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) Incidence of Treatment-Related Neutropenia and Growth Factor Support: mUC Studies

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]), incidence of treatment-related neutropenia, and the use of growth factors in metastatic urothelial cancer (mUC).

Gilead continually assesses safety data from all sources for unidentified drug reactions and updates the product label information accordingly to reflect the safety profile of SG. Because case reports of potential adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. For this reason, Gilead does not provide information from post-marketing spontaneous reports.

This document includes content from, or references to, clinical practice guidelines, and inclusion should not be interpreted as a treatment recommendation or an endorsement of the guidelines by Gilead Sciences, Inc.

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 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

Incidence of SG-Related Neutropenia and Growth Factor Use in mUC Clinical Studies

TROPiCS-04, a global, multicenter, open-label, randomized, controlled, phase 3 study, evaluated the efficacy and safety of SG vs chemo TPC in patients with LA unresectable or mUC who progressed after prior PLT-based and checkpoint inhibitor CPI-based therapy in the advanced setting.[1,2]

- Grade ≥3 neutropenia occurred in 35% of patients in the SG group and in 10% in the TPC group; Grade ≥3 febrile neutropenia occurred in 12% of patients treated with SG and in 4% of patients treated with TPC. Sixteen patients treated with SG died due to neutropenia-related infections (7 events were considered treatment related); of these patients, 9 had received therapeutic G-CSF and 2 had received G-CSF as primary prophylaxis.

- In the SG and TPC groups, G-CSF was used as primary prophylaxis in 21% and 22% of patients; as secondary prophylaxis in 15% and 4%; and therapeutically in 30% and 10%, respectively.

TROPHY-U-01, a global, multicohort, open-label, phase 2 study, is investigating the efficacy and safety of SG in patients with unresectable LA or mUC.[3-6]

- In Cohorts 1 and 2 of this study, Grade ≥3 neutropenia occurred in 35% and 34% of patients treated with SG as monotherapy, respectively, and febrile neutropenia occurred in 10% and 8% of patients.[4,6,7] In Cohort 3, Grade ≥3 neutropenia and febrile neutropenia occurred in 37% and 10% of patients treated with SG + pembro.[5] One treatment-related death occurred due to febrile neutropenia-related sepsis in Cohort 1.[4]
- In Cohort 1, 22% of patients received G-CSF as primary prophylaxis and 23% as secondary prophylaxis. In Cohort 2, G-CSF was used as prophylaxis and treatment in 18% and 26% of SG-treated patients, respectively. In patients treated with SG + pembro in Cohort 3, G-CSF was used as prophylaxis and treatment in 22% and 20% of patients, respectively.[4-6]

In the phase 1/2 IMMU-132-01 basket study in patients with metastatic epithelial cancers, including mUC (n=45), SG-related Grade ≥3 neutropenia/neutrophil count decrease was reported in 38% of patients.[8,9]

- Growth factor support (filgrastim, pegfilgrastim, or G-CSF) was permitted; however, incidence of its use was not reported within the mUC cohort.

Incidence of SG-Related Neutropenia and Growth Factor Use in Real-World Studies

A retrospective, observational study evaluated the safety of SG in 220 patients with LA or mUC.[10]

- Neutropenia occurred in 77 patients (35%) in the overall cohort. Neutropenia rates were numerically higher with SG in 4L and 5L+ settings vs SG in earlier lines of therapy.
- Overall, 56 patients received treatment for neutropenia; 54 had their treatment held, 42 had dose/schedule changes, and 3 discontinued SG. No treatment-related deaths attributed to neutropenia were identified.
- During SG treatment, 47% of patients received G-CSF at any time. Sixty-four patients (29%) received G-CSF as primary prophylaxis, 29 (13%) received G-CSF as secondary prophylaxis, and 36 (16%) received G-CSF therapeutically.
- Patients who received G-CSF as primary prophylaxis had lower rates of severe neutropenia.

A retrospective, single-center study evaluated the effectiveness and safety of SG in 82 patients with mUC who had received ≥1 dose of SG following prior exposure to EV.[11]

- Grade 3 or 4 neutropenia occurred in 36% of patients. Three patients (4%) required dose reductions of SG due to febrile neutropenia, and 1 patient with Grade 3 neutropenia and pyelonephritis discontinued treatment. No treatment-related deaths occurred.
- Primary G-CSF prophylaxis was administered in 57 patients (70%) and was not associated with a reduced risk of neutropenia. Grade 3 or 4 neutropenia occurred despite prophylactic G-CSF, initiation of SG at a reduced dose, or both.

