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Trodelvy® (sacituzumab govitecan-hziy) Use of SG With Radiation Therapy

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

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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

Relevant Product Labeling[1]

The US FDA-approved Prescribing Information for SG does not include information regarding the use of SG with radiation therapy.

Clinical Studies: Use of SG With RT

In SG studies (ASCENT in mTNBC,[2] TROPiCS-02 in HR+/HER2- mBC,[3] TROPHY-U-01 in mUC,[4] and IMMU-132-01 in various metastatic epithelial cancers[5]), RT was to be discontinued ≥2 wk prior to study participation. Prior to study enrollment, toxicities associated with previous treatment(s), including RT, were required to have recovered to Grade ≤1. During SG studies, palliative procedures were permitted at the discretion of the study investigator. Palliative RT was not permitted for tumor progression across the four studies.[6]

Retrospective and Real-World Studies: Use of SG With RT

In a retrospective, observational study of SG in 33 patients with mBC and CNS metastases (treated/stable BrM, n=18; active BrM, n=7; LMD, n=8), the overall median (95% CI) CNS and extra-CNS PFS was 2.9 (2–4.3) mo and 2.6 (1.9–4) mo, respectively; CNS PFS was similar across patient subgroups. Three patients (TNBC, n=2; HR+/HER2-, n=1) had bicompartmental PFS that was >10 mo; each had surgery and brain RT. No safety data were reported.[7]

A retrospective, multicenter cohort study evaluated SG and concurrent (sequential, n=9; simultaneous, n=8) palliative RT in female patients with TNBC (N=17). Prior to SG administration, 12 patients received RT, while 17 patients received 34 local RT series concurrently with SG. At the first follow-up (4–8 wk post-RT), the response rate per treatment course was 82.1%. RT response was not available in 6 lesions. The most common AEs were neutropenia and fatigue; 3 and 4 patients who received simultaneous and sequential RT administration, respectively, reported acute Grade 2 to 3 AEs.[8]

In a retrospective, single-center study in patients (N=13; 19 metastatic lesions) with mBC treated with SG and concurrent EBRT, 10 sites received SBRT, and 9 sites received

conformal VMAT. The median (95% CI) OS at Months 6 and 12 was 45.1% (22.9–88.9%) and 16.9% (3.27–87.5%), respectively. Most SG-related AEs were Grade 1 or 2 in severity and included nausea/vomiting, asthenia, alopecia, diarrhea, and anemia. No patients had RT-induced AEs, and none required disruption of SG.[9]

In a subgroup analysis of a retrospective, real-world study that evaluated patients with mTNBC who had received ≥1 dose of SG following ≥2 prior lines of chemotherapy, one of which could have been in the (neo)adjuvant setting, 11 of 24 patients with CNS disease received RT for BrM prior to or during SG treatment. Compared with patients with CNS disease who had not been treated with RT, PFS was significantly longer in RT-treated patients (HR, 0.27; 95% CI: 0.1–0.71; *P*=0.006). No safety data were reported.[10]

In a retrospective cohort study that investigated whether SRT for intact BrM used concurrently with an ADC (including SG) was associated with an increased risk of SRN, concurrent ADC use (data were pooled across ADCs) was associated with a higher risk of SRN in a multivariable analysis that controlled for prior RT and BrM volume. Among patients with BrM who were treated with concurrent ADC therapy, no ADC was associated with an increased risk of SRN (*P*=0.74). Grade 4 to 5 SRN after SRT was observed in 11 of 156 sites (7.1%) of metastasis treated with concurrent ADC therapy.[11]

Clinical Studies: Use of SG With RT

Use of RT Prior to SG Study Participation

In SG studies (ASCENT in mTNBC,[2] TROPiCS-02 in HR+/HER2- mBC,[3] TROPHY-U-01 in mUC,[4,12] and IMMU-132-01 in various metastatic epithelial cancers[5]), RT was to be discontinued ≥2 wk prior to study participation, as described in the protocols. Prior to study enrollment, toxicities associated with previous treatment(s), including RT, were required to have recovered to Grade ≤1.[6] See Figure 1 for details of prior use of RT.

Figure 1. Prior Use of RT in SG Studies[2-6,12]

ASCENT, Phase 3 (SG Safety Population, n=258)
An open label, randomized, confirmatory study, in patients with refractory or relapsed mTNBC who had received ≥2 prior chemotherapies for unresectable, locally advanced, or metastatic disease.

Prior RT Use, n (%)	BrMNeg Population		ITT Population	
	SG (n=235)	TPC (n=233)	SG (n=267)	TPC (n=262)
Non-brain	196 (83.4)	185 (79.4)	223 (83.5)	206 (78.6)
Brain	0	3 (1.3)	32 (12)	31 (11.8)

TROPiCS-02, Phase 3 (SG Safety Population, n=268)
An open-label, randomized, multicenter study, in patients with HR+/HER2- mBC who had received ≥1 taxane, ≥1 endocrine therapy, and ≥1 CDK4/6i in any setting and 2–4 prior chemotherapy regimens for metastatic disease.

