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

This document is in response to your request for information regarding the use of Trodelvy® (sacituzumab govitecan-hziy [SG]) in patients with cervical cancer.

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Trodelvy is not indicated for use in patients with cervical 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 Data on the Use of SG in Cervical Cancer

The phase 2 EVER-132-003 study evaluated the efficacy and safety of SG in patients with recurrent or metastatic solid tumors, including cervical cancer (N=40).[1]

- ORR in the cervical cancer cohort was 43%, with a median DOR of 9.2 mo. Median PFS and OS were 7.1 mo and 16.5 mo, respectively.
- Grade ≥3 TEAEs were reported in 25 patients (63%), all of which were related to SG. The most common Grade ≥3 TEAEs were neutropenia (n=17 [43%]), leukopenia (n=15 [38%]), and anemia (n=8 [20%]).

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

- One patient with cervical cancer was included and achieved SD.
- Safety data specific to the patient with cervical cancer were not reported.

A 73-y-old female with cervical SCC achieved a CR after initial treatment with definitive concurrent chemoradiotherapy. She subsequently developed recurrence, with pulmonary and mediastinal lymph node metastases detected and achieved a second CR with paclitaxel, carboplatin, and bevacizumab, followed by bevacizumab maintenance. After multifocal recurrence, she achieved a PR after second-line treatment with 3 cycles of SG + tislelizumab and a best overall response (reduction in target lesions and SCCA levels) after 6 cycles. Grade 4 neutropenia occurred during treatment and was managed with G-CSF, with no further Grade ≥3 neutropenia observed. Grade 1 hypothyroidism also occurred during treatment and was successfully managed with levothyroxine. SG was subsequently discontinued and tislelizumab monotherapy was continued for an additional 6 cycles. After disease progression, she discontinued treatment with tislelizumab and was referred for brachytherapy. Her overall PFS was 9 mo, and she had an OS of 13 mo that was ongoing at the last follow-up.[3]

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Clinical Data on the Use of SG in Cervical Cancer

EVER-132-003 Study in Solid Tumors

Study design and demographics[1]

A single-arm, multicohort, open-label, phase 2 study evaluated the efficacy and safety of SG in Chinese patients with locally advanced or metastatic solid tumors, including cervical cancer. Eligible patients had histologically confirmed recurrent or metastatic cervical cancer that was refractory or intolerant to PLT- or taxane-based chemotherapy, had an ECOG PS 0 to 1, had no prior treatment experience with topoisomerase I inhibitors, and did not have central nervous system metastases. Patients received SG 10 mg/kg IV on Days 1 and 8 of a 21-d treatment cycle. The primary endpoint was ORR, as assessed per RECIST v1.1 by investigators. Secondary endpoints included DCR, DOR, PFS, OS, and safety.

The full analysis set included 40 patients with cervical cancer who had received ≥1 dose of SG at the data cutoff (Table 1). A subgroup analysis was performed in patients who had previously received immunotherapy (n=27).

Table 1. EVER-132-003: Select Baseline Demographics and Disease Characteristics of the Cervical Cancer Cohort[1]

Key Demographics and Characteristics		Full Analysis Set (N=40)	Prior Immunotherapy Subgroup (n=27)
Age, median (range), y		54 (31–71)	54 (33–71)
ECOG PS, 0/1, n (%)		16 (40)/24 (60)	15 (56)/12 (44)
Histological subtype, n (%)	SCC[a]	34 (85)	24 (89)
	Adenocarcinoma	5 (13)	2 (7)
	Adenosquamous carcinoma	1 (3)	1 (4)
Disease status at study entry, metastatic[b]/recurrent without distant metastases, n (%)		28 (70)/12 (30)	20 (74)/7 (26)
Number of prior regimens in the recurrent or metastatic setting,[c] median (range)		2 (1–5)	2 (1–5)
Number of prior regimens, 0/1/2/≥3, n (%)		6 (15)/11 (28)/17 (43)/6 (15)	0/7 (26)/15 (56)/5 (19)
Types of prior therapy, n (%)	Chemotherapy	40 (100)	27 (100)
	Immunotherapy	27 (68)	27 (100)
	PD-1 inhibitor	24 (60)	24 (89)
	PD-1/CTLA4 bispecific	3 (8)	3 (11)
	PD-L1 inhibitor	2 (5)	2 (7)
	CTLA-4	1 (4)	1 (3)
	Targeted agents[d]	26 (65)	19 (70)
	Other (investigational drug)	5 (13)	4 (15)

