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

GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Use in Patients With Advanced, Recurrent, or Metastatic Endometrial Cancer

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and its use in patients with advanced, recurrent, or metastatic endometrial cancer (EC).

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 EC. 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 of SG Use in Advanced, Recurrent, or Metastatic EC

The phase 2 TROPiCS-03 study is evaluating the efficacy and safety of SG in adult patients with metastatic solid tumors, including advanced/metastatic EC, who progressed after PLT-based chemotherapy and anti-PD-L1-directed therapy.[1,2]

- At the data cutoff, the ORR was 27%. The median DOR was 9 mo, the median PFS was 5 mo, and the median OS was 15 mo.[2]
- Any-grade TEAEs were reported in all patients, and 85% reported Grade ≥3 TEAEs. The most common Grade ≥3 TEAEs were neutropenia (49%), diarrhea (22%), and anemia (20%).[2]
- Any-grade and Grade ≥3 TRAEs were reported in 95% and 76% of patients, respectively.[2]
- Deaths due to TEAEs occurred in 3 patients; 1 was deemed related to SG.[2]

An open-label, phase 2 study is evaluating the safety and efficacy of SG in patients with persistent or recurrent EC who progressed after ≥1 line of PLT-based chemotherapy (N=50).[3]

- ORR was 28% (n=14; 95% CI: 16–42%); CBR was 52% (n=26; 95% CI: 37–66%); and median (95% CI) DOR was 9.3 (2–12.9) mo. Median (95% CI) PFS and OS were 5.52 (3.75–7.36) mo and 17.5 (10.4–22.2) mo, respectively. Overall, 70.8% of patients (34/48) had a reduction from baseline in the diameter of the target lesion.
- In an analysis of efficacy according to Trop-2 expression in 43 patients with available data, expression of Trop-2 did not significantly correlate with objective response (*P*=0.07). ORR (*P*=0.19) and median PFS (*P*=0.83) were not significantly different between subgroups according to H-score.
- The most common Grade 3/4 TEAEs were neutropenia (52%), anemia (38%), and fatigue (20%). The most common SAEs were neutropenia (14%), febrile neutropenia

(10%), sepsis (8%), and diarrhea (8%). Three patients discontinued treatment due to Grade 3/4 TEAEs.

The phase 1/2 IMMU-132-01 study investigated the efficacy and safety of SG in patients with metastatic epithelial cancers, including EC, who had relapsed after or were refractory to ≥1 prior therapy for metastatic disease. The EC cohort consisted of 18 patients.[4]

- In the EC cohort, the ORR was 22.2%, the median PFS was 3.2 mo, and the median OS was 11.9 mo.
- Safety data specific to patients with EC were not reported. In the OSP (n=495), the most common TRAEs were nausea (62.6%), neutropenia (57.8%), diarrhea (56.2%), fatigue (48.3%), and alopecia (40.4%).

The ongoing, phase 3 ASCENT-GYN-01 study is evaluating the efficacy and safety of SG vs TPC in patients with recurrent or persistent EC who have received up to three prior lines of systemic treatment, including PLT-based chemotherapy and PD-(L)1 inhibitor therapy. Eligible patients will receive SG or TPC (doxorubicin or paclitaxel). Dual primary endpoints will be PFS (BICR) and OS. Approximately 640 patients will be enrolled.[5]

Ongoing Clinical Studies of SG Use in Advanced, Recurrent, or Metastatic EC

Ongoing clinical studies are summarized below.

Clinical Studies of SG Use in EC

TROPiCS-03 Study in Metastatic Solid Tumors

Study design and demographics

TROPiCS-03 (NCT03964727) is a multicohort, open-label, phase 2 basket study evaluating the efficacy and safety of SG in adult patients with metastatic solid tumors, including advanced/metastatic EC, who progressed after PLT-based chemotherapy and anti-PD-L1-directed therapy. Patients received SG 10 mg/kg IV on Days 1 and 8 of a 21-d treatment cycle.[1]

As of the data cutoff, 41 patients were enrolled, with a median (range) follow-up of 19.4 (14.4–30.3) mo.[2] Key baseline demographics for the EC cohort can be found in Table 1.

