serious hypersensitivity reactions including life-threatening anaphylactic reactions have occurred with TRODELVY. Severe signs and symptoms included cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions. Hypersensitivity reactions within 24 hours of dosing occurred in 37% of patients. Grade 3-4 hypersensitivity occurred in 2% of patients. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.3%. The incidence of anaphylactic reactions was 0.3%. Pre-infusion medication is recommended. Observe patients closely for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. Medication to treat such reactions, as well as emergency equipment, should be available for immediate use. Permanently discontinue TRODELVY for Grade 4 infusion-related reactions.





# IMPORTANT SAFETY INFORMATION

## INDICATION

TRODELVY® (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.

## IMPORTANT SAFETY INFORMATION

### BOXED WARNING: NEUTROPENIA AND DIARRHEA

- **Severe or life-threatening neutropenia may occur. Withhold TRODELVY for absolute neutrophil count below 1500/mm<sup>3</sup> or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.**
- **Severe diarrhea may occur. Monitor patients with diarrhea and give fluid and electrolytes as needed. Administer atropine, if not contraindicated, for early diarrhea of any severity. At the onset of late diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤Grade 1 and reduce subsequent doses.**

## CONTRAINDICATIONS

- Severe hypersensitivity reaction to TRODELVY.

## WARNINGS AND PRECAUTIONS

**Neutropenia:** Severe, life-threatening, or fatal neutropenia can occur and may require dose modification. Neutropenia occurred in 61% of patients treated with TRODELVY. Grade 3-4 neutropenia occurred in 47% of patients. Febrile neutropenia occurred in 7%. Withhold TRODELVY for absolute neutrophil count below 1500/mm<sup>3</sup> on Day 1 of any cycle or neutrophil count below 1000/mm<sup>3</sup> on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever.

**Diarrhea:** Diarrhea occurred in 65% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 12% of patients. One patient had intestinal perforation following diarrhea. Neutropenic colitis occurred in 0.5% of patients. Withhold TRODELVY for Grade 3-4 diarrhea and resume when resolved to ≤Grade 1. At onset, evaluate for infectious causes and if negative, promptly initiate loperamide, 4 mg initially followed by 2 mg with every episode of diarrhea for a maximum of 16 mg daily. Discontinue loperamide 12 hours after diarrhea resolves. Additional supportive measures (e.g., fluid and electrolyte substitution) may also be employed as clinically indicated. Patients who exhibit an excessive cholinergic response to treatment can receive appropriate premedication (e.g., atropine) for subsequent treatments.

**Hypersensitivity and Infusion-Related Reactions:** Serious hypersensitivity reactions including life-threatening anaphylactic reactions have occurred with TRODELVY. Severe signs and symptoms included cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions. Hypersensitivity reactions within 24 hours of dosing occurred in 37% of patients. Grade 3-4 hypersensitivity occurred in 2% of patients. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.3%. The incidence of anaphylactic reactions was 0.3%. Pre-infusion medication is recommended. Observe patients closely for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. Medication to treat such reactions, as well as emergency equipment, should be available for immediate use. Permanently discontinue TRODELVY for Grade 4 infusion-related reactions.

**Nausea and Vomiting:** Nausea occurred in 66% of all patients treated with TRODELVY and Grade 3 nausea occurred in 4% of these patients. Vomiting occurred in 39% of patients and Grade 3-4 vomiting occurred in 3% of these patients. Premedicate with a two or three drug combination regimen (e.g., dexamethasone with either a 5-HT<sub>3</sub> receptor antagonist or an NK<sub>1</sub> receptor antagonist as well as other drugs as indicated) for prevention of chemotherapy-induced nausea and vomiting (CINV). Withhold TRODELVY doses for Grade 3 nausea or Grade 3-4 vomiting and resume with additional supportive measures when resolved to Grade ≤1. Additional antiemetics and other supportive measures may also be employed as clinically indicated. 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:** Patients homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)\*28 allele are at increased risk for neutropenia, febrile neutropenia, and anemia and may be at increased risk for other adverse reactions with TRODELVY. The incidence of Grade 3-4 neutropenia was 67% in patients homozygous for the UGT1A1\*28, 46% in patients heterozygous for the UGT1A1\*28 allele and 46% in patients homozygous for the wild-type allele. The incidence of Grade 3-4 anemia was 25% in patients homozygous for the UGT1A1\*28 allele, 10% in patients heterozygous for the UGT1A1\*28 allele, and 11% in patients homozygous for the wild-type allele. Closely monitor patients with known reduced UGT1A1 activity for adverse reactions. Withhold or permanently discontinue TRODELVY based on clinical assessment of the onset, duration and severity of the observed adverse reactions in patients with evidence of acute early-onset or unusually severe adverse reactions, which may indicate reduced UGT1A1 function.