Abbreviation: CTLA4=cytotoxic T-lymphocyte associated protein 4.
[a]Included 1 patient with partial adenosquamous differentiation.
[b]In the full analysis set and the prior immunotherapy subgroup, metastases were present in the lymph node (n=15 [38%] and n=12 [44%], respectively), lung (n=14 [35%] and n=9 [33%]), bone (n=6 [15%] and n=5 [19%]), and liver (n=5 [13%] and n=3 [11%]).
[c]Included 6 patients who were not treated in the recurrent or metastatic setting but had received PLT-based chemotherapy in the early, locally advanced setting. One patient had received prior bevacizumab. Disease progression due to recurrence or metastasis occurred ≤6 mo after PLT- or taxane-based (neo)adjuvant treatment.
[d]Included bevacizumab (full analysis set, n=20 [50%]; prior immunotherapy subgroup, n=14 [52%]).

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Efficacy

Median (range) duration of SG exposure was 5.8 (0.3–17.3) mo, and patients received a median (range) of 8 (1–22) cycles of SG. Median (range) follow-up was 9.6 (1.4–30.9) mo.[1] Efficacy outcomes are summarized in Table 2.[1,4]

Table 2. EVER-132-003: Efficacy Outcomes in the Cervical Cancer Cohort[1,4]

Efficacy Outcomes		Full Analysis Set (N=40)	Prior Immunotherapy Subgroup (n=27)
ORR (confirmed CR + PR), n (%); 95% CI		17 (43); 27–59	13 (48); 29–68
DCR (confirmed CR + PR, and SD), n (%); 95% CI		34 (85); 70–94	26 (96); 81 to >99
CBR (confirmed CR + PR + SD ≥6 mo), n (%); 95% CI		22 (55); 39–71	16 (59); 39–78
Best overall response, n (%)	Confirmed CR	1 (3)	1 (4)
	Confirmed PR	16 (40)	12 (44)
	SD	17 (43)	13 (48)
	SD ≥6 mo	5 (13)	3 (11)
	PD	5 (13)	0
	Not evaluable[a]	1 (3)	1 (4)
DOR, median (95% CI), mo		9.2 (4.6–11.7)	9.5 (7–11.7)
PFS	Number of events, n (%)	32 (80)	21 (78)
	Median (95% CI), mo	7.1 (4.2–8.4)	8.3 (4.2–11.8)
	6-mo rate, % (95% CI)	51 (35–66)	62 (41–78)
	12-mo rate, % (95% CI)	20 (8–36)	27 (11–47)
OS	Number of events, n (%)	19 (48)	12 (44)
	Median (95% CI), mo	16.5 (13.4–NE)	17.2 (13.4–NE)
	12-mo rate, % (95% CI)	71 (54–83)	79 (57–91)
	24-mo rate, % (95% CI)	38 (19–57)	37 (15–60)

Abbreviations: NE=not estimable; PD=progressive disease.
[a]One patient died on Day 43 without a post-baseline tumor assessment and could not be evaluated for response.

Safety[1]

All patients experienced ≥1 TEAE (Table 3). The most common any-grade TEAEs that occurred in ≥50% of patients were anemia (n=38 [95%]), leukopenia (n=33 [83%]), alopecia (n=28 [70%]), vomiting (n=25 [63%], neutropenia (n=23 [58%], diarrhea (n=22 [55%], fatigue (n=21 [53%]), and nausea (n=20 [50%]). The most frequently reported Grade ≥3 TEAEs were neutropenia (n=17 [43%]), leukopenia (n=15 [38%]), and anemia (n=8 [20%]). No TEAEs led to death.

Table 3. EVER-132-003: Safety Outcomes in the Cervical Cancer Cohort[1]

Safety Outcomes, n (%)	Full Analysis Set (N=40)
Any-grade TEAEs	40 (100)
Related to SG	40 (100)
Grade ≥3 TEAEs	25 (63)
Related to SG	25 (63)
Serious TEAEs	15 (38)
Related to SG	12 (30)
TEAEs that led to SG interruption	29 (73)
TEAEs that led to SG dose reduction	8 (20)

Safety Outcomes, n (%)	Full Analysis Set (N=40)
TEAEs that led to SG discontinuation	3 (8)
Related to SG	2 (5)[a]

[a]Infection related to SG (n=1) and thrombocytopenia associated with SG (n=1).
Note: The analysis of adverse events included events that occurred after SG initiation through 30 d after the last dose. Grades of severity were defined by the National Cancer Institute Common Terminology Criteria for Adverse Events v5.0.

