



Trodelvy[®] (sacituzumab govitecan-hziy)

Incidence and Management of Rash

This document is provided in response to your request for information about Trodelvy[®] (sacituzumab govitecan-hziy [SG]) and the incidence and management of rash.

Gilead continually assesses safety data from all sources for unidentified drug reactions and updates the product label information accordingly to reflect the safety profile of SG. Because case reports of potential adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish causal relationship to drug exposure. For this reason, Gilead does not provide information from post-marketing spontaneous reports.

Information summarized in this document includes data for SG monotherapy (10 mg/kg IV on Days 1 and 8 of a 21-day treatment cycle) from phase 2 and 3 clinical studies that constitute the largest pooled safety population of SG.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warnings for neutropenia and diarrhea are available at:

www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi

Relevant Product Labeling¹

Dosage and Administration

Recommended dosage

Premedication

Prior to each dose of SG, premedication for prevention of infusion reactions is recommended. Premedicate with antipyretics, H1 and H2 blockers prior to infusion, and corticosteroids may be used for patients who had prior infusion reactions.

Management of adverse reactions may require temporary interruption, dose reduction, or treatment discontinuation of SG as described in Tables 1 and 2. Do not re-escalate the SG dose after a dose reduction for adverse reactions has been made.

Table 1. Dosage Reduction Levels¹

Dose Level	Dosage and Schedule
Recommended starting dose	10 mg/kg once weekly on Days 1 and 8 of 21-day treatment cycles
First dose reduction	Reduce to 7.5 mg/kg
Second dose reduction	Reduce to 5 mg/kg
Requirement for further dose reduction	Permanently discontinue SG

The recommended dosage modifications for adverse infusion-related reactions (IRRs) are provided in Table 2.

Table 2. Dose Modifications for IRRs¹

Severity	Dose Modification
Grade 1-3 IRRs	Slow infusion rate or interrupt the infusion
Grade 4 IRRs	Discontinue SG

Warnings and Precautions

Hypersensitivity and IRRs

SG can cause serious hypersensitivity reactions including life-threatening anaphylactic reactions. Severe signs and symptoms included cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions.

Incidence and Management of Rash in SG Clinical Studies

Pooled Safety Analysis

A pooled safety analysis (Figure 1) examined exposure to SG 10 mg/kg IV as monotherapy in 1063 patients from four studies of multiple epithelial tumors (IMMU-132-01,² ASCENT,³ TROPiCS-02,⁴ and TROPHY-U-01⁵⁻⁷). These studies included patients with metastatic triple negative breast cancer (mTNBC), hormone receptor-positive/human epidermal growth factor receptor 2-negative metastatic breast cancer (HR+/HER2- mBC), and metastatic urothelial cancer (mUC).⁸

The median treatment duration of SG in this population was 4.1 (range: 0–63) mo¹; rash was not among the most common (≥15%) treatment-emergent adverse events (TEAEs) reported.⁸

Figure 1. Pooled Clinical Studies⁸

ASCENT, Phase 3 (n=258) An open label, randomized, confirmatory study, in patients with refractory or relapsed mTNBC who had received ≥2 prior chemotherapies for unresectable, locally advanced, or metastatic disease.	TROPiCS-02, Phase 3 (n=268) An open-label, randomized, multicenter study, in patients with HR+/HER2- mBC who had received ≥1 taxane, ≥1 endocrine therapy, and ≥1 CDK4/6i in any setting and 2–4 prior chemotherapy regimens for metastatic disease.
SG 10 mg/kg IV on Days 1 and 8 of a 21-day cycle Continue treatment until loss of clinical benefit or unacceptable toxicity	
TROPHY-U-01, Phase 2 (n=135) A multi-cohort, open-label study in patients with unresectable locally advanced, or mUC whose disease progressed: <ol style="list-style-type: none"> 1. After prior PLT-based and CPI-based therapies 2. After CPI-based therapies and who were ineligible for PLT-based therapy. 	IMMU-132-01, Phase 1/2 (n=402) A single-arm, open-label basket study in patients with metastatic epithelial cancers (including cervical, colorectal, endometrial, esophageal, gastric adenocarcinoma, glioblastoma multiforme, hepatocellular, non-small cell lung, non-TNBC, ovarian, pancreatic, prostate, renal cell, small-cell lung, squamous cell head and neck, TNBC, and urothelial) who had relapsed after or were refractory to ≥1 prior therapy for metastatic disease.

Abbreviations: CKD4/6i=cyclin-dependent 4/6 inhibitor; CPI=checkpoint inhibitor therapies; PLT=platinum; TNBC=triple-negative breast cancer.

