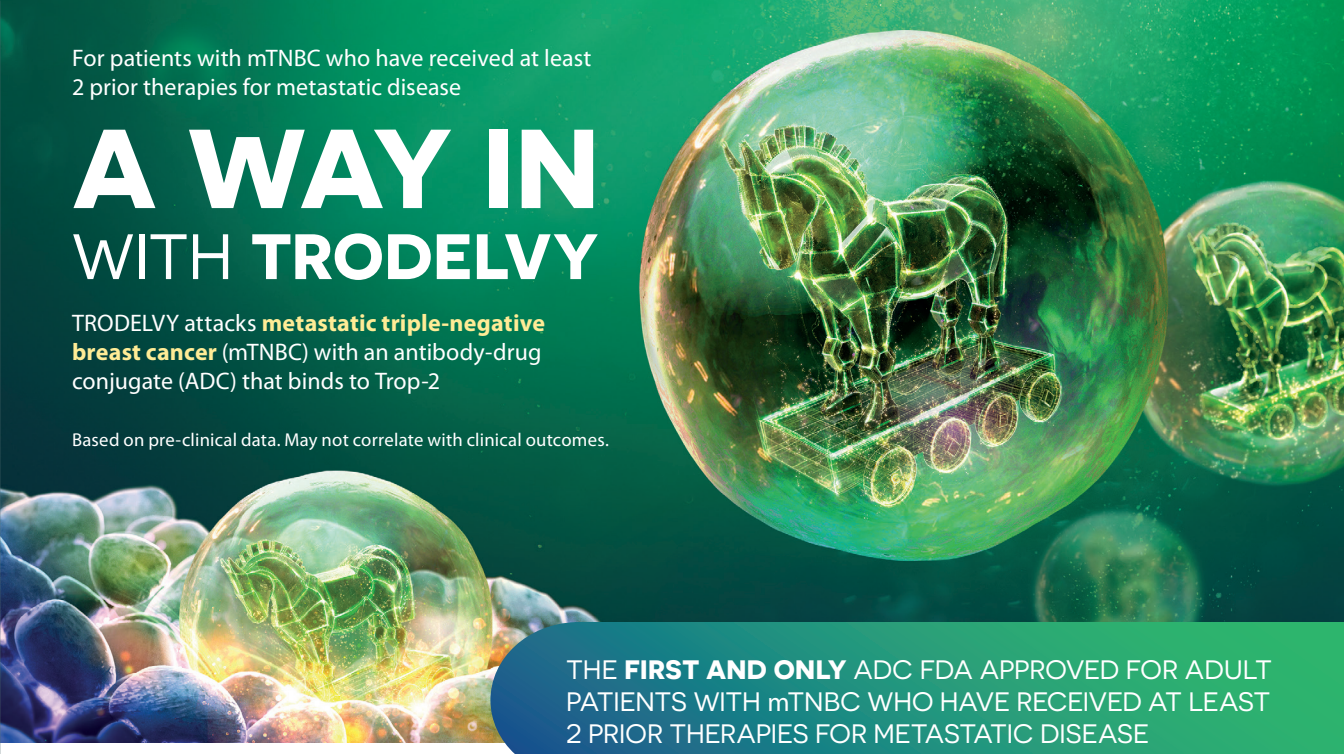
For patients with mTNBC who have received at least 2 prior therapies for metastatic disease

A WAY IN WITH TRODELVY

TRODELVY attacks **metastatic triple-negative breast cancer** (mTNBC) with an antibody-drug conjugate (ADC) that binds to Trop-2

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



THE **FIRST AND ONLY** ADC FDA APPROVED FOR ADULT PATIENTS WITH mTNBC WHO HAVE RECEIVED AT LEAST 2 PRIOR THERAPIES FOR METASTATIC DISEASE

CLINICAL TRIAL RESULTS

INDICATION

TRODELVY™ (sacituzumab govitecan-hziy) is indicated for the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least 2 prior therapies for metastatic disease.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

WARNING: NEUTROPENIA AND DIARRHEA

TRODELVY can cause severe or life-threatening neutropenia. Withhold TRODELVY for absolute neutrophil count (ANC) below 1500/mm³ on Day 1 of any cycle or ANC below 1000/mm³ on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever.

Monitor blood cell counts periodically during treatment. Consider Granulocyte Colony-Stimulating Factor (G-CSF) for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.