A US retrospective study evaluated SG after EV monotherapy use in 18 patients with advanced UC. Fourteen patients required a dose reduction in Cycle 1 and prophylactic growth factor support.[12]

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

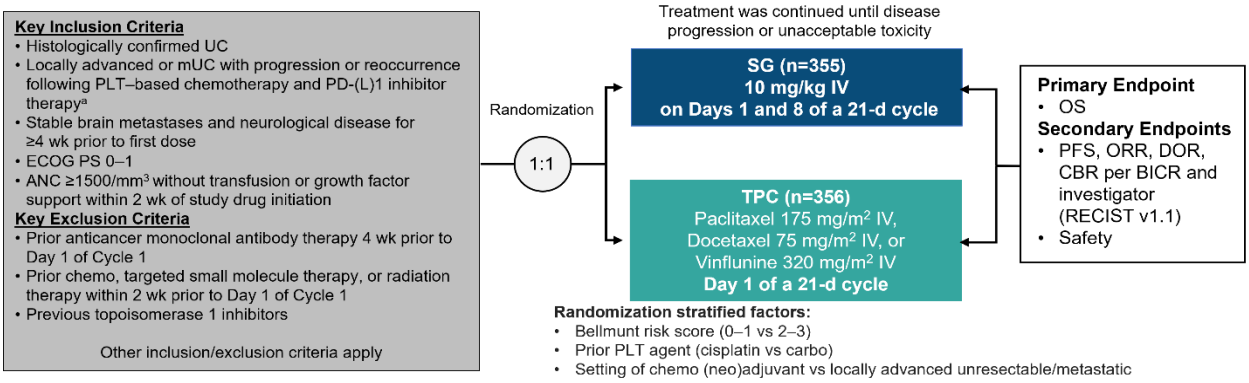
Incidence of SG-Related Neutropenia and Use of Growth Factors in mUC Clinical Studies

TROPiCS-04 Study in LA or mUC

Study design

TROPiCS-04 was a global, multicenter, open-label, randomized, controlled, phase 3 study that evaluated the efficacy and safety of SG vs TPC in patients with LA unresectable or mUC who progressed after prior PLT-based and CPI-based therapy in the advanced setting (Figure 1).[1]

Figure 1. TROPiCS-04: Study Design[1,13]



Abbreviations: BICR=blinded independent central review; CBR=clinical benefit rate; ORR=objective response rate; OS=overall survival; PFS=progression-free survival; RECIST=Response Evaluation Criteria in Solid Tumors.
[a]Patients who received prior EV were eligible for the study, as were patients who were ineligible for or unable to tolerate EV.

Neutropenia management with growth factor support[1]

Investigators were encouraged to consider the use of G-CSF as primary prophylaxis for neutropenia, but it was not required per study protocol. AESIs included neutropenia and serious infections secondary to neutropenia.

Safety[1,2]

The incidence of neutropenia and G-CSF use is summarized in Table 1. Neutropenia was the most common TEAE of special interest, and neutropenia and febrile neutropenia were among the most common any-grade and Grade ≥3 TRAEs.

Table 1. TROPiCS-04: Incidence of Neutropenia and Febrile Neutropenia and G-CSF Use (Safety Population)[1,2]

n (%)		SG (n=349)	TPC (n=337)
Neutropenia TEAEs	AESIs	194 (56)	67 (20)
	Any grade	167 (48)	55 (16)
	Grade ≥3	124 (36)	38 (11)

n (%)		SG (n=349)	TPC (n=337)
Febrile neutropenia TEAEs	Any grade	41 (12)	16 (5)
	Grade ≥3	41 (12)	16 (5)
Neutropenia TRAEs[a]	Any grade	166 (48)	51 (15)
	Grade ≥3	122 (35)	35 (10)
Febrile neutropenia TRAEs[a]	Any grade	41 (12)	15 (4)
	Grade ≥3	41 (12)	15 (4)
Serious infections secondary to neutropenia		27 (8)	13 (4)
G-CSF use	Any prophylaxis	128 (37)	87 (26)
	Primary prophylaxis[b]	74 (21)	73 (22)
	Secondary prophylaxis[c]	54 (15)	14 (4)
	Therapeutic[d]	106 (30)	33 (10)

[a]AEs that occurred after the first dose of study drug through 30 d after the last dose of study drug are included.
[b]Defined as G-CSF use on or after Day 1 of Cycle 1 and before the onset of neutropenia.
[c]Defined as G-CSF use after resolution of Grade ≥2 to Grade ≤1 neutropenia or after occurrence of Grade 1 neutropenia and before any subsequent incidence of Grade ≥2 neutropenia.
[d]Defined as G-CSF use during Grade ≥2 neutropenia.
Note: The safety population included all patients who received ≥1 dose of study drug.