Premedication and Management of SG-Related Toxicities

Premedication for the prevention of IRRs such as rash included antihistamines that were to be administered before each SG infusion. Corticosteroids (hydrocortisone 50 mg or equivalent [oral or IV]) could also be administered prior to subsequent infusions if the patient experienced an IRR with a previous infusion.^{2,9-11}

SG-associated toxicities were assessed and managed in accordance with standard clinical/institutional practices and accepted treatment guidelines.^{2,9-11}

Metastatic Breast Cancer Studies

Treatment durations and rash-related safety data for the ASCENT study in patients with mTNBC are shown in Table 3. No frequency data are available for pre-infusion medication use of corticosteroids or systemic antihistamines for the prevention of IRRs in either treatment group.³

Table 3. ASCENT: Treatment Duration and Rash-Related Safety Data in OSP^{3,12}

	SG (n=258)	TPC (n=224)
Treatment duration, median (range), mo	4.4 (0.03–22.9)	1–1.6 ^a
Any-grade TRAE of rash of any kind, n (%)	22 (9)	3 (1)
Grade 3 TRAE of rash, n	1	1
Any-grade TEAE of rash, n (%)	32 (12)	12 (5)

Abbreviations: OSP=overall safety population; TPC=treatment of physicians' choice; TRAE=treatment-related adverse event.

^aTreatment durations for TPC agents: eribulin, 1.6 (0.03–15.3) mo; vinorelbine, 1 (0.03–11.5) mo; gemcitabine, 1.4 (0.2–8.1) mo; and capecitabine, 1.2 (0.3–10.6) mo. Data were unavailable for 6 patients who received capecitabine.

Within the TROPiCS-02 study in patients with HR+/HER2- mBC, IRRs were defined as symptoms, including rash, that occurred within the first 6 hours after SG administration and could occur at any cycle.¹⁰ Treatment durations and pre-infusion use of medications are shown in Table 4. Rash was not among the any-grade TRAEs with a reported incidence of ≥10%.¹³

Table 4. TROPiCS-02: Treatment Duration and Pre-Infusion Medications^{4,14-16}

		SG (n=268)	TPC (n=249)
Treatment duration, median (range), mo		4.1 (0.03–24.2)	2.3 (0.03–22.3) ^a
Pre-infusion/concomitant use of medication, ^b %	Corticosteroids	54	39
	Systemic antihistamines	72	21

^aTreatment durations for TPC agents: eribulin, 3.4 (0.03–18.3) mo; vinorelbine, 1.2 (0.03–8.1) mo; gemcitabine, 1.5 (0.03–22.3) mo; and capecitabine, 4.5 (0.2–12.9) mo.

^bData are from the ITT population (N=543). Use of pre-infusion medication in the OSP was not reported.¹³

Metastatic Urothelial Cancer Study

Within the multi-cohort TROPiCS-02 study in mUC, patients in Cohort 1 received a median of 6 SG cycles; treatment duration and rash-related TRAEs are shown in Table 5.^{17,18} All adverse events associated with rash were Grade ≤ 2 .⁵

Table 5. TROPiCS-02 Cohort 1: Treatment Duration and Rash-Related TRAEs^{5,17}

		SG (N=113)
Treatment duration, median (range), mo		3.7 (0–20)
Rash-related TRAEs, %	Maculopapular rash	7
	Skin rash	6

In Cohort 2, patients treated with SG had median (range) follow-up duration of 9.3 (0.5–30.6) mo; median treatment duration was not provided for this cohort. Rash was not among the reports of any-grade TRAEs with an incidence of $>20\%$.¹⁸

IRRs were defined as symptoms, including rash, that occurred within the first 6 hours after SG administration and could occur at any cycle.¹¹ No frequency data are available for pre-infusion medication use for the prevention of IRRs in the SG arms within these two cohorts.^{5,17,18}

Metastatic Epithelial Cancer Study

Within IMMU-132-01, in patients with various advanced epithelial cancers (including mTNBC, HR+/HER2- mBC, or mUC), 402 of the 495 patients in the OSP received SG 10 mg/kg.² Treatment duration, rash-related safety data, and pre-infusion medications are shown in Table 6.

Table 6. IMMU-132-01 (OSP): Treatment Duration, Treatment-Related Rash, and Pre-Infusion Medications^{2,19}

		SG (n=492)
Treatment duration, median (range), mo		3.7 (0–55.2)
TRAE of rash, n (%)		49 (12)
Pre-infusion medications, %	Systemic corticosteroids	54.7
	Antihistamines	29.3

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Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Trodelvy US Prescribing Information available at:

www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.

Follow-Up

For any additional questions, please contact Trodelvy Medical Information at:

☎ 1-888-983-4668 or 🌐 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or

🌐 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🌐 www.accessdata.fda.gov/scripts/medwatch

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