GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Use in Patients With Ovarian Cancer

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

SG Clinical Data in Patients With Ovarian Cancer

An ongoing, phase 2, open-label, single-institution study is investigating the efficacy and safety of SG in patients with PROC (N=20). After a median follow-up of 9 mo, the ORR was 35%, with no CRs observed; SD was achieved in 40% of patients. The mPFS (95% CI) was 8 (3.8–14.8) mo, and the mOS was NR. The most common Grade 3 to 4 treatment-emergent AEs were neutropenia (n=15), hypokalemia (n=3), and anemia (n=2). Fourteen SAEs were reported (Grade 3: n=9; Grade 4: n=5). No deaths were reported.[1]

A phase 1/2, single-arm, open-label basket study investigated the efficacy and safety of SG in patients with metastatic epithelial cancers, including EOC, who had relapsed after or were refractory to ≥1 prior therapy for metastatic disease. The ORR in patients with EOC (n=8) was 0%, and SD was achieved by 2 patients (25%). The median DOR, mOS, mPFS, and CBR were not provided due to the small sample size. Safety data specific to patients with EOC were not reported.[2]

SG Real-World Data in Patients With Ovarian Cancer

A retrospective analysis evaluated the efficacy and safety of SG in patients with recurrent breast cancer (n=24) or PLT-resistant EOC (n=10). In patients with EOC, the ORR was 0%, DCR was 40%, mPFS was 2.5 mo, and the 6-mo PFS rate was 20%. Treatment-related Grade 4 neutropenia and Grade 4 diarrhea were reported in 60% and 30% of patients, respectively.[3]

SG Clinical Data in Patients With Ovarian Cancer

Phase 2 Study in PROC[1]

Study design and demographics

An ongoing phase 2, open-label, single-institution study (NCT06028932) is evaluating the efficacy and safety of SG in patients with PROC (N=20). Eligible patients received SG 10 mg/kg administered IV on Days 1 and 8 of a 21-d treatment cycle until unacceptable toxicity or disease progression. The primary endpoint is ORR, assessed per RECIST v1.1. Secondary endpoints are PFS, OS, and safety. Baseline demographics and disease characteristics are presented in Table 1.

Table 1. Baseline Demographics and Disease Characteristics[1]

Key Demographics and Characteristics		SG (N=20)
Age, median (range), y		67 (45–84)
Race, White/unknown, n (%)		17 (85)/3 (15)
Ethnicity, non-Hispanic/Hispanic/unknown		16 (80)/2 (10)/ 2 (10)
ECOG PS, 0/1, n (%)		16 (80)/4 (20)
Histology	Serous	15 (75)
	Clear cell	3 (15)
	Carcinosarcoma	1 (5)
	Endometrioid	1 (5)
Stage	I/II	3 (15)
	III/IV	17 (85)
Trop-2 membrane H-score,[a] range		85–260
Prior lines of therapy, median (range), n		3 (1–8)

Abbreviation: H-score=histochemical score

[a]Trop-2 H-scores (range, 0–300) were calculated as follows: (1 × % of cells with 1+ staining) + (2 × % of cells with 2+ staining) + (3 × % of cells with 3+ staining).

Efficacy

After a median follow-up of 9 mo, the ORR was 35%, with no CRs observed; SD was achieved in 40% of patients. The mPFS (95% CI) was 8 (3.8–14.8) mo, and the mOS was NR at the time of analysis.

Safety

No new safety signals were identified. The most common Grade 3 to 4 treatment-emergent AEs were neutropenia (n=15), hypokalemia (n=3) and anemia (n=2). Fourteen SAEs were reported (Grade 3: n=9; Grade 4: n=5). No deaths were reported.

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

Study design

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

In the EOC cohort (n=8), SG 8 or 10 mg/kg IV was administered on Days 1 and 8 of a 21-d treatment cycle until disease progression or unacceptable toxicity, death, or withdrawal of consent.

Efficacy endpoints in the overall basket study included the following: ORR (defined as both PR and CR confirmed by investigator's assessment per RECIST v1.1), DOR, CBR (defined as CR + PR + SD ≥6 mo), PFS, and OS.

Efficacy

The ORR in patients with EOC was 0%. SD was achieved by 2 patients (25% of patients with EOC). The median DOR, mOS, mPFS, and CBR were not provided due to the small sample size.

Safety

Safety data specific to patients with EOC were not reported.

