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.

# DOSING AND ADMINISTRATION INFORMATION

## 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..

**Please see additional Important Safety Information, including boxed Warning, throughout.**

*Efficacy. Directed.*

TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

See inside for dose modification information.

# 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 | 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% |
| **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.

- 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%), vomiting (5%), diarrhea (4%), nausea (3%), dyspnea (3%), anemia, pleural effusion, neutropenia, pneumonia, and dehydration (each 2%)

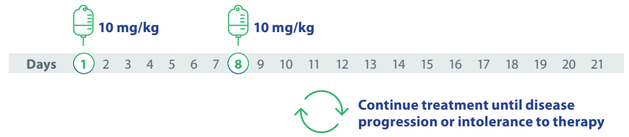
**Most patients who receive TRODELVY experience lab abnormalities. See Table 3 in PI for complete listing.**

# TRODELVY IS ADMINISTERED AS AN INTRAVENOUS INFUSION

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

- Do not administer TRODELVY at doses greater than 10 mg/kg
- Administer TRODELVY as an intravenous infusion only . Do not administer as an intravenous push or bolus

**Continuous 21-day treatment cycles**




**First infusion**

- 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**

- 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**

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 $NK_1$ 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

## 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.

**Please see additional Important Safety Information, including boxed Warning, throughout.**

# DOSAGE MODIFICATIONS FOR THE MANAGEMENT OF ADVERSE REACTIONS

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

- 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

**Dose modifications for adverse reactions**

### Severe neutropenia

| Adverse reaction | Occurrence | Dose modification |
|---|---|---|
| Grade 4 neutropenia ≥7 days,<br>OR<br>Grade 3 febrile neutropenia (absolute neutrophil count <1000/mm$^3$ and fever ≥38.5°C),<br>OR<br>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 |

### Severe non-neutropenic toxicity

| Adverse reaction | Occurrence | Dose modification |
|---|---|---|
| Grade 4 non-hematologic toxicity of any duration,<br>OR<br>Any Grade 3-4 nausea, vomiting, or diarrhea due to treatment that is not controlled with antiemetics and antidiarrheal agents,<br>OR<br>Other Grade 3-4 non-hematologic toxicity persisting >48 hours despite optimal medical management,<br>OR<br>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 |

## 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.

**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.

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# A WAY IN WITH TRODELVY

**TRODELVY attacks mTNBC with an ADC that binds to Trop-2**

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

- The recommended dose of TRODELVY is 10 mg/kg on Days 1 and 8 of continuous 21-day treatment cycles
- Severe diarrhea and neutropenia may occur. Patients must be closely monitored; supportive care, dose modification and/or discontinuation may be required (see boxed Warning inside for recommended dose reduction schedule)
- The most common adverse reactions (incidence >25%) were nausea, neutropenia, diarrhea, fatigue, anemia, vomiting, alopecia, constipation, decreased appetite, rash, abdominal pain, and respiratory infections

VISIT **TRODELVY.COM** TO LEARN MORE

*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 *(cont'd)*

### 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%).

**Please see additional Important Safety Information throughout and full Prescribing Information, including boxed Warning, in pocket.**

Immunomedics


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180 mg for injection