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Trodelvy® (sacituzumab govitecan-hziy) Use in Patients With Head/Neck Cancer

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and its use in patients with head and neck cancer. 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.

Trodelvy is not indicated for use in patients with head and neck cancer. 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.

Summary

Clinical Studies in Patients With R/R Head and Neck Squamous Cell Carcinoma (HNSCC)

TROPiCS-03 is a phase 2 study evaluating the efficacy and safety of SG in adult patients with metastatic solid tumors, including patients with R/R advanced HNSCC, who progressed after prior PLT-based chemotherapy and anti–PD-(L)1 therapy. Results from the R/R HNSCC cohort (n=43) showed[1]:

- The ORR (95% CI) was 16% (7–31), median (95% CI) PFS was 4.1 months (2.6–5.8), median (95% CI) OS was 9 (7.1–10.5) months, and CBR (95% CI) was 28% (15–44).
- Median (95% CI) DOR was 4.2 months (2.6–NR), and DOR rate (95% CI) at 6 months was 43% (10–73).
- The most common any grade TEAEs (>35%) were diarrhea (47%), nausea (47%), neutropenia (47%), fatigue (44%), and alopecia (37%). The most common Grade 3 TEAEs (>8%) were neutropenia (23%), anemia (9%), and leukopenia (9%). The only Grade 4 TEAE observed was neutropenia (9%).
- TEAEs led to treatment interruptions in 47% of patients, discontinuations in 5% of patients, and dose reduction in 21% of patients.

IMMU-132-01, a phase 1/2, single-arm basket study investigated the efficacy and safety of SG in patients with metastatic epithelial cancers, including 4 patients with HNSCC, who had relapsed after or were refractory to ≥1 prior therapy for metastatic disease.[2]

- No patient had a CR or PR (ORR=0%), and SD was observed in 3 (75%) patients in the HNSCC cohort. CBR, DOR, OS, and PFS were not provided due to small size.
- To date, safety data specific to patients with HNSCC have not been published.

Clinical Studies in Patients With R/R HNSCC

TROPiCS-03 Study in Metastatic Solid Tumors

Study design and demographics[1]

TROPiCS-03 is a multicohort, open-label, single-arm, phase 2 basket study evaluating the efficacy and safety of SG in adult patients with histologically confirmed metastatic or locally advanced solid tumors, including patients with R/R advanced HNSCC, who progressed after prior PLT-based chemotherapy and anti–PD-(L)1 therapy (given sequentially in either order or in combination). Patients received SG 10 mg/kg IV on Days 1 and 8 of a 21-day treatment cycle, which was continued until progressive disease, unacceptable toxicity, study withdrawal, or death.

The primary endpoint was investigator's assessment ORR (confirmed CR + PR) per RECIST version 1.1. Key secondary endpoints included OS, safety, and investigator-assessed DOR, CBR (confirmed CR + PR + SD ≥6 months), and PFS.

Forty-three patients were enrolled in the study and the median (range) duration of exposure to SG was 2.5 (0.3–12.3) months. Patients received a median (range) of 4 (1–17) cycles of SG. At the time of data cutoff, 2 patients remained on treatment and 31 patients (72%) had discontinued treatment due to progression (radiologic progression [n=26]; clinical progression [n=5]). Demographics and baseline characteristics are shown in Table 1.

Table 1. TROPiCS-03 (HNSCC Cohort): Demographics and Characteristics[1]

Demographics and Characteristics		HNSCC Cohort (N=43)
Age, median (range), years		62 (46–75)
≥65 years, n (%)		11 (26)
Male, n (%)		33 (77)
Race, n (%)	White	33 (77)
	Asian	4 (9)
	Other/not reported	4 (9)/2 (5)
Current or former smoker, n (%)		32 (74)
Eastern Cooperative Oncology Group performance status 0/1, n (%)		9 (21)/34 (79)
HPV Status,[a] n (%)	Positive	18 (42)
	Negative	22 (51)
Primary site of disease,[b] n (%)	Oropharynx	19 (44)
	Larynx	11 (26)
	Oral cavity	8 (19)
	Nasal cavity	2 (5)
	Nasopharynx	1 (2)
Current disease stage, n (%)	Metastatic	37 (86)
	Locally Advanced	6 (14)
Number of prior anticancer regimens, n (%)	2	16 (37)
	3	18 (42)
	>3	9 (21)
Prior anticancer regimens, median (range), n		3 (2–9)
Number of prior regimens in advanced/metastatic setting, n (%)	1	14 (33)
	2	15 (35)
	>2	14 (33)
Prior anticancer therapy type,[c] n (%)	Chemotherapy	43 (100)

Demographics and Characteristics		HNSCC Cohort (N=43)
	Immunotherapy	43 (100)
	Targeted therapy	22 (51)
Best response to last prior anticancer therapy,[d] n (%)	Responsive (CR/PR)	4 (9)
	Nonresponsive (SD/PD)	37 (86)

[a]Unknown (n=3; 7%).
[b]Unknown (n=2; 5%).
[c]Other (n=1; 2%).
[d]Unknown (n=2; 5%).

