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Trodelvy® (sacituzumab govitecan-hziy) Use After Enfortumab Vedotin in mUC

This document is in response to your request for information regarding the use of Trodelvy® (sacituzumab govitecan-hziy [SG]) after enfortumab vedotin (EV) treatment in metastatic urothelial cancer (mUC).

Gilead Sciences is not the manufacturer of EV and therefore cannot provide information regarding the use of this product. Please contact the appropriate manufacturer for information.

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Trodelvy is not indicated for use in patients with mUC. 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: SG Use After EV in Patients With mUC

TROPiCS-04, an open-label, randomized, phase 3 study, compared outcomes with SG vs single-agent TPC in patients with locally advanced and unresectable or mUC who progressed after prior PLT-based and CPI therapies (N=38). In the SG and TPC groups, 24 (7%) and 15 patients (4%), respectively, previously received EV.[1]

- In a prespecified subgroup analysis that compared treatment with SG vs TPC, prior treatment with EV resulted in the following: median (95% CI) OS: 10.2 (6.4–13.6) months vs 8 (3.4–13.7) months, respectively (HR, 0.75; 95% CI: 0.37–1.5).
- Overall, the most common (≥10%) Grade ≥3 TRAEs in the SG vs TPC groups were neutropenia (35% vs 10%, respectively), diarrhea (15% vs 3%), anemia (13% vs 7%), fatigue (12% vs 5%), febrile neutropenia (12% vs 4%), and leukopenia (10% vs 3%).
- In the SG and TPC groups, TRAEs led to dose interruption in 52% and 18% of patients and to dose reduction in 37% and 26% of patients, respectively; 11% and 12% of patients had TRAEs that led to treatment discontinuation.

TROPHY-U-01 is an ongoing, multicohort, global, phase 2, open-label study evaluating the safety and efficacy of SG in patients with unresectable locally advanced/mUC.[2]

- In Cohort 1 (N=113; patients with mUC after progression on PLT-based chemotherapy ± CPIs), the ORR in the subgroup of 10 patients who had previously received EV was 30%, and 4 patients had a BOR of SD. In the overall study population, the most common Grade ≥3 TRAEs were neutropenia (35%), leukopenia (18%), and anemia (14%). Due to TRAEs, SG doses were interrupted in 47% discontinued in 7% of patients and the SG dose was reduced in 40%.[3]
- In Cohort 2 (N=38; patients with mUC who were ineligible for PLT-based chemotherapy and progressed after previous CPIs in the metastatic setting), 7 patients received prior

EV or enfortumab, and to date, 4 patients (57%) have had SD, 1 (3%) was not evaluable, and 2 (29%) were not assessed. Grade ≥3 serious TRAEs included the following: diarrhea, n=4; colitis, n=3; sepsis, n=2 (1 patient was neutropenic); febrile neutropenia, n=2. TEAEs led to treatment interruption, dose reduction, and discontinuation in 61%, 37%, and 21% of patients, respectively.[4]

RWE: SG Use After EV in Patients With mUC

Several retrospective observational studies have evaluated the safety and efficacy of SG after EV in patients with locally advanced or mUC. Results from studies that included >10 patients are summarized below.[5-10]

Clinical Data: SG Use After EV in Patients With mUC

TROPiCS-04 Study of SG vs TPC in Patients With mUC

Study design and demographics[1,11]

TROPiCS-04, an open-label, global, multicenter, randomized, phase 3 study, compared the efficacy and safety of SG (n=355; 10 mg/kg IV on Days 1 and 8 of a 21-day cycle) vs single-agent chemotherapy TPC (n=356; ie, paclitaxel, docetaxel, or vinflunine) in patients with locally advanced and unresectable or mUC who progressed after prior PLT-based and CPI therapies. Patients who received prior EV were eligible for the study, as were patients who were ineligible for or unable to tolerate EV.