Table 1. TROPiCS-03 EC Cohort: Baseline Demographics and Disease Characteristics[2]

Key Demographics and Characteristics		Overall (N=41)
Age, median (range), y		68 (44–83)
Race, n (%)	White	21 (51)
	Asian	8 (20)
	Other/not reported	6 (15)/6 (15)
ECOG PS, n (%)	0/1	18 (44)/23 (56)
Microsatellite instability high, n (%)	Yes	8 (20)
Histological diagnosis, n (%)	Endometrioid	20 (49)
	Serous	17 (42)
	Other	4 (10)
Number of prior anticancer regimens, median (range)		3 (1–6)

Key Demographics and Characteristics		Overall (N=41)
Prior anticancer therapy type, n (%)	Chemotherapy	41 (100)
	Immunotherapy	35 (85)
	Targeted agents	26 (63)
	Hormonal therapy	5 (12)
	Other	1 (2)
Prior PLT-based chemotherapy + immunotherapy, n (%)		35 (85)

Efficacy[2]

Efficacy outcomes are shown in Table 2.

Table 2. TROPiCS-03 EC Cohort: Efficacy Outcomes[2]

Outcome		SG (N=41)
ORR (confirmed CR + PR; primary endpoint),[a] n (%; 95% CI)		11 (27; 14–43)
Best overall response, n (%)	Confirmed CR	1 (2)
	Confirmed PR	10 (24)
	SD	17 (42)
	PD	8 (20)
	Not evaluable	1 (2)
	Not assessed[b]	4 (10)
CBR (confirmed CR + PR + SD ≥6 mo),[c] n (%; 95% CI)		17 (42; 26–58)
DOR (confirmed CR or PR),[c] median (95% CI), mo		9 (2.8–NR)
PFS,[c] median (95% CI), mo		5 (2.8–9.8)
PFS rate,[d] 6-/12-mo, % (95% CI)		41 (25–56)/23 (11–38)
OS, median (95% CI), mo		15 (5.9–NR)
OS rate,[d] 6-/12-mo, % (95% CI)		65 (49–78)/50 (34–64)
Patients with target lesion reduction from baseline, n (%)		26 (63)

[a]Assessed by investigators per RECIST v1.1.
[b]Patients without any post-baseline assessment were not assessed.
[c]Per investigator assessment and BICR.
[d]Assessed per Kaplan-Meier.

Safety[2]

Any-grade TEAEs were reported in all patients, and Grade ≥3 TEAEs were reported in 85% of patients. The most common Grade ≥3 TEAEs were neutropenia, diarrhea, and anemia (Table 3). Seven percent of patients discontinued due to TEAEs. Three patients died due to TEAEs (unknown cause, n=2; pneumonia, n=1); 1 death of unknown cause was deemed SG-related by the investigator. Any-grade TRAEs were reported in 39 patients (95%), and Grade ≥3 TRAEs were reported in 31 patients (76%).

Table 3. TROPiCS-03 EC Cohort: Most Common (>20% Any-Grade) TEAEs[2]

TEAE, n (%)	Any-Grade	Grade ≥3
Neutropenia	26 (63)	20 (49)
Diarrhea	23 (56)	9 (22)
Fatigue	23 (56)	3 (7)
Nausea	22 (54)	3 (7)
Anemia	20 (49)	8 (20)
Alopecia	17 (42)	0
Constipation	15 (37)	0
Vomiting	11 (27)	2 (5)

TEAE, n (%)	Any-Grade	Grade ≥3
Hypomagnesemia	11 (27)	0
Hypokalemia	10 (24)	6 (15)

Study in Persistent/Recurrent EC[3]

Study design and demographics

An open-label, single-center, 2-stage, phase 2 study evaluated the efficacy and safety of SG in patients with persistent or recurrent EC who progressed after ≥1 line of PLT-based chemotherapy with or without PD-1 inhibitor therapy. Patients received SG 10 mg/kg IV on Days 1 and 8 of a 21-d treatment cycle until disease progression, unacceptable toxicity, study withdrawal or death, whichever occurred first. Stage 1 evaluated patients whose tumors expressed Trop-2 of 2+ staining intensity in ≥50% of tumor cells; in Stage 2, patients were included without requiring prospective Trop-2 testing. The primary endpoint was ORR by investigator assessment per RECIST v1.1. Secondary endpoints included CBR, DOR and PFS by investigator assessment per RECIST v1.1, OS, and safety. Exploratory endpoints evaluated the correlation between Trop-2 expression levels and ORR, CBR, DOR, and PFS.