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

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 cervical cancer, who had relapsed after or were refractory to ≥1 prior therapy for metastatic disease.

One patient with cervical cancer was included in the study and received SG 10 mg/kg IV on Days 1 and 8 of a 21-d treatment cycle.

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

Efficacy and safety

The patient with cervical cancer achieved SD. Additional efficacy endpoints were not evaluated due to the small sample size.

Safety data specific to the patient with cervical cancer were not reported.

Case Report

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. Additionally, 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.[5]

SG + tislelizumab in a patient with metastatic cervical cancer[3]

A 73-y-old female with stage IIIC1r cervical SCC achieved a CR, according to RECIST v1.1, after initial treatment with definitive concurrent chemoradiotherapy. She subsequently developed recurrence, with pulmonary and mediastinal lymph node metastases detected and achieved a second CR with paclitaxel, carboplatin, and bevacizumab, followed by bevacizumab maintenance; treatment was then stopped due to patient request. Elevated SCCA levels (15.2 ng/mL) were noted and a subsequent PET/CT revealed multifocal recurrence involving the cervical remnant, peritoneal carcinomatosis, and para-aortoiliac lymphadenopathy. Immunohistochemistry showed trophoblast cell surface antigen 2 overexpression, a PD-L1 combined positive score of 3, and human epidermal growth factor receptor 2-negative disease.

Second-line treatment with SG (10 mg/kg on Days 1 and 8) + tislelizumab (200 mg on Day 1) every 3 wk was initiated. The patient developed afebrile Grade 4 neutropenia on Day 12 after Cycle 1, requiring hospitalization and short-acting G-CSF 200 mcg daily for 6 d until leukocyte and neutrophil counts returned to normal. Cycle 2 was delayed by 1 d, and

treatment was resumed without dose reduction. Prophylactic G-CSF was administered in subsequent cycles (short-acting G-CSF daily for 3 consecutive days starting on Day 4 of each 21-d cycle and a single long-acting dose of G-CSF on Day 8 after SG administration); no further Grade ≥3 neutropenia occurred, and treatment continued as scheduled. Grade 1 hypothyroidism also occurred during treatment and was successfully managed with levothyroxine. A PR was confirmed after Cycle 3, with a 70.3% reduction in target lesions and a reduction in SCCA levels to 2.48 ng/mL. Best overall response occurred after Cycle 6, with an 88.1% reduction in target lesions and a further reduction in SCCA to 2.1 ng/mL. After Cycle 6, the patient elected to permanently discontinue SG and received 6 additional cycles of tislelizumab as monotherapy. After disease progression, she discontinued treatment with tislelizumab and was referred for brachytherapy. Her overall PFS was 9 mo, and she had an OS of 13 mo that was ongoing at the last follow-up.

References

1. An J, Li G, Zhang Y, et al. Sacituzumab govitecan in Chinese patients with recurrent/metastatic cervical cancer: results from the phase 2 EVER-132-003 basket study (NCT05119907). *Gynecologic Oncology.* 2025;202:33-40.
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. Li H, Wu M, Xing Y, Li J, Lin Z, Wang D. Sacituzumab govitecan combined with tislelizumab as second-line therapy for recurrent or metastatic cervical cancer: a case report and literature review. *BMC Womans Health.* 2026;26(1):284.
4. An J, Li G, Zhang Y, et al. Sacituzumab govitecan in Chinese patients with recurrent/metastatic cervical cancer: results from the phase 2 EVER-132-003 basket study (NCT05119907). [Supplement]. *Gynecologic Oncology.* 2025;202:33-40.
5. Nissen T, Wynn R. The clinical case report: a review of its merits and limitations. *BMC research notes.* 2014;7:264.

Abbreviations

CBR=clinical benefit rate
CR=complete response
DCR=disease control rate
DOR=duration of response
ECOG PS=Eastern Cooperative Oncology Group Performance Status
G-CSF=granulocyte colony-stimulating factor
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
SCCA=serum squamous cell carcinoma antigen
SCC=squamous cell carcinoma
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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