- Dose modifications may be required due to neutropenia. Febrile neutropenia occurred in 6% (24/408) of patients treated with TRODELVY, including 8% (9/108) of patients with mTNBC after at least 2 prior therapies. Less than 1% (1/408) of patients had febrile neutropenia leading to permanent discontinuation. The incidence of Grade 1-4 neutropenia was 64% in patients with mTNBC (n=108). In all patients treated with TRODELVY (n=408), the incidence of Grade 1-4 neutropenia was 54%; Grade 4 neutropenia occurred in 13%. Less than 1% (2/408) of patients permanently discontinued treatment due to neutropenia.

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.

- Diarrhea occurred in 63% (68/108) of patients with mTNBC and 62% (254/408) of all patients treated with TRODELVY. In each population, events of Grade 3-4 occurred in 9% (10/108) of mTNBC patients and 9% (36/408) of all patients treated with TRODELVY. Four out of 408 patients (<1%) discontinued treatment because of diarrhea. Neutropenic colitis was observed in 2% (2/108) of patients in the mTNBC cohort and 1% of all patients treated with TRODELVY.

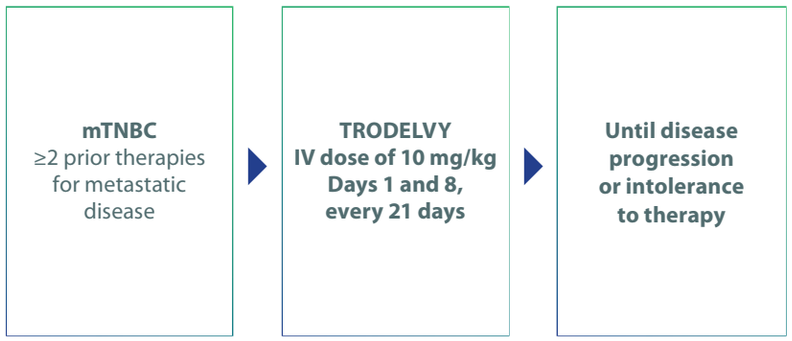
Efficacy. Directed.

TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

Please see additional Important Safety Information, including boxed Warning, throughout and on page 7.

EFFICACY AND SAFETY WERE EVALUATED IN PATIENTS WHO WERE HEAVILY PRETREATED

TRODELVY was studied in an open-label, uncontrolled, single-arm phase 1/2 trial (N=108)



Median treatment duration was 5.1 months (range: 0-51 months)

Major efficacy outcome measures
- Investigator-assessed overall response rate (ORR) using RECIST 1.1
- Duration of response (DOR)

Additional outcome measures[1]
- Time to response
- Progression-free survival (PFS)
- Overall survival (OS)

Demographics and patient characteristics (N=108)

Female/male, n: 107/1

Median age, years (range): 55 (31-80), age <65: 87%

ECOG status 0: 29%

ECOG status 1: 71%

Race[1]: White 76%, Black 7%, Asian 3%, Other 14%

- 76% had visceral disease, 42% had hepatic metastases, 56% had lung/pleura metastases, and 2% had brain metastases
- 12 patients (11%) had Stage IV disease at the time of initial diagnosis

Patients received a median of 3 prior therapies (range: 2, 10)

- 40% of patients received 2 prior therapies[1]
- 60% of patients received 3 or more prior therapies[1]
- 17% of patients received a checkpoint inhibitor (including pembrolizumab) in a prior investigational setting[1]

Key eligibility criteria for the trial

Age ≥18 years, Eastern Cooperative Oncology Group (ECOG) status of 0-1, ≥2 prior therapies in metastatic setting and refractory to or relapsed after ≥1 prior standard therapeutic regimen, prior taxane therapy, and measurable disease by CT or MRI.[2] Patients with bulky disease, defined as a mass >7 cm, were not eligible. Patients with treated brain metastases not receiving high-dose steroids (>20 mg prednisone or equivalent) for at least 4 weeks were eligible. Patients with Gilbert's disease were excluded.