Fifty patients were screened for Stage 1, with 21 being evaluable; 34 were screened for Stage 2 and 29 were evaluable. Baseline demographics and disease characteristics are summarized below (Table 4). Of the 46 patients with mismatch repair status available, 44 (96%) were proficient.

Table 4. Recurrent/Persistent EC: Baseline Demographics and Disease Characteristics[3]

Key Demographics and Characteristics		SG (N=50)
Age, median (range), y		68 (30–82)
<65/≥65 y, n (%)		32 (64)/18 (36)
Race and ethnicity, n (%)	Non-Hispanic White	33 (66)
	Non-Hispanic Black	7 (14)
	Non-Hispanic Asian	2 (4)
	Non-Hispanic other	3 (6)
	Hispanic	5 (10)
ECOG PS, 0/1, n (%)		27 (54)/23 (46)
Histology, n (%)	Serous	21 (42)
	Endometrioid[a]	11 (22)
	Carcinosarcoma	11 (22)
	Other	4 (8)
	Mixed serous	3 (6)
Disease status, recurrent/refractory, n (%)		36 (72)/14 (28)
Number of prior anticancer regimens, median (range)		2 (1–4)
Prior anticancer therapy type, n (%)	Pembrolizumab	21 (42)
	Doxorubicin	13 (26)
	Other	8 (16)

[a]Grade 1, n=1 (2%); Grade 2, n=2 (4%); Grade 3, n=8 (16%).

Efficacy

The median (range) duration of follow-up was 11 (2.9–65.5) mo. Primary and secondary efficacy outcomes are shown in Table 5.

Table 5. Recurrent/Persistent EC: Efficacy Outcomes[3]

Outcome		SG (N=50)
ORR (primary endpoint; >10%; confirmed CR + PR), n (%; 95% CI)		14 (28; 16–42)
Best overall response, n (%)	CR	2 (4)
	PR	12 (24)
	SD	26 (52)
	PD	10 (20)
CBR (confirmed CR + PR + SD for ≥6 mo), n (%; 95% CI)		26 (52; 37–66)
DOR,[a] median (95% CI), mo		9.3 (2–12.9)
PFS	Events, n (%)	42 (84)
	Median (95% CI), mo	5.52 (3.75–7.36)
	6-/12-mo rate, % (95% CI)	44 (30–58)/26 (13–39)
OS	Deaths, n (%)	35 (70)
	Median (95% CI), mo	17.5 (10.4–22.2)
	6-/12-mo rate, % (95% CI)	82 (71–93)/58 (44–73)
Patients with reduction from baseline in diameter of target lesion, n/N (%)		34/48 (70.8)

[a]Evaluated in the 14 patients who achieved ORR.

By histology, objective response was achieved in 33% of patients (7/21) with serous tumors, by 36% (4/11) with endometrioid tumors, by 9% (1/11) with carcinosarcoma, by none (0/3) with mixed serous tumors, and by 50% (2/4) with other types.

In patients with Trop-2 expression data available (n=43 [86%]), the median H-score was 240. Expression of Trop-2 did not significantly correlate with objective response (*P*=0.07). Non-significant differences in patients with H-score ≥ median vs < median were observed for ORR (40% vs 19%, respectively; *P*=0.19) and median (95% CI) PFS (5.6 [3.5–9.2] mo vs 3.8 [3.4–11.3] mo; hazard ratio, 0.93 [95% CI: 0.47–1.81]; *P*=0.83). Additionally, there was a negative correlation between the maximum change in tumor volume at best overall response and baseline H-score (correlation coefficient=-0.454; *P*=0.0029).

Safety

Safety outcomes were consistent with the known safety profile of SG. See Table 6 for a safety summary.