In the SG and TPC groups, 24 (7%) and 15 patients (4%), respectively, previously received EV; 93% and 90% had mUC at enrollment. At the data cutoff of March 8, 2024, the median treatment duration was 3 months of SG and 2.1 months of TPC, and the median (range) follow-up was 9.2 (0–33.7) months.

Results

Overall, the primary endpoint was not met (ie, improved OS with SG vs TPC); median (95% CI) OS in the SG and TPC groups was 10.3 (9.1–11.8) months and 9 (7.5–9.7) months, respectively (*P*=0.087). In a prespecified subgroup analysis of treatment with SG vs TPC, prior treatment with EV resulted in the following: median (95% CI) OS: 10.2 (6.4–13.6) months vs 8 (3.4–13.7) months, respectively (HR: 0.75; 95% CI: 0.37–1.5).[1]

Safety outcomes according to prior EV use were not reported. Overall, most patients experienced any-grade TEAEs: SG, 99%; TPC, 95%. Grade ≥3 TEAEs occurred more frequently in the SG group than in the TPC group (77% vs 51%, respectively). The most common (≥10%) Grade ≥3 TRAEs in the SG vs TPC groups were neutropenia (35% vs 10%, respectively); diarrhea (15% vs 3%); anemia (13% vs 7%); fatigue (12% vs 5%); febrile neutropenia (12% vs 4%); and leukopenia (10% vs 3%). In the SG and TPC groups, TRAEs led to dose interruption in 52% and 18% of patients, respectively, and to dose reduction in 37% and 26% of patients; 11% and 12% of patients had TRAEs that led to treatment discontinuation, and 4% and 1% had TRAEs that led to death.[1] In the SG and TPC groups, G-CSF was administered for primary prophylaxis in 21% and 22%, respectively, and for secondary prophylaxis in 15% and 4% of patients; 30% and 10% received therapeutic G-CSF.[11]

TROPHY-U-01 Study in mUC

TROPHY-U-01, an ongoing, global, open-label, multicohort, phase 2 study (NCT03547973), is investigating the safety and efficacy of SG in approximately 827 patients with unresectable and locally advanced or mUC.[2] Results from Cohorts 1 and 2 are summarized.

Cohort 1

Cohort 1 investigated the efficacy and safety of SG 10 mg/kg IV on Days 1 and 8 of a 21-day treatment cycle in 113 patients with mUC after progression on PLT-based chemotherapy ± CPIs (ie, PD-[L]1 therapy). After a median (range) follow-up of 10.5 (0.3–40.9) months, the ORR in the subgroup of 10 patients who had previously received EV was 30%, and 4 patients had a BOR of SD. A comparison of treatment efficacy by prior EV treatment can be found in Table 1.[3]

Table 1. TROPHY-U-01 Cohort 1: Efficacy by Prior EV Treatment[12]

Variable		Prior EV (n=10)	No Prior EV (n=103)
BOR, n (%)	CR	0	6 (6)
	PR	3 (30)	23 (22)
	SD	4 (40)	33 (32)
	SD ≥6 months	1 (10)	10 (10)
	PD	3 (30)	19 (18)
	Not evaluable	0	8 (8)
	Not assessed	0	14 (14)
ORR, n (%); 95% CI		3 (30); 6.7–65.2	29 (28); 19.7–37.9
CBR (CR + PR + SD for ≥6 months), n (%); 95% CI		4 (40); 12.2–73.8	39 (38); 28.5–48

In the overall study population, Grade ≥3 TRAEs occurred in 65% of patients; neutropenia (35%), leukopenia (18%), and anemia (14%) were the most frequently reported TRAEs. SG dose was interrupted in 47%, reduced in 40%, and discontinued in 7% of patients due to TRAEs. One patient died due to neutropenia-related sepsis. G-CSF was given as primary prophylaxis in 22% of patients and as secondary prophylaxis in 23% of patients.[3]

Cohort 2[4]

Cohort 2 is evaluating the efficacy and safety of SG mg/kg IV on Days 1 and 8 of a 21-day treatment cycle in 38 patients with mUC who were ineligible for PLT-based chemotherapy and progressed or had a recurrence after previous CPIs in the metastatic setting. Patients in Cohort 2 received a median (range) of 6 (1–27) cycles and 11.5 (1–54) doses of SG. The median (range) duration of treatment and follow-up were 4.4 (0–19) months and 9.3 (0.5–30.6) months, respectively.