The incidence of neutropenia with SG by primary G-CSF prophylaxis is summarized below (Table 2).

Table 2. Incidence of Neutropenia With SG Stratified by G-CSF Use[1,2]

n (%)		With Primary Prophylaxis (n=74)	Without Primary Prophylaxis (n=275)
AESIs	Neutropenia	32 (43)	162 (59)
	Grade ≥3 neutropenia	24 (32)	131 (48)
	Serious secondary infections after first event[a]	1 (1)	22 (8)
Febrile neutropenia		7 (9)	33 (12)
Fatal infection secondary to neutropenia		2 (3)[b,c]	14 (5)

[a]Serious infections secondary to neutropenia were investigator-assessed serious infections occurring on or within 11 d after onset of the AESI of neutropenia.
[b]One patient with a preexisting wound/ulceration died of sepsis; the other patient experienced rapid tumor progression and kidney damage requiring nephrostomy and died of septic shock. Both patients underwent procedures without adequate healing before the next SG dose. In addition, the patient with a preexisting wound/ulceration did not receive prophylactic G-CSF with their last SG dose.
[c]Includes 1 patient with a serious infection occurring 15 d after neutropenia onset, which was outside the AESI-defined window for serious infection secondary to neutropenia.

Infections in the setting of neutropenia resulted in 16 deaths in patients treated with SG (treatment related, n=7; possibly treatment related, n=7; unlikely related, n=1; not related, n=1); 14 deaths occurred within the first mo of treatment. In the TPC group, 4 patients died due to infections in the setting of neutropenia. Of the SG-treated patients who died, 9 had received therapeutic G-CSF and 2 had received G-CSF as primary prophylaxis. Patients who received SG and experienced fatal infections with neutropenia were generally older (81% were aged ≥65 y), 81% had a history of major urinary tract procedure, 56% had prior cystectomy, 50% had prior radiotherapy, and 50% had received ≥3 prior anticancer regimens.[1,2]

TROPHY-U-01 Study in LA or mUC

Study design

TROPHY-U-01 (NCT03547973), an ongoing, global, multicohort, open-label, phase 2 study, is investigating the efficacy and safety of SG in patients with unresectable LA or mUC.[5-7,14]

All patients will receive SG 10 mg/kg IV on Days 1 and 8 of a 21-d cycle (with and without other therapies) until loss of clinical benefit or unacceptable toxicity. Results are currently available for Cohorts 1 through 3.[4-6,15]

Cohort 1 (n=113) included patients whose disease had progressed after previous treatment with PLT-based chemo + CPI therapy. Median (range) follow-up was 10.5 (0.3–40.9) mo.[4,15]

Cohort 2 (n=38) included patients in a 1L metastatic setting who were ineligible for PLT-based chemo and who had progressed after prior CPI monotherapy. Median (range) follow-up was 9.3 (0.5–30.6) mo.[6]

Cohort 3 (n=41) included CPI-naive patients who had progressed after prior PLT-based chemo. Patients were treated with SG + pembro 200 mg on Day 1 of a 21-d cycle. Median follow-up was 14.8 mo (95% CI: 12.6–16.8).[5]

Neutropenia management with growth factor support[3]

Prior to each SG infusion, complete blood counts were obtained, and SG was administered only if ANC was ≥1500/mm^3 and ≥1000/mm^3 on Days 1 and 8, respectively. Use of growth factors was permitted in addition to treatment modifications (dose delay and/or reduction) for patients with febrile neutropenia, Grade ≥3 neutropenia following previous infusions, or for those at high risk of poor neutropenia-related clinical outcomes (ie, prolonged neutropenia, ANC <100/mm^3, febrile neutropenia, and serious infections). Growth factors could be administered prophylactically as clinically indicated.

Cohort 3: neutropenia management in patients treated with SG + pembro[3]

Neutropenia is one of the main AEs associated with both SG and pembro treatment.