Table 6. Recurrent/Persistent EC: Safety Summary[3]

Parameter		SG (N=50)	
		Events, n	Patients (%)
Grade 3/4 TEAEs		323	44 (88)
Most common Grade 3/4 TEAEs	Neutropenia	80	26 (52)
	Anemia	38	19 (38)
	Fatigue	14	10 (20)
SAEs		85	25 (50)
Most common SAEs	Neutropenia	8	7 (14)
	Febrile neutropenia	5	5 (10)
	Sepsis	5	4 (8)
	Diarrhea	4	4 (8)

Treatment delays and dose reductions with SG were required in 27 and 9 patients, respectively. Three patients discontinued treatment due to Grade 3/4 TEAEs: myocardial infarction, cerebral edema, and pleural effusion/hypoxia/dyspnea (each, n=1).

IMMU-132-01 Study in Metastatic Epithelial Cancer[4]

Study design

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 EC, who had relapsed after or were refractory to ≥1 prior therapy for metastatic disease. In the EC cohort (n=18), SG 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

Efficacy data for the EC cohort are presented in Table 7.

Table 7. IMMU-132-01: Response Rates in Patients With EC (n=18)[4]

ORR,[a,b] % (95% CI)	CR,[b] n (%)	PR,[b] n (%)	SD, n (%)	DOR, Median (95% CI), mo	OS,[c] Median (95% CI), mo	PFS, Median (95% CI), mo	CBR,[d] n (%) [95% CI]
22.2 (6.4–47.6)	0	4 (22.2)	6 (33.3)	NR (9.1–NR)	11.9 (4.7–NR)	3.2 (1.9–9.4)	8 (44.4) [21.5–69.2]

[a]Primary endpoint; defined as PR + CR.
[b]Confirmed by investigator's assessment per RECIST version 1.1.
[c]Assessed per Kaplan-Meier.
[d]Defined as CR + PR + SD ≥6 mo.

Safety

Safety data specific to patients with EC were not reported.

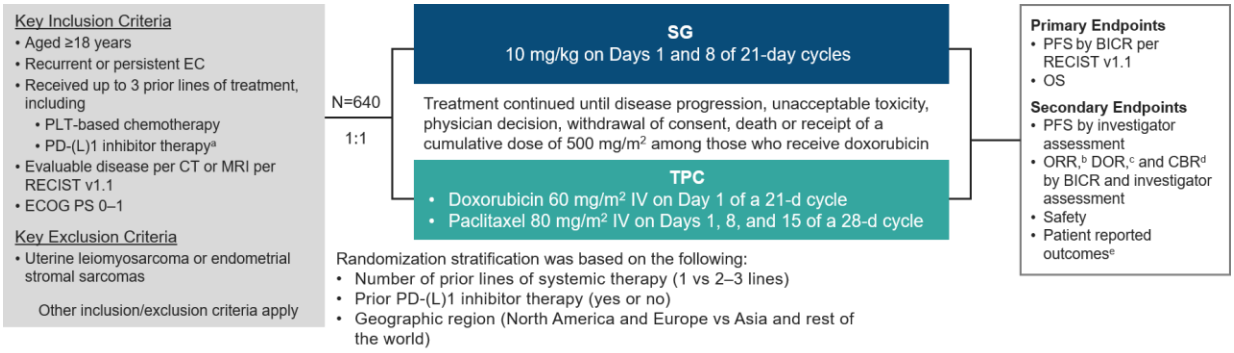
In the OSP (n=495), 41 patients (8.3%) permanently discontinued treatment due to adverse events. The most common TRAEs were nausea (62.6%), neutropenia (57.8%), diarrhea (56.2%), fatigue (48.3%), and alopecia (40.4%). Grade ≥3 neutropenia and febrile neutropenia occurred in 42.4% and 5.3% of patients, respectively.

ASCENT-GYN-01[5]

An ongoing, randomized, open-label, phase 3 study (NCT06486441) is evaluating the efficacy and safety of SG vs TPC in patients with recurrent or persistent EC who have received up to three prior lines of systemic treatment, including PLT-based chemotherapy and PD-(L)1 inhibitor therapy (Figure 1). Eligible patients are randomly assigned (1:1) to receive SG 10 mg/kg IV on Days 1 and 8 of a 21-d cycle or either doxorubicin (60 mg/m^2 IV on Day 1 of a 21-d cycle) or paclitaxel (80 mg/m^2 IV on Days 1, 8, and 15 of a 28-d cycle). The dual primary endpoints are PFS (by BICR per RECIST v1.1) and OS.