Of the 38 patients included in the analysis, 7 patients received prior treatment with EV (n=6) or enfortumab (n=1). To date, 4 patients (57%) had SD, 1 (3%) was not evaluable, and 2 (29%) were not assessed.

Safety data were not provided according to prior treatment. In the overall study population, 87% had Grade ≥3 TEAEs and 95% of patients experienced ≥1 TRAE; Grade ≥3 serious TRAEs included the following: diarrhea, n=4; colitis, n=3; sepsis, n=2 (1 patient had neutropenia); febrile neutropenia, n=2. No TEAEs led to death; TEAEs led to treatment interruption, dose reduction, and discontinuation in 61%, 37%, and 21% of patients, respectively. G-CSF was administered to 7 patients (18%) for primary prophylaxis and 10 (26%) for secondary prophylaxis.

RWE: SG Use After EV in Patients With mUC

Longitudinal Safety Study of SG in mUC

Study design and demographics[8]

A retrospective, longitudinal, observational cohort study evaluated the safety of SG using data from a longitudinal database in the US (Flatiron Health; study period, January 2011–October 2023; treatment initiation or index period, December 2019–July 2023) in a mostly community-based setting and included 220 patients with locally advanced/mUC.

The median (IQR) age of the patients at the index date was 71 (65–76) years, 73% were male, 29% had an ECOG PS 2 to 3, and 16% and 40% had Stage 0 to 2 and Stage 3 to 4 disease at locally advanced/mUC diagnosis, respectively (45% had unknown/not documented staging). The primary sites of disease were as follows: bladder, 73%; renal pelvis, 16%; ureter, 10%; and urethra, <1%. Most patients (95%) received SG as monotherapy at 2L+: 1L, n=10; 2L/3L, n=108 (49%); 4L+, n=102 (46%). Most patients received EV in the line immediately prior to SG: EV monotherapy, 67% before 2L/3L SG and 60% before 4L+ SG; EV combination therapy, 4% before 2L/3L SG and 6% before 4L+ SG. Prior to the SG-containing regimen, 11% and 3% received PD-L1 monotherapy and PD-L1 + chemotherapy.

Results

Of the 220 patients, the most common AEs of interest were diarrhea (50%; n=110), neutropenia (35%; n=77), and nausea (35%; n=76); additional AEs are shown in Table 2.[8]

Table 2. Prespecified AEs of Interest Overall and by ≥2L-SG-Containing Lines[a] (Parikh et al)[8]

AE Incidence, n (%)	Overall (N=220)	2L/3L (n=109)	4L+ (n=107)
Diarrhea	110 (50)	61 (56)	45 (42)
Neutropenia	77 (35)	32 (29)	42 (39)
Febrile neutropenia[b]	18 (8)	6 (6)	11 (10)
Infection secondary to neutropenia[b,c]	9 (4)	4 (4)	5 (5)
Nausea	76 (35)	37 (34)	32 (30)
Fatigue	52 (24)	22 (20)	26 (24)
Vomiting	41 (19)	19 (17)	18 (17)
Anemia	36 (16)	26 (24)	9 (8)
Urinary tract infection	34 (15)	14 (13)	18 (17)
Sepsis	25 (11)	14 (13)	12 (11)
Stomatitis	21 (10)	15 (14)	6 (6)
Infusion-related reaction	1 (<1)	0	1 (<1)

[a]SG could have been administered in multiple lines.
[b]The prevalence of these AEs was assessed, as no baseline status was available.
[c]Included any infection that occurred during treatment lines containing SG.