TRODELVY is currently being evaluated in a confirmatory phase 3 trial

TRODELVY PROVIDED IMPRESSIVE RESPONSES

Overall response rate

33.3%

(95% CI: 24.6; 43.1)

(CR+PR; n=36/108)

Complete response (CR): 2.8%

Partial response (PR): 30.6%

- 34.3% ORR based on BICR (95% CI: 25.4; 44.0)[3]

Duration of response

7.7 **Median months (range 1.9, 30.4)**

(95% CI: 4.9; 10.8)

55.6% with duration ≥6 months

16.7% with duration ≥12 months

- 9.1 months DOR based on BICR (95% CI: 4.6; 11.3)[3]

BICR: important limitations

Blinded, independent, central review (BICR) of staging scans was obtained for the 56 patients determined to have a CR, PR, or ≥20% reduction in target lesions by investigator assessment. Since the BICR analyses were conducted in a subgroup of preselected patients based on investigator assessment, the results are subject to bias and should be interpreted with caution.

Tumor imaging occurred every 8 weeks initially with confirmatory scans to confirm responses 4 to 6 weeks after the first apparent response.

CI=confidence interval.

IMPORTANT SAFETY INFORMATION *(cont'd)*

Contraindications: Severe hypersensitivity reaction to TRODELVY.

Hypersensitivity

- TRODELVY can cause severe and life-threatening hypersensitivity, including anaphylactic reactions. Hypersensitivity reactions occurred within 24 hours of dosing in 37% (151/408) and Grade 3-4 hypersensitivity occurred in 1% (6/408) of all patients treated with TRODELVY (n=408). The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 1% (3/408).
- Pre-infusion medication for patients receiving TRODELVY is recommended. Observe patients closely for infusion-related reactions during each TRODELVY 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.

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SAFETY PROFILE OF TRODELVY

Adverse reactions in ≥10% of patients with mTNBC who had received at least 2 prior therapies for metastatic disease

	TRODELVY (n=108) Grade 1-4	TRODELVY (n=108) Grade 3-4
Any adverse reaction	100%	71%
Gastrointestinal disorders	95%	21%
Nausea	69%	6%
Diarrhea	63%	9%
Vomiting	49%	6%
Constipation	34%	1%
Abdominal pain[i]	26%	1%
Mucositis[ii]	14%	1%
General disorders and administration site conditions	77%	9%
Fatigue[iii]	57%	8%
Edema[iv]	19%	0%
Pyrexia	14%	0%
Blood and lymphatic system disorders	74%	37%
Neutropenia	64%	43%
Anemia	52%	12%
Thrombocytopenia	14%	3%
Metabolism and nutrition disorders	68%	22%
Decreased appetite	30%	1%
Hyperglycemia	24%	4%
Hypomagnesemia	21%	1%
Hypokalemia	19%	2%
Hypophosphatemia	16%	9%
Dehydration	13%	5%

	TRODELVY (n=108) Grade 1-4	TRODELVY (n=108) Grade 3-4
Skin and subcutaneous tissue disorders	63%	4%
Alopecia	38%	0%
Rash[v]	31%	3%
Pruritis	17%	0%
Dry skin	15%	0%
Nervous system disorders	56%	4%
Headache	23%	1%
Dizziness	22%	0%
Neuropathy[vi]	24%	0%
Dysgeusia	11%	0%
Infections and infestations	55%	12%
Urinary tract infection	21%	3%
Respiratory infection[vii]	26%	3%
Musculoskeletal and connective tissue disorders	54%	1%
Back pain	23%	0%
Arthralgia	17%	0%
Pain in extremity	11%	0%
Respiratory, thoracic, and mediastinal disorders	54%	5%
Cough[viii]	22%	0%
Dyspnea[ix]	21%	3%
Psychiatric disorders	26%	1%
Insomnia	13%	0%

Graded per NCI CTCAE v. 4.0

[i]Including abdominal pain, distention, pain (upper), discomfort, and tenderness. [ii]Including stomatitis, esophagitis, and mucosal inflammation. [iii]Including fatigue and asthenia. [iv]Including edema; and peripheral, localized, and periorbital edema. [v]Including rash; maculopapular, erythematous, and generalized rash; dermatitis acneiform; skin disorder, irritation, and exfoliation. [vi]Including gait disturbance, hypoesthesia, muscular weakness, paresthesia, and peripheral and sensory neuropathy. [vii]Including lower and upper respiratory tract infection, pneumonia, influenza, viral upper respiratory infection, bronchitis, and respiratory syncytial virus infection. [viii]Includes cough and productive cough. [ix]Includes dyspnea and exertional dyspnea.

Most patients who receive TRODELVY experience lab abnormalities. See Table 3 in PI for complete listing.