In the overall safety population (n=495), 41 patients (8.3%) permanently discontinued treatment due to AEs. The most common TRAEs 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.

SG Real-World Data in Patients With Ovarian Cancer

SG Use in PLT-Resistant EOC[3]

A retrospective analysis evaluated the efficacy and safety of SG in patients with recurrent breast cancer (n=24) or PLT-resistant EOC (n=10). Data for the 10 patients with PLT-resistant EOC is presented here. All patients with EOC were heavily pretreated, with a median (range) of 4.5 (4–7) prior lines of systemic therapy. Patients received a median of 2.5 treatment cycles. ORR was 0%, DCR was 40%, mPFS was 2.5 mo and the 6-mo PFS rate was 20%. Grade ≥3 TRAEs occurred in 9 (90%) patients and included Grade 4 neutropenia (n=6 [60%]), with a median onset of 13.5 d after treatment cycle initiation, and Grade 4 diarrhea (n=3 [30%]), with a median onset of 13 d.

Case Report of SG Use in HGSOC

There are limitations in the interpretation of case reports. Case reports cannot be generalized. Unlike controlled clinical trials, causality cannot be inferred based on uncontrolled observational data. In addition, incidence or prevalence cannot be estimated due to the lack of a representative population sample. Other limitations of case reports include the retrospective design and publication bias.[4]

A 69-y-old female patient with recurrent, metastatic, PLT-resistant HGSOC received multiple lines of chemotherapy and targeted treatments over approximately the previous 10 y. The tumor was known to overexpress Trop-2, and the patient was initiated on SG 10 mg/kg on Days 1 and 8 of 21-d cycles. Following initiation of SG, CA-125 serum value dropped from 342 to 109 units/mL and continued to decline over time. CT scans showed regression of metastatic sites, and her umbilical lesion decreased in size. Adenopathy improved, a pancreatic tail mass decreased in size and numerous hepatic metastases also decreased in

size with no new lesions reported. At the time of publication, she had received 8 cycles of SG; intermittent gastrointestinal symptoms were reported, with no need for dose reductions.[5]

Ongoing Clinical Studies

An open-label, phase 1 study (NCT06040970) is evaluating the efficacy and safety of SG in combination with cisplatin, in PLT sensitive recurrent ovarian and endometrial cancer, conducted in two separate disease groups; the primary objective of the study is to determine the optimal dose of SG in combination with cisplatin for treatment of epithelial ovarian and endometrial cancers.

References

1. Santin AD, Roque DM, Siegel E, et al. A phase II evaluation of sacituzumab govitecan in platinum-resistant ovarian cancer (NCT06028932) [Abstract 540098]. Presented at: American Society of Clinical Oncology (ASCO) Annual Meeting; May 29-June 2, 2026; Chicago, IL.
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. Prast I, Marth C, Zeimet AG, Tsibulak I. Sacituzumab Govitecan In Platinum-Resistant Epithelial Ovarian Cancer In A Real-Life Clinical Setting. Presented at: European Society of Gynaecological Oncology (ESGO); February 20-23, 2025; Rome, Italy.
4. Nissen T, Wynn R. The clinical case report: a review of its merits and limitations. *BMC Res Notes.* 2014;7:264.
5. Greenman M, Bellone S, Demirkiran C, Hartwich TMP, Santin AD. Sacituzumab govitecan in heavily pretreated, platinum-resistant high grade serous ovarian cancer. *Gynecologic Oncology Reports.* 2024;54:101459.

Abbreviations

AE=adverse events
CBR=clinical benefit rate
CR=complete response
DCR=disease control rate
DOR=duration of response
ECOG PS=Eastern Cooperative Oncology Group performance status
EOC=epithelial ovarian cancer
HGSOC=high-grade serous ovarian cancer
mOS=median overall survival
mPFS=median progression-free survival
NR=not reached
ORR=objective response rate
OS=overall survival
PFS=progression-free survival
PLT=platinum
PR=partial response
PROC=platinum-resistant ovarian cancer
RECIST=Response Evaluation Criteria in Solid Tumors
SAE=serious adverse event
SD=stable disease
SG=sacituzumab govitecan-hziy
TRAE=treatment-related adverse event
Trop-2=trophoblast cell-surface antigen-2

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.

Gilead Sciences, Inc. is providing this document to you, a US Healthcare Professional, in response to your unsolicited request for medical information.

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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