Dose reduction was not permitted for pembro; however, suspension of pembro treatment was recommended for repeat episodes of Grade ≥3 neutropenia that occurred despite a 50% reduction of SG and prophylactic growth factor support. Pembro could also be suspended following prolonged (>3 weeks) neutropenia that failed to recover to Grade ≤1, despite growth factor support. If either agent was discontinued due to toxicity, the second agent could be continued until disease progression or toxicity.

Safety

Neutropenia was one of the most common all-grade and Grade ≥3 TRAEs across the three cohorts (Table 3).[4-7,15]

Table 3. TROPHY-U-01: Incidence of Neutropenia and Febrile Neutropenia and G-CSF Use[4-6,15]

n (%)		Cohort 1 SG (N=113)	Cohort 2 SG (N=38)	Cohort 3 SG + Pembro (N=41)
Neutropenia	All Grade	53 (47)	17 (45)	21 (51)
	Grade 3	25 (22)	6 (16)	8 (20)
	Grade 4	14 (12)	7 (18)	7 (17)
Febrile neutropenia	All Grade	11 (10)	3 (8)	4 (10)[a]
	Grade 3	8 (7)	2 (5)	4 (10)[a]
	Grade 4	3 (3)	1 (3)	0
G-CSF use	Prophylaxis	Not reported (22)	17 (44)[b]	9 (22)
	Treatment	Not reported (23)	Not reported	8 (20)

[a]None of these patients received prophylactic G-CSF.
[b]Primary prophylaxis, n=7 (18%); secondary prophylaxis, n=10 (26%).

Cohort 1: safety analysis by UGT1A1

A total of 45, 47, and 14 patients were homozygous for the WT *UGT1A1* allele, heterozygous for the *UGT1A1*28* allele, and homozygous for the *UGT1A1*28* allele, respectively. A safety analysis by *UGT1A1* genotype status demonstrated that the rates of all-grade neutropenia were 44%, 47%, and 57% in patients homozygous for the WT allele, heterozygous, and homozygous for the *UGT1A1*28* allele, respectively.[4]

One treatment-related death occurred due to febrile neutropenia-related sepsis in a 65-y-old male homozygous for the WT *UGT1A1* allele and with mUC, Stage 3 chronic kidney disease, and a history of lung cancer.[4]

IMMU-132-01 Study in Metastatic Epithelial Cancer

A phase 1/2, single-arm, open-label basket study investigated SG 8 to 18 mg/kg IV on Days 1 and 8 of a 21-d cycle in patients with metastatic epithelial cancers, including mUC (n=45), who had relapsed after or were refractory to ≥1 prior therapy for metastatic disease. Patients who received SG 10 mg/kg for mUC were analyzed.[8]

Growth factor support (eg, filgrastim, pegfilgrastim, or G-CSF) was allowed as clinically necessary; however, prophylactic growth factor support was not permitted before Day 1 of Cycle 1.[8] In the mUC cohort, Grade ≥3 neutropenia/neutrophil count decreased was reported in 38% of patients. Incidence of growth factor use was not reported in this cohort.[9]

Incidence of SG-Related Neutropenia and Use of Growth Factors in Real-World Studies

Retrospective, Observational Study in LA or mUC[10]

Study design and patient characteristics

A retrospective, descriptive, observational cohort study evaluated treatment patterns and safety of SG using the Flatiron Health Research Database in 220 patients with LA or mUC (transition cell or urothelial carcinoma) who had ≥3 mo of follow-up data. The primary outcomes were treatment patterns; dose modifications, interruptions and discontinuations; AESIs; and G-CSF use. The exploratory outcome was to describe infections secondary to neutropenia that were absent at diagnosis. Most patients (95%) received SG monotherapy in the index line; 2% received SG + EV, and 3% received SG combined with cisplatin, carbo, a taxane, a PD-(L)1 inhibitor, or erdafitinib. The index line was defined as the first SG-containing treatment line during the index period. See Table 4 below for select baseline demographics and disease characteristics.