Of the patients who received G-CSF as primary prophylaxis, 35% did not experience neutropenia and 18% experienced any neutropenia. Additional G-CSF administration data are shown in Table 3.[8] In an earlier dataset, 1 patient (4.5%) who received primary prophylaxis with G-CSF developed Grade ≥3 neutropenia.[13]

Table 3. G-CSF Use by Occurrence of Neutropenia and Severity[a] (Parikh et al)[8]

G-CSF Use, n (%)	Overall (N=220)		Neutropenia Severity (n=79)	
	No Neutropenia (n=141)	Any Neutropenia (n=79)	Severe Neutropenia (n=69)	Non-Severe Neutropenia (n=10)
Primary prophylaxis[b]	50 (35)	14 (18)	11 (16)	3 (30)
Secondary prophylaxis[c]	0	29 (37)	28 (41)	1 (10)
Therapeutic[d]	0	36 (46)	30 (43)	6 (60)

[a]Severity of neutropenia was determined by proxy using the incidence of the following events: febrile neutropenia, infections secondary to neutropenia, death in patients who experienced neutropenia (unknown cause of death), sepsis, hospitalization, discontinuation or pausing of therapy, and change of dose or therapy schedule.
[b]Defined as administration prior to neutropenia onset and ≤7 days of the index date.
[c]Defined as administration prior to the end of the index treatment and after the neutropenia resolution date.
[d]Defined as administration at or after the onset of neutropenia and prior to the resolution date of neutropenia, if applicable, or at the end of the index treatment.
Note: Due to the small number of patients with non-severe neutropenia, no definitive conclusions can be made.

Hospitalization due to AEs occurred in 62 patients (28%). The reason for SG discontinuation was available in 141 patients (64%), including 106 (75%) who discontinued due to disease progression and 19 (13%) who discontinued due to AEs or toxicities. Of the 19 patients who discontinued due to AEs or toxicities, 3 patients (16%) each discontinued SG due to neutropenia and fatigue. Seven patients (3%) discontinued SG due to one of the prespecified AEs shown in Table 2.[8]

Retrospective UNITE Study: Response Biomarkers to SG After EV in Heavily Pretreated Patients With aUC[9]

Study design and demographics

An analysis of patients from UNITE, a retrospective study of heavily pretreated patients in the US with aUC, was conducted to determine effectiveness of SG in 90 patients previously treated with EV and whether molecular biomarkers were associated with ORR, OS, and PFS. Overall, the median age was 68 years; 72% were male; 81% were Caucasian; 74% had an ECOG PS score of 0 or 1, and 18% had a score ≥2; 63% had received <4 prior lines in the metastatic setting; the primary tumor location was the bladder in 67% and the upper tract in 28%; 72% had visceral metastases, including 28% with liver metastases. Of the 90 patients in the analysis, 84 patients (93%) received SG after previous EV treatment, and 78 patients had next-generation sequencing data available.

Results

After a median (95% CI) follow-up duration of 8.7 (8.1–NR) months, the median (95% CI) OS and PFS were 6 (5.1–9.7) months and 3.5 (2.5–4.1) months, respectively, and the ORR was 23% (16/71). Of the 49 patients who achieved CR, PR, or SD with EV, the median (95% CI) OS and PFS from the start of SG were 7.1 (5.5–17.5) months and 3.7 (3–5.1) months, respectively, and the ORR was 24% (12/49). Of the 14 patients with primary PD after EV, the median (95% CI) OS and PFS from the start of SG were 5.3 (3.2–NR) months and 2 (1.4–NR) months, respectively, and the ORR was 14% (2/14). In a multivariable analysis, the presence of alterations in the composite *TP53/MDM2* biomarker (vs wild type) was associated with prolonged OS (HR, 0.36; 95% CI: 0.15–0.84; *P*=0.02), but not PFS (HR, 0.81; 95% CI: 0.4–1.64; *P*=0.55). The ORR was significantly higher among those with an alteration for *MTAP* (n=8) than among those without one: 50% vs 19%, respectively (*P*=0.05); none of the other biomarkers significantly impacted ORRs to SG.

