GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Incidence and Management of Rash in mBC

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

This document summarizes 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, with a focus on patients with mBC.

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.

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 Labeling[1]

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 Levels[1]

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 IRRs[1]

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 mBC Studies

Premedication and Management of SG-Related Toxicities

Premedication for the prevention of infusion-related reactions (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.[2-5]

SG-associated toxicities were assessed and managed in accordance with standard clinical/institutional practices and accepted treatment guidelines.[2-5]

ASCENT Study in 2L+ mTNBC

Treatment durations and rash-related safety data for the ASCENT study 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.[6]

Table 3. ASCENT: Treatment Duration and Rash-Related Safety Data in OSP[6,7]

	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

	SG (n=258)	TPC (n=224)
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.

[a]Treatment 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.

TROPiCS-02 Study in Pretreated 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.[3] 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%.[8]

Table 4. TROPiCS-02: Treatment Duration and Pre-Infusion Medications[9-12]

		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

[a]Treatment 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.

[b]Data are from the ITT population (N=543). Use of pre-infusion medication in the OSP was not reported.[8]

IMMU-132-01 Study in Metastatic Epithelial Cancer

IMMU-132-01 investigated the safety and efficacy of SG in patients with metastatic epithelial cancers, including mTNBC and HR+/HER2- mBC; 402 of the 495 patients in the OSP received SG 10 mg/kg.[4] Treatment duration, rash-related safety data, and pre-infusion medications are shown in Table 5.

Table 5. IMMU-132-01 (OSP): Treatment Duration, Treatment-Related Rash, and Pre-Infusion Medications[4,13]

		SG (n=402)
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

In the mTNBC cohort (n=108), a total of 30 (28%) and 2 (2%) patients experienced any-grade and Grade 3 rash (which could include maculopapular rash, generalized rash, dermatitis acneiform, and skin disorder), respectively. The median treatment duration in this cohort was 5.1 mo.[14] In the HR+/HER2- mBC cohort (n=54), rash was not among the any-grade or Grade 3 TRAEs reported in ≥15% or ≥5% of patients, respectively. The median (range) treatment duration in this cohort was 4.6 (0-29.4) mo.[15]

References

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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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