**Embryo-Fetal Toxicity:** Based on its mechanism of action, TRODELVY can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. TRODELVY contains a genotoxic component, SN-38, and targets rapidly dividing cells. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TRODELVY and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRODELVY and for 3 months after the last dose.

## ADVERSE REACTIONS

**In the ASCENT study (IMMU-132-05),** the most common adverse reactions (incidence ≥25%) were fatigue, neutropenia, diarrhea, nausea, alopecia, anemia, constipation, vomiting, abdominal pain, and decreased appetite. The most frequent serious adverse reactions (SAR) (>1%) were neutropenia (7%), diarrhea (4%), and pneumonia (3%). SAR were reported in 27% of patients, and 5% discontinued therapy due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in the ASCENT study were reduced neutrophils, leukocytes, and lymphocytes.

## DRUG INTERACTIONS

**UGT1A1 Inhibitors:** Concomitant administration of TRODELVY with inhibitors of UGT1A1 may increase the incidence of adverse reactions due to potential increase in systemic exposure to SN-38. Avoid administering UGT1A1 inhibitors with TRODELVY.

**UGT1A1 Inducers:** Exposure to SN-38 may be substantially reduced in patients concomitantly receiving UGT1A1 enzyme inducers. Avoid administering UGT1A1 inducers with TRODELVY.

Please see full [Prescribing Information](#), including BOXED WARNING.



# A WAY IN WITH TRODELVY

**TRODELVY attacks mTNBC as the first and only Trop-2-directed ADC. Based on preclinical data. May not correlate with clinical outcomes.**

**For adult patients with unresectable locally advanced or mTNBC who have received 2 or more prior systemic therapies, at least one of them for metastatic disease<sup>1</sup>**

- The recommended dose of TRODELVY is 10 mg/kg once weekly on Days 1 and 8 of continuous 21-day treatment cycles until disease progression or unacceptable toxicity
- Administer TRODELVY as an intravenous infusion only. Do not administer as an intravenous push or bolus
- After initiation on starting dose, doses can be modified as needed to help manage adverse reactions
- See page 2 for more dosing and administration information. Additional resources, including a reconstitution guide, are available at [TRODELVYHCP.com](https://trodelvyhcp.com)



To enroll a patient into **TRODELVY Access Support**, please complete the Enrollment Form with your patient and fax to 1-833-851-4344.

For more information on the TRODELVY Savings Program, visit [TRODELVYHCP.com/hcp/access-support](https://trodelvyhcp.com/hcp/access-support), or call **1-844-TRODELVY** (1-844-876-3358), Monday–Friday, 9 AM–7 PM ET

## INDICATION

TRODELVY® (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.

## IMPORTANT SAFETY INFORMATION

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- **Severe diarrhea may occur. Monitor patients with diarrhea and give fluid and electrolytes as needed. Administer atropine, if not contraindicated, for early diarrhea of any severity. At the onset of late diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤Grade 1 and reduce subsequent doses.**

**WARNINGS AND PRECAUTIONS** include neutropenia, diarrhea, hypersensitivity and infusion-related reactions, nausea and vomiting, increased risk of adverse reactions in patients with reduced UGT1A1 activity, and embryo-fetal toxicity.

**The most common adverse reactions in ASCENT (≥25%) were** fatigue, neutropenia, diarrhea, nausea, alopecia, anemia, constipation, vomiting, abdominal pain, and decreased appetite.

**Reference:** 1. TRODELVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2021.

**Please see full Important Safety Information on pages 6-7. Please see full [Prescribing Information](#), including BOXED WARNING.**



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2021-US-TROT-00030 04/21



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180 mg for injection