Single-Center Retrospective Study of SG After EV in mUC[10]

Study design and demographics

A single-site retrospective analysis in the US evaluated clinical outcomes in 82 patients with mUC treated with SG after EV between April 2021 and November 2023. Patients had received a median (range) of 3 (1–8) prior lines of treatment, with 56 patients (68%) receiving SG directly after EV. Most patients (88%) received prior EV as a single agent, and 10% and 2% of patients received EV + pembrolizumab or EV + investigational agent in the line prior to SG, respectively. CR/PR, SD, and PD were reported in 40 (49%), 20 (24%) and 22 (27%) of patients as the BOR to EV.

The median age (range) of patients was 71 (47–83) years, 70% were male, 19% had an ECOG PS ≥2, and 37% had upper tract primary UC. Lung, bone, liver and brain metastases were present in 67%, 62%, 50%, and 13% of patients, respectively.

Results

The ORR was 11% (95% CI: 5.2–20%); 9 patients (11%) achieved PR, and none had a CR. SD was reported in 16 patients (20%), and the DCR was 31% (95% CI: 21.1–42.1%). The median (95% CI) PFS and OS were 2.1 (1.9–2.5) months and 6 (4.5–6.9) months, respectively.

Administration of SG directly after EV was associated with an improved ORR of 13% vs 8% and a DCR of 40% vs 12% (*P*=0.024). It was also associated with improved PFS (HR, 0.46; 95% CI: 0.24–0.88; *P*=0.019), but not improved OS (HR, 0.59; 95% CI: 0.35–1.01; *P*=0.053).

Prior response to EV did not determine patient outcomes on SG. In a multivariable analysis, liver metastases were associated with worse PFS rates (HR, 2.17; 95% CI: 1.32–3.56; *P*=0.002), and an ECOG PS of 2 or 3 was associated with a worse OS rate (HR, 1.63; 95% CI: 0.9–2.97; *P*=0.11).

When SG was administered at reduced doses in 22 patients (27%), lower doses were not associated with a decreased response rate (*P*=0.8), PFS (*P*=0.7) or OS (*P*=0.9). Prophylactic G-CSF was used in 57 patients (70%). Grade 3 and 4 neutropenia, anemia, and thrombocytopenia were reported in 36%, 36%, and 4% of patients, respectively.

Single-Center Retrospective Study of SG After EV in EV Responders and Non-Responders With aUC

Study design and demographics[5]

In a single-site retrospective analysis in the US that evaluated clinical outcomes in 23 patients with aUC treated with SG after EV, the ORRs of patients who did and did not have a response to EV and subgroups of interest were compared. SG was the next line of therapy following EV in 16 patients (69.6%); 6 patients (26.1%) had received 1 other therapy, and 1 patient (4.3%) had received 2 other therapies between EV and SG. SG was given as 3L treatment in 5 patients (21.7%) and as ≥4L treatment in 18 patients (78.3%).

The median (range) age of patients was 71 (63–80) years, 10 (44%) were female, and 19 (83%) were White. Four patients (17%) had variant histology. Eleven patients (48%) had upper tract UC, 11 (48%) had lower tract UC, and 1 patient (4%) had UC in both the upper

and lower tracts. Eleven patients (48%) had metastatic disease in the liver, and 4 patients (17%) had metastatic disease in bone. Most patients (97%) had an ECOG PS ≤2.