Efficacy

Efficacy results by investigator assessment are shown in Table 2. Twenty-two patients (51%) had a reduction in tumor size, with 16% (n=7) having a reduction of >30%. The median (95% CI) PFS was 4.1 (2.6–5.8) months and the PFS (95% CI) rates at 6 and 12 months were 32% (17–47) and 12% (3–28), respectively. The median (95% CI) OS was 9 (7.1–10.5) months and the OS (95% CI) rates at 6 and 12 months were 75% (59–86) and 28% (13–45), respectively. The median (range) duration of OS follow-up was 7.8 (0.6–19.8) months.[1] Efficacy outcomes by HPV status and oropharynx vs non-oropharynx subsites are shown in Table 3.[3]

Table 2. TROPiCS-03 (HNSCC Cohort): Efficacy by Investigator Assessment[1]

Efficacy per RECIST version 1.1		N=43
ORR (confirmed CR + PR), % (95% CI)		16 (7–31)
Best overall response, n (%)	Confirmed PR	7 (16)
	SD	21 (49)
	PD	9 (21)
	Not evaluable[a]	2 (5)
	Not assessed[b]	4 (9)
CBR (confirmed CR + PR + SD ≥6 months), % (95% CI)		28 (15–44)
Time to response,[c] median (95% CI), months		1.4 (1.3–3)
DOR,[c,d] median (95% CI), months		4.2 (2.6–NR)
DOR rate at 6 months,[d] % (95% CI)		43 (10–73)

[a]1 patient had a partial measurement of target lesions postbaseline, and 1 patient had a noncontrast scan due to a low glomerular filtration rate.
[b]Patients without any postbaseline tumor assessment.
[c]Patients with confirmed CR or PR.
[d]Calculated using Kaplan-Meier method.

Table 3. TROPiCS-03 (HNSCC Cohort): Efficacy Outcomes by HPV Status and Subsites[3]

Efficacy		HPV Positive (n=18)	HPV negative[a] (n=25)	Oropharynx carcinoma (n=19)	Non-Oropharynx carcinoma (n=24)
ORR (confirmed CR + PR), % (95% CI)		17 (4–41)	16 (5–36)	26 (9–51)	8 (1–27)
Best overall response, n (%)	Confirmed PR	3 (17)	4 (16)	5 (26)	2 (8)
	SD	10 (56)	11 (44)	10 (53)	11 (46)
	PD	3 (17)	6 (24)	4 (21)	5 (21)
	Not evaluable[b]	1 (6)	1 (4)	0	2 (8)
	Not assessed[c]	1 (6)	3 (12)	0	4 (17)
CBR (confirmed CR + PR + SD ≥6 months), % (95% CI)		28 (10–54)	28 (12–49)	37 (16–62)	21 (7–42)

PFS, median (95% CI), months	4.4 (1.7–1.5)	2.7 (1.4–7.8)	4.6 (2.6–6.7)	2.8 (1.4–7.8)
PFS rate at 6 months, % (95% CI),	20 (5–42)	44 (24–63)	30 (11–52)	35 (15–56)
PFS rate at 12 months, % (95% CI),	13 (2–35)	NR	NR	13 (1–40)
OS, median (95% CI), months	9 (4.6–12.2)	8.9 (6.1–19.5)	8.9 (7.1–12.2)	9.9 (6.1–10.1)

[a]3 patients had unknown HPV status.
[b]Patients with non-evaluable response.
[c]Patients without any post-baseline tumor assessment.

Safety[1]

A summary of TEAEs is presented in Table 4 and the most common TEAEs reported are detailed in Table 5.

Table 4. TROPiCS-03 (HNSCC Cohort): Safety Summary[1]

TEAEs, n (%)	N=43
Any-grade TEAEs	43 (100)
Treatment-related	43 (100)
Grade ≥3 TEAEs	25 (58)
Treatment-related	19 (44)
Serious TEAEs	13 (30)
Treatment-related	5 (12)
TEAEs that led to interruption of SG	20 (47)
TEAEs that led to dose reduction of SG[a]	9 (21)
TEAEs that led to discontinuation of SG[b]	2 (5)
Treatment-related	1 (2)[c]
TEAEs that led to death[d]	3 (7)
Treatment-related	1 (2)

[a]4 patients with neutropenia; 2 patients with nausea; others unspecified.
[b]1 patient with respiratory failure underwent interruption of SG, but the patient died before SG could be resumed; event was recorded as discontinuation due to a TEAE.
[c]1 patient discontinued SG due to treatment-related fatigue.
[d]Sepsis (n=1), septic shock (n=1), and unknown cause (n=1). The 1 case of septic shock that led to death was deemed related to study treatment.