Table 4. Select Baseline Demographics and Disease Characteristics[10]

Key Baseline Demographics and Characteristics		Overall (N=220)	1L (n=10)	2L (n=33)	3L (n=75)	4L (n=56)	5L+ (n=46)
Age at index, median (IQR), y		71 (65–76)	70 (65–73)	70 (65–73)	73 (66–77)	71 (65–77)	70 (63–76)
Male, n (%)		161 (73)	9 (90)	23 (70)	54 (72)	40 (71)	35 (76)
Race, n (%) or n	White	152 (69)	6 (60)	27 (82)	55 (73)	33 (59)	31 (67)
	Black/African American	11 (5)	≤7	≤7	≤7	≤7	≤7
	Other	36 (16)	≤7	≤7	10 (13)	11 (20)	10 (22)
	Unknown	21 (10)	≤7	≤7	≤7	≤7	≤7

Key Baseline Demographics and Characteristics		Overall (N=220)	1L (n=10)	2L (n=33)	3L (n=75)	4L (n=56)	5L+ (n=46)
ECOG PS, n (%)	0–1	134 (61)	3 (30)	23 (69)	47 (63)	32 (57)	29 (64)
	≥2	63 (29)	2 (20)	4 (12)	22 (29)	21 (38)	14 (30)
	Unknown	23 (10)	5 (50)	6 (18)	6 (8)	3 (5)	3 (7)

Treatment immediately preceding SG is summarized below (Table 5).

Table 5. Treatment Immediately Prior to SG[10]

Therapy, n (%)	Overall (N=220)[a]	2L (n=33)	3L (n=75)	4L (n=56)	5L+ (n=46)
EV monotherapy	133 (63)	12 (36)	60 (80)	37 (66)	24 (52)
EV combination therapy	10 (5)	1 (3)	3 (4)	3 (5)	3 (7)
PD-(L)1 monotherapy	24 (11)	7 (21)	10 (13)	5 (9)	2 (4)
PD-(L)1 + chemo	7 (3)	3 (9)	1 (1)	0	3 (7)
PLT-based chemo	12 (6)	8 (24)	0	2 (4)	2 (4)
Other[b]	24 (11)	2 (6)	1 (1)	9 (16)	12 (26)

[a]Ten patients who received SG in the 1L setting were not included in this analysis.
[b]Other therapies included targeted therapy (eg, erdafitinib), non-PLT chemo, and investigational agents; 8 patients received docetaxel or paclitaxel, and 29 patients had received >1 prior cytotoxic regimen.

Results

Median (IQR) duration of follow-up from index date to last patient activity was 4.4 mo (2–8.8), and the median (IQR) duration of treatment with SG was 2.3 mo (1–4.9).

Incidence of neutropenia

Neutropenia was among the most frequently occurring AESIs and was reported in 77 patients (35%) in the overall cohort (Table 6).

Table 6. AESIs of Neutropenia: Overall and by SG-Containing Line[10]

AESI,[a] n (%)	Overall (N=220)	1L (n=10)	2L (n=33)	3L (n=76)	4L (n=57)	5L+ (n=50)
Neutropenia	77 (35)	3 (30)	11 (33)	21 (28)	23 (40)	19 (38)
Febrile neutropenia[b]	18 (8)	1 (10)	3 (9)	3 (4)	8 (14)	3 (6)
Infections secondary to neutropenia[b,c]	9 (4)	0	2 (6)	2 (3)	4 (7)	1 (2)

[a]Patients may have received SG in multiple lines.
[b]Febrile neutropenia and infections secondary to neutropenia were assessed as prevalent AEs only, as baseline status was not abstracted. These were assessed only in patients with neutropenia, and their occurrence during the 30-d pre-index period was not assessed.
[c]Included any infections occurring during an SG-containing line.

Overall, 56 patients received treatment for neutropenia. Neutropenia resulted in a treatment hold in 54 patients and a dose or schedule change in 42 patients; 3 patients discontinued SG due to neutropenia. No treatment-related deaths attributed to neutropenia were identified from the abstracted clinical records.

G-CSF use

G-CSF use during SG treatment is summarized below (Table 7).

Table 7. G-CSF Use[10]

n (%)	Any Use During SG Treatment	Primary Prophylaxis[a]	Secondary Prophylaxis[b]	Therapeutic Use[c]
G-CSF use	104 (47)	64 (29)	29 (13)	36 (16)

[a]Use prior to neutropenia onset and within 7 d of index date.
[b]Use prior to end of index treatment and after neutropenia resolution to Grade ≤1.
[c]Use on/after neutropenia onset and prior to date of resolution (if applicable) or end of index treatment.

G-CSF use according to neutropenia status and severity is summarized in Table 8. Patients who received G-CSF as primary prophylaxis had lower rates of severe neutropenia.