Results

In the overall cohort, the ORR was 17.4%. No difference in ORR was observed among all subgroups, including patients with impaired renal function, upper tract UC, variant histology, and liver and bone metastasis.[5]

The median PFS for SG in EV responders was 2.04 (95% CI: 1.35–3.88) months (vs non-responders HR, 0.31; 95% CI: 0.12–0.83; *P*=0.02), and the median OS for SG in EV responders was 5.36 (95% CI: 3.15–NR) months (vs non-responders HR, 0.82; 95% CI: 0.27–2.46; *P*=0.7). No difference was observed in PFS or OS between the following subgroups: upper vs lower tract primary tumor, presence vs absence of liver or bone metastasis at SG initiation, variant histology vs pure UC, and eGFR ≥30 mL/min vs <30 mL/min.[5]

Treatment was discontinued in 16 patients (69.6%) due to PD and in 7 patients (30.4%) due to toxicity/functional decline.[6]

Single-Center Retrospective Study of SG After EV in aUC[7]

Study design and demographics

In a single-site retrospective analysis in the US that evaluated clinical outcomes in 18 patients with aUC treated with SG after EV between November 2020 and December 2022, 14 patients received SG as the next line of therapy following EV, and 4 patients received other therapies between EV and SG. Eight patients (44%) were female, 15 (83%) were Caucasian, and 3 (17%) were African American, with a median (range) age of 71 (46–81) years. Three patients (17%) had disease in the lymph node only; 8 (44%) had metastases in the lungs, 8 (44%) had metastases in the liver, and 2 (11%) had metastases in bone.

Results

The median (range) number of EV cycles was 6 (1–12) in 18 patients, and the PFS with EV was 6.9 months. The BORs with EV were as follows: CR, 1 patient (5.5%); PR, 10 (55.6%); SD, 2 (11.1%); PD, 5 (27.8%).

Patients received SG as ≥3L therapy. After EV therapy, in 14/18 patients received prophylactic growth factor support, and their dose of SG was also reduced in Cycle 1.

The median (range) number of SG cycles was 2.8 (0.5–9.5). Of the 13 patients with evaluable responses, the PFS with SG was 2.5 months. PR and SD were reported in 3 patients each (each, 23.1%), for a CBR (ie, CR + PR + SD) of 46.2%. Seven patients (53.8%) had PD.

In the overall population, SG was discontinued in 8 patients due to PD and functional decline and in 6 patients due to clinical progression or toxicity. One patient in the SG group had PD during Cycle 2 but received 3 additional cycles due to therapeutic benefit. One patient (5.6%) discontinued SG due to intolerance and had a durable response for 3.7 months off treatment. One patient (5.6%) continued SG after 8 cycles with PR, and 1 patient (5.6%) was continuing SG and was pending scans at the time of publication.

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Abbreviations

1/2/3/4L=first-/second-/third-/fourth-line
AE=adverse event
aUC=advanced urothelial carcinoma
BOR=best overall response
CBR=clinical benefit rate
CPI=checkpoint inhibitor
CR=complete response
DCR=disease control rate
ECOG PS=Eastern Cooperative Oncology Group Performance Status
EV=enfortumab vedotin
G-CSF=granulocyte colony stimulating factor
HR=hazard ratio
MDM2=mouse double minute 2
MTAP=methylthioadenosine phosphorylase
mUC=metastatic urothelial cancer
NR=not reached
ORR=objective response rate
OS=overall survival
PD=progressive disease
PD-(L)1=programmed death (ligand)-1
PFS=progression-free survival
PLT=platinum
PR=partial response
RWE=real-world evidence
SD=stable disease
SG=sacituzumab govitecan-hziy
TEAE=treatment-emergent adverse event
TP53=tumor protein p53
TPC=treatment of physician's choice
TRAE=treatment-related adverse event
UC=urothelial cancer
UNITE=Urothelial Cancer Network to Investigate Therapeutic Experiences

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.

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For any additional questions, please contact Trodelvy Medical Information at:

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