2% OF PATIENTS DISCONTINUED DUE TO DRUG-RELATED ADVERSE REACTIONS

- Adverse reactions leading to treatment discontinuation were anaphylaxis, anorexia/fatigue, and headache (each: <1%; 1 patient for each event)
- 45% of patients experienced an adverse reaction leading to treatment interruption. The most common adverse reaction leading to treatment interruption was neutropenia (33%)
- Adverse reactions leading to dose reduction occurred in 33% of patients treated with TRODELVY
  - 24% had 1 dose reduction
  - 9% had 2 dose reductions
- The most common adverse reactions leading to dose reductions were neutropenia and febrile neutropenia

Serious adverse reactions were reported in 31% of patients

The most frequent serious adverse reactions, reported in >1% of the patients, were:

Febrile neutropenia	6%	Anemia	2%
Vomiting	5%	Dehydration	2%
Diarrhea	4%	Neutropenia	2%
Nausea	3%	Pleural effusion	2%
Dyspnea	3%	Pneumonia	2%

Management of certain adverse reactions may require dose delays and/or dose reductions. In some instances, discontinuation may be required

Please refer to Section 2.2, Table 1 of the Prescribing Information for the recommended dose reduction schedule of TRODELVY.

IMPORTANT SAFETY INFORMATION *(cont'd)*

Nausea and Vomiting

- TRODELVY is emetogenic. Nausea occurred in 69% (74/108) of patients with mTNBC and 69% (281/408) of all patients treated with TRODELVY. Grade 3 nausea occurred in 6% (7/108) and 5% (22/408) of these populations, respectively. Vomiting occurred in 49% (53/108) of patients with mTNBC and 45% (183/408) of all patients treated with TRODELVY. Grade 3 vomiting occurred in 6% (7/108) and 4% (16/408) of these patients, respectively.
- Premedicate with a 2- or 3-drug combination regimen (e.g., dexamethasone with either a 5-HT3 receptor antagonist or an NK-1 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 at the time of scheduled treatment administration 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.

Please see additional Important Safety Information, including boxed Warning, throughout and on page 7.

TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

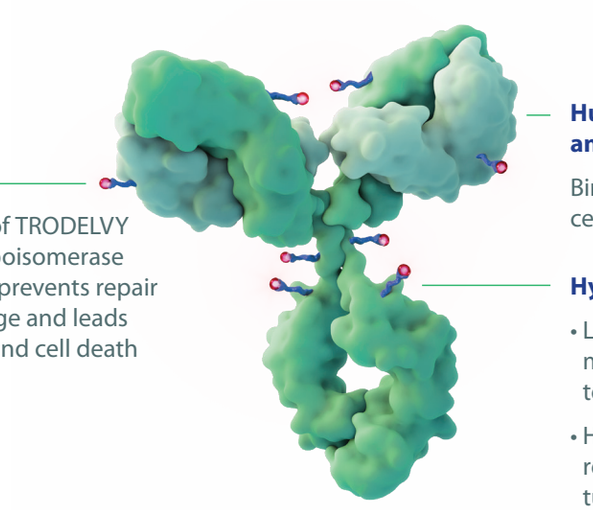
THE FIRST AND ONLY ADC THAT TARGETS TROP-2 AS A WAY INTO mTNBC TUMORS

Trop-2 is a surface protein highly expressed by many cancers, including approximately 90% of TNBC tumors[2]*

Trop-2 biomarker testing is not required for use with TRODELVY

TRODELVY binds to the antigen Trop-2 and delivers and concentrates a potent cytotoxic into tumor tissue[4]

The proposed mechanism of action is based on preclinical data, which may not correlate with clinical outcomes.



Cytotoxic

The payload of TRODELVY is SN-38, a topoisomerase inhibitor that prevents repair of DNA damage and leads to apoptosis and cell death

Humanized monoclonal antibody

Binds to Trop-2, the trophoblast cell-surface antigen-2

Hydrolysable linker

- Links the humanized monoclonal antibody to SN-38
- Hydrolysis of the linker releases the SN-38 to kill tumor cells

TRODELVY has a high drug-to-antibody ratio, with an average of 7 to 8 molecules of SN-38 per antibody molecule.

- ADCs use a monoclonal antibody to deliver an attached cytotoxic drug into tumors[5]
- Once inside the tumor, the linker connecting the antibody to the cytotoxic is cleaved, releasing the active drug[5]

*As measured by immunohistochemical (IHC) assay.