Table 5. TROPiCS-03 (HNSCC Cohort): Most Common TEAEs (N=43)[1]

TEAE, n (%)	Any Grade[a]	Grade 3	Grade 4
Diarrhea	20 (47)	1 (2)	0
Nausea	20 (47)	3 (7)	0
Neutropenia	20 (47)	10 (23)	4 (9)
Fatigue	19 (44)	1 (2)	0
Alopecia	16 (37)	0	0
Vomiting	14 (33)	1 (2)	0
Anemia	13 (30)	4 (9)	0
Dyspnea	11 (26)	3 (7)	0
Decreased appetite	10 (23)	1 (2)	0
Leukopenia	8 (19)	4 (9)	0
Hyponatremia	7 (16)	1 (2)	0

[a]TEAE reported in ≥15% of patients are presented.

IMMU-132-01 Study in Metastatic Epithelial Cancer[2]

Study design and demographics

IMMU-132-01, a phase 1/2, single-arm, open-label basket study, investigated the efficacy and safety of SG in patients with metastatic epithelial cancers, including 4 patients with HNSCC, who had relapsed after or were refractory to ≥1 prior therapy for metastatic disease. In the HNSCC cohort, SG 8 or 10 mg/kg IV was administered on Days 1 and 8 of a 21-day treatment cycle until disease progression or unacceptable toxicity, death, or withdrawal of consent. Efficacy endpoints in the overall basket study included ORR (confirmed PR + CR by investigator assessment per RECIST version 1.1), DOR, CBR (CR + PR + SD ≥6 months), PFS, and OS.

Efficacy

No patient had a CR or PR (ORR=0%), and SD was observed in 3 (75%) patients in the HNSCC cohort. CBR, DOR, OS, and PFS were not provided due to small size.

Safety

To date, safety data specific to patients with HNSCC have not been published. In the overall safety population (N=495), the most common treatment-related adverse events were nausea (62.6%), neutropenia (57.8%), diarrhea (56.2%), fatigue (48.3%), and alopecia (40.4%). Grade ≥3 neutropenia and febrile neutropenia occurred in 42.4% and 5.3% of patients, respectively. Adverse events led to treatment discontinuation in 41 (8.3%) patients.

Ongoing Clinical Studies

A phase 2, single-center, open-label, single-arm study (NCT05884320) is investigating the use of SG in adult patients with histology-proven recurrent and/or metastatic secretory gland cancers.

SETHY is a phase 2, prospective, multicohort, single-arm, non-randomized, non-blinded study (NCT06235216) investigating the use of SG in adult patients with advanced or metastatic radioactive-iodine refractory differentiated thyroid carcinoma or anaplastic thyroid carcinoma.

References

1. Michel L, Jimeno A, Sukari A, et al. Sacituzumab govitecan in patients with relapsed/refractory advanced head and neck squamous cell carcinoma: results from the phase 2 TROPiCS-03 basket study. *Clin Cancer Res.* 2025;3(31):832-838.
2. Bardia A, Messersmith WA, Kio EA, et al. Sacituzumab govitecan, a Trop-2-directed antibody-drug conjugate, for patients with epithelial cancer: final safety and efficacy results from the phase I/II IMMU-132-01 basket trial. *Ann Oncol.* 2021;32(6):746-756.
3. Michel L, Jimeno A, Sukari A, et al. Sacituzumab govitecan in patients with relapsed/refractory advanced head and neck squamous cell carcinoma: results from the phase 2 TROPiCS-03 basket study [supplemntary material]. *Clin Cancer Res.* 2025;3(31):832-838.

Abbreviations

BICR=blinded independent central review
CBR=clinical benefit rate
CR=complete response
DOR=duration of response
HPV= human papillomavirus
HNSCC=head and neck squamous cell carcinoma
NR=not reached

ORR=objective response rate
OS=overall survival
PD-(L)1=programmed death (ligand)-1
PFS=progression-free survival
PLT=platinum
PR=partial response
RECIST=Response Evaluation Criteria in Solid Tumors
R/R=relapsed/refractory
SD=stable disease
SG=sacituzumab govitecan-hziy
TEAE=treatment-emergent adverse event

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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