No results have been reported.

Figure 1. ASCENT-GYN-01: Study Design[5]



Abbreviation: EORTC QLQ-C30=European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire-Core 30.
[a]Patients with comorbidities that prevented treatment with PD-(L)1 inhibitor therapy or for whom it was not available as standard of care per local standards were eligible for inclusion (enrollment cap, 10%).
[b]Confirmed CR or PR.
[c]Time from confirmed CR or PR to PD or death from any cause.
[d]Confirmed CR or PR ≥4 weeks or SD for ≥6 mo.
[e]Change from baseline to Week 16 in the physical functioning and Global Health Score/Quality of Life domains of the EORTC QLQ-C30.

Ongoing Clinical Studies on SG Use in EC

An open-label, non-randomized, single-arm, phase 2 study (NCT04251416) is evaluating the efficacy and safety of SG in patients with persistent or recurrent endometrial carcinoma of epithelial origin that has progressed after or is refractory to PLT-based chemotherapy.

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

References

1. Santin D, Corr B, Spira A, et al. Efficacy and safety of sacituzumab govitecan in patients with advanced solid tumors (TROPiCS-03): analysis in patients with advanced endometrial cancer. Journal of Clinical Oncology. 2024;42(29):3421-3429.
2. Corr B, Dumbrava E, Spira A, et al. Efficacy and safety of sacituzumab govitecan in patients with advanced/metastatic endometrial cancer: updated results from TROPiCS-03 (Poster #733P). Presented at: European Society for Medical Oncology (ESMO); September 13-17, 2024; Barcelona, Spain.
3. Santin AD, Roque DM, Siegel ER, et al. A phase II evaluation of the efficacy and safety of sacituzumab govitecan in patients with recurrent uterine cancer. Clin Cancer Res. 2026;32(15):3169-3178.
4. 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.
5. Eskander RN, Corr B, Cibula D, et al. A randomized, phase III study of sacituzumab govitecan versus treatment of the physician's choice in patients with endometrial cancer after platinum-based chemotherapy and immunotherapy: the ASCENT-GYN-01 study (GOG-3104/ENGOT-en26/APGOT-EN2). Int J Gynecol Cancer. 2025;36(6):102654. https://www.ncbi.nlm.nih.gov/pubmed/41073155

Abbreviations

BICR=blinded independent central review
CBR=clinical benefit rate
CR=complete response
DOR=duration of response
EC=endometrial cancer
ECOG PS=Eastern Cooperative Oncology Group Performance Status
H-score=histochemical score
NR=not reached or not calculable
ORR=objective response rate
OS=overall survival
OSP=overall safety population
PD=progressive disease
PD-(L)1=programmed death-(ligand) 1
PFS=progression-free survival
PLT=platinum
PR=partial response
RECIST=Response Evaluation Criteria in Solid Tumors
SAE=serious adverse event
SD=stable disease
SG=sacituzumab govitecan-hziy
TEAE=treatment-emergent adverse event
TPC=treatment of physician's choice
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.

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

Data Privacy

The Medical Information service at Gilead Sciences may collect, store, and use your personal information to provide a response to your medical request. We may share your information with other Gilead Sciences colleagues to ensure that your request is addressed appropriately. If you report an adverse event or concern about the quality of a Gilead or Kite product, we will need to use the information you have given us in order to meet our regulatory requirements in relation to the safety of our medicines.

It may be necessary for us to share your information with Gilead's affiliates, business partners, service providers, and regulatory authorities located in countries besides your

own. Gilead Sciences has implemented measures to protect the personal information you provide. Please see the Gilead Privacy Statement (www.gilead.com/privacy-statements) for more information about how Gilead handles your personal information and your rights. If you have any further questions about the use of your personal information, please contact gilead.privacy@gilead.com.

TRODELVY, GILEAD, and the GILEAD logo are registered trademarks of Gilead Sciences, Inc., or its related companies.
© 2026 Gilead Sciences, Inc.