IMPORTANT SAFETY INFORMATION *(cont'd)*

Use in Patients with Reduced UGT1A1 Activity

- Individuals who are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia and may be at increased risk for other adverse events following initiation of TRODELVY treatment. Closely monitor patients with reduced UGT1A1 activity for severe neutropenia. The appropriate dose for patients who are homozygous for UGT1A1*28 is not known and should be considered based on individual patient tolerance to treatment.
- In 84% (343/408) of patients who received TRODELVY (up to 10 mg/kg on Days 1 and 8 of a 21-day cycle) and had retrospective UGT1A1 genotype results available, the incidence of Grade 4 neutropenia was 26% (10/39) in patients homozygous for the UGT1A1*28 allele, 13% (20/155) in patients heterozygous for the UGT1A1*28 allele, and 11% (16/149) in patients homozygous for the wild-type allele.

Embryo-Fetal Toxicity

- TRODELVY contains a genotoxic component and can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. 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 following 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.

Lactation

Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment and for 1 month after the last dose of TRODELVY.

Adverse Reactions

Most common adverse reactions (incidence >25%) in patients with mTNBC are nausea (69%), neutropenia (64%), diarrhea (63%), fatigue (57%), anemia (52%), vomiting (49%), alopecia (38%), constipation (34%), rash (31%), decreased appetite (30%), abdominal pain (26%), and respiratory infection (26%).

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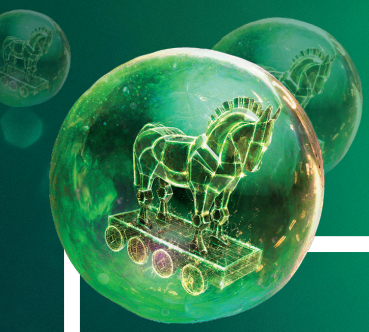

A WAY IN WITH TRODELVY

For your adult patients with mTNBC who have received at least 2 prior therapies for their metastatic disease*

Impressive response rates in heavily pretreated patients

Overall response rate†

33.3%

(95% CI: 24.6; 43.1)
(CR+PR; n=36/108)

Duration of response

7.7 **Median months (range 1.9, 30.4)**

(95% CI: 4.9; 10.8)

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†Based on investigator assessment.

IMPORTANT SAFETY INFORMATION

- **SEVERE DIARRHEA AND NEUTROPENIA MAY OCCUR. Patients must be closely monitored; supportive care, dose modification and/or discontinuation may be required. See boxed Warning on the cover.** Patients with homozygous UGT1A1 allele are at increased risk of neutropenia.
- **Hypersensitivity reactions** including severe anaphylactic reactions have been observed. Monitor patients for infusion-related reactions. Permanently discontinue TRODELVY if severe or life-threatening reactions occur.
- **Nausea/Vomiting:** Use antiemetic preventive treatment and withhold TRODELVY for patients with Grade 3 nausea or Grade 3-4 vomiting at the time of scheduled treatment.
- **Embryo-Fetal Toxicity:** TRODELVY can cause fetal harm. Advise patients of potential risk to fetus and use effective contraception.
- The most common adverse reactions are nausea (69%), neutropenia (64%), diarrhea (63%), fatigue (57%), anemia (52%), vomiting (49%), alopecia (38%), constipation (34%), rash (31%), decreased appetite (30%), abdominal pain (26%), and respiratory infection (26%).

VISIT TRODELVY.COM TO LEARN MORE

References: 1. Data on file. **2.** Bardia A, Mayer IA, Diamond JR, et al. Efficacy and safety of anti-Trop-2 antibody drug conjugate sacituzumab govitecan (IMMU-132) in heavily pretreated patients with metastatic triple-negative breast cancer. *J Clin Oncol*. 2017;35(19):2141-2148. **3.** Bardia A, Mayer IA, Vahdat LT et al. Sacituzumab govitecan-hziy in refractory metastatic triple-negative breast cancer. *N Engl J Med*. 2019;380(8):741-751. **4.** Goldenberg D, Cardillo TM, Govindan S et al. Trop-2 is a novel target for solid cancer therapy with sacituzumab govitecan (IMMU-132), an antibody-drug conjugate (ADC). *Oncotarget*. 2015;6(26):22496-22512. **5.** Peters C, Brown S. Antibody-drug conjugates as novel anti-cancer chemotherapeutics. *Biosci Rep*. 2015;35(4):1-20.

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Immunomedics

2020-US-TROT-00028

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