Table 8. G-CSF Use Stratified by Incidence of Neutropenia and Severity[10]

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

[a]During the index line of treatment, neutropenia occurred in 79 patients.
Note: Neutropenia severity was not directly captured and was assessed using proxy measures, defined as the occurrence of febrile neutropenia, infections secondary to neutropenia, neutropenia resulting in death, sepsis (≤14 d after neutropenia onset), hospitalization, treatment discontinuation or hold, or dose/treatment schedule change.

Retrospective Study of SG Following EV in mUC[11]

A retrospective, single-center study evaluated the effectiveness and safety of SG in 82 patients with mUC who had received ≥1 dose of SG following prior exposure to EV. The median (range) age was 71 (47–83) y and 57 patients (70%) were male. Sixty-one patients (81%) had an ECOG PS of 0 to 1 and 14 (19%) had an ECOG PS of 2 to 3; ECOG PS was unknown for 7 patients. Most patients (72 [88%]) had received prior EV as monotherapy; 8 (10%) had received EV + pembro, and 2 (2%) had received EV + an investigational agent.

Overall, Grade 3 or 4 neutropenia occurred in 36% of patients (Table 9). Three patients (4%) had dose reductions of SG due to febrile neutropenia, and 1 patient with Grade 3 neutropenia and pyelonephritis discontinued treatment. No treatment-related deaths occurred.

Table 9. Incidence of Neutropenia[11a]

n (%)	Grade 1 or 2	Grade 3	Grade 4
Neutropenia	15 (19)	17 (21)	12 (15)

[a]Data were available for 81 patients.

Primary G-CSF prophylaxis was administered in 57 patients (70%) and was not associated with a reduced risk of neutropenia. Grade 3 or 4 neutropenia occurred despite prophylactic G-CSF, initiation of SG at a reduced dose, or both.

Retrospective Study of SG Following EV in Advanced UC[12]

In a US retrospective study at the Johns Hopkins Greenberg Bladder Cancer Institute, 18 patients with advanced UC were treated with SG after progression on EV monotherapy. The median (range) age was 71 (46–81) y, 10 patients (56%) were male, 15 (83%) were

White or Caucasian, and 3 (17%) were African American. Eight patients (44%) had metastatic disease in the liver, 8 (44%) had metastatic disease in the lungs, 3 (17%) had metastatic disease in the lymph nodes only, and 2 (11%) had metastatic disease in bone.

The median (range) number of SG cycles was 3.8 (1.5–6). Fourteen patients required a dose reduction in Cycle 1 and prophylactic growth factor support.

Clinical Guidelines for Neutropenia Management

For guidance on the management of neutropenia, please refer to NCCN,[16] ASCO,[17] and ESMO[18] Guidelines.

References

1. Powles T, Tagawa S, Vulsteke C, et al. Sacituzumab govitecan in advanced urothelial carcinoma: TROPiCS-04, a phase III randomized trial. *Annals of Oncology.* 2025;36(5):561-571.
2. Powles T, Tagawa S, Vulsteke C, et al. Sacituzumab govitecan in advanced urothelial carcinoma: TROPiCS-04, a phase III randomized trial [Supplementary Appendix]. *Annals of Oncology.* 2025;36(5):561-571.
3. Tagawa ST, Balar AV, Petrylak DP, et al. TROPHY-U-01: a phase II open-label study of sacituzumab govitecan in patients with metastatic urothelial carcinoma progressing after platinum-based chemotherapy and checkpoint inhibitors. *J Clin Oncol.* 2021;39(22):2474-2485.
4. Loriot Y, Petrylak DP, Kalebasty AR, et al. TROPHY-U-01, a phase II open-label study of sacituzumab govitecan in patients with metastatic urothelial carcinoma progressing after platinum-based chemotherapy and checkpoint inhibitors: updated safety and efficacy outcomes. *Ann Oncol.* 2024;35(4):392-401.
5. Grivas P, Pouessel D, Park CH, et al. Sacituzumab govitecan in combination with pembrolizumab for patients with netastatic urothelial cancer that progressed after platinum-based chemotherapy: TROPHY-U-01 Cohort 3. *J Clin Oncol.* 2024;JCO2202835.
6. Petrylak DP, Tagawa ST, Jain RK, et al. TROPHY-U-01 cohort 2: a phase II study of sacituzumab govitecan in cisplatin-ineligible patients with metastatic urothelial cancer progressing after previous checkpoint inhibitor therapy. *J Clin Oncol.* 2024;42(29):3410-3420.
7. Loriot Y, Petrylak DP, Kalebasty AR, et al. TROPHY-U-01, a phase II open-label study of sacituzumab govitecan in patients with metastatic urothelial carcinoma progressing after platinum-based chemotherapy and checkpoint inhibitors: updated safety and efficacy outcomes [Supplementary Appendix]. *Ann Oncol.* 2024;S0923-7534(24)00009-7.
8. 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.
9. Tagawa ST, Faltas BM, Lam ET, et al. Sacituzumab govitecan (IMMU-132) in patients with previously treated metastatic urothelial cancer (mUC): Results from a phase I/II study [Abstract]. *American Society of Clinical Oncology.* 2019;37(7):354-354.
10. Parikh M, McMahon P, Eng S, et al. Retrospective, observational analysis of real-world safety outcomes in patients with locally advanced/metastatic urothelial cancer treated with sacituzumab govitecan. *Clin Genitourin Cancer.* 2026;24(3):102516.
11. Sternschuss M, Toumbacaris N, Das JP, et al. Real-world clinical outcomes of sacituzumab govitecan after prior exposure to enfortumab vedotin in patients with metastatic urothelial carcinoma. *ESMO Open.* 2025;10(6):105305.
12. Vlachou E, Hahn N, Dabb A, Johnson B, Lefande M, Hoffman-Censits J. Evaluation of clinical benefit of sacituzumab govitecan (SG) following enfortumab vedotin (EV) in advanced urothelial cancer (UC) - real world experience [Poster]. American Society of Clinical Oncology Genitourinary (ASCO GU) Cancers Symposium; 16-18 February, 2023; San Francisco, CA.

13. ClinicalTrials.gov. Study of sacituzumab govitecan (IMMU-132) in metastatic or locally advanced unresectable urothelial cancer (TROPiCS-04). ClinicalTrials.gov Identifier: NCT04527991. Available at: https://www.clinicaltrials.gov/ct2/show/NCT04527991. Accessed: 02 October 2026. Last Updated: 02 June. 2026.
14. Tagawa ST, Balar AV, Petrylak DP, et al. TROPHY-U-01: A phase II open-label study of sacituzumab govitecan in patients with metastatic urothelial carcinoma progressing after platinum-based chemotherapy and checkpoint inhibitors [Protocol]. *J Clin Oncol.* 2021;39(22):2474-2485.
15. Tagawa ST, Balar AV, Petrylak DP, et al. Updated outcomes in TROPHY-U-01 cohort 1, a phase 2 study of sacituzumab govitecan in patients with metastatic urothelial cancer who progressed after platinum-based chemotherapy and a checkpoint inhibitor [Poster 526]. Presented at: American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium; 16-18 February, 2023; San Francisco, CA.
16. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Hematopoietic Growth Factors, Version 1.2027-September 8, 2026.
17. Gyawali B, Bohlke K, Dickter JK, et al. WBC Growth Factors: ASCO Guideline Update. *Journal of Clinical Oncology.* 2026;44(9):812-824.
18. Klastersky J, de Naurois J, Rolston K, et al. Management of febrile neutropaenia: ESMO Clinical Practice Guidelines. *Ann Oncol.* 2016;27(suppl 5):v111-v118.

Abbreviations

1L/2L/3L/4L/5L+=first-line/second-line/third-line/fourth-line/fifth-line or later
AE=adverse event
AESI=adverse event of special interest
ANC=absolute neutrophil count
ASCO=American Society of Clinical Oncology
carbo=carboplatin
chemo=chemotherapy
CPI=checkpoint inhibitor
ECOG PS=Eastern Cooperative Oncology Group Performance Status
ESMO=European Society for Medical Oncology
EV=enfortumab vedotin
G-CSF=granulocyte colony-stimulating factor
LA=locally advanced
mUC=metastatic urothelial cancer
NCCN=National Comprehensive Cancer Network
pembro=pembrolizumab
PD-(L)1=programmed death-(ligand)1
PLT=platinum
SG=sacituzumab govitecan-hziy
TEAE=treatment-emergent adverse event
TPC=treatment of physicians' choice
TRAE=treatment-related adverse event
UC=urothelial cancer
UGT1A1=uridine diphosphate glucuronosyltransferase 1A1
WT=wild-type

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
https://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.