Prior RT Use, n (%)	ITT Population	
	SG (n=272)	TPC (n=271)
Any prior RT	212 (77.9)	227 (83.8)
Brain	7 (2.6)	10 (3.7)

SG 10 mg/kg IV on Days 1 and 8 of a 21-day cycle
Continue treatment until loss of clinical benefit or unacceptable toxicity

TROPHY-U-01, Phase 2 (All Treated Patients, n=135)
A multi-cohort, open-label study in patients with unresectable locally advanced, or mUC whose disease progressed:
1. After prior PLT-based and CPI-based therapies
2. After CPI-based therapies and who were ineligible for PLT-based therapy.

Prior RT Use, n (%)	Cohort 1	Cohort 2
	SG (n=113)	SG (n=22)
Non-brain	50 (44.2)	6 (27.3)
Brain	1 (0.9)	0

IMMU-132-01, Phase 1/2
(Treated With SG 10 mg/kg, n=402)
A single-arm, open-label basket study in patients with metastatic epithelial cancers (including cervical, colorectal, endometrial, esophageal, gastric adenocarcinoma, glioblastoma multiforme, hepatocellular, non-small cell lung, non-TNBC, ovarian, pancreatic, prostate, renal cell, small-cell lung, squamous cell head and neck, TNBC, and urothelial) who had relapsed after or were refractory to ≥1 prior therapy for metastatic disease.

Data for prior use of RT are not available for this study.

Abbreviations: BrMNeg=brain metastases negative; CDK4/6i=cyclin-dependent 4/6 inhibitor; CPI=checkpoint inhibitor; PLT=platinum.

Use of RT During SG Studies[6]

During SG studies, palliative procedures were permitted at the discretion of the study investigator. Palliative RT was permitted in ASCENT, for the treatment of BrM, and in TROPHY-U-01, for general palliative treatment; both studies required that SG be interrupted 1 wk before the procedure and reinstated 2 wk after the procedure. Palliative RT was permitted in TROPiCS-02, for the treatment of a symptomatic solitary non-target lesion or to the brain, and in ASCENT, for the treatment of bone metastases; there was no requirement to interrupt SG treatment in these instances.

Palliative RT was not permitted for tumor progression across the four studies.

Retrospective and Real-World Studies: Use of SG With RT

Retrospective, Observational Real-World Study[7]

A retrospective, observational real-world study evaluated clinical outcomes with SG (≥1 dose of SG between 2018 and 2022) treatment in patients with mBC and CNS metastases. Of the 33 patients included (median [range] age at SG initiation, 56.7 [51.3–65.7] y), 23 and 10 had TNBC and HR+/HER2- mBC, respectively. Overall, 18 patients had treated/stable BrM (defined as lesions that had been previously treated with CNS-specific therapies), 7 had active BrM (defined as those with new BrM or progressed BrM that had not been treated with CNS-specific therapies since progression), and 8 had LMD (defined as metastases in the leptomeningeal space with or without BrM). One patient had CNS metastases without extra-CNS involvement.

Table 1. Select Baseline Patient and Treatment Characteristics: Overall and by Subtype (Grinda et al)[7]

Select Patient and Treatment Characteristics		Overall (N=33)	Treated/Stable BrM (n=18)	Active BrM (n=7)	LMD (n=8)
Time between events, median (range), mo	Diagnosis of BrM to SG	7.5 (0.6–94.8)	4.6 (0.7–94.8)	9.3 (0.6–21)	9.3 (2.7–21.5)
	Prior RT for BrM to SG	2 (0.2–44)	1 (0.2–44)	7.4 (5–17.5)	8.8 (1.2–15.2)
Prior RT for BrM, n (%)		28 (84.8)	17 (94.9)	6 (85.7)	5 (62.5)
Type of prior RT for BrM, n (%)	SRS	16 (57.1)	10 (58.8)	3 (50)	3 (60)
	WBRT	7 (25)	4 (23.5)	2 (33.3)	1 (20)
	SRS and WBRT	4 (14.3)	3 (17.6)	1 (16.7)	0

Abbreviations: SRS=stereotactic radiosurgery; WBRT=whole brain radiation therapy.

Results

The overall median (95% CI) duration of follow-up was 6.7 (3.1–10) mo; responses were evaluable in 30 patients in the CNS subgroup and 29 patients in the extra-CNS subgroup. The CNS PFS was similar across patient subgroups; additional results are found in Table 2. The CNS ORR by mBC type was as follows: HR+/HER2-, 11.1%; TNBC, 14.3%.

Table 2. Outcomes Overall and by Subgroup (Grinda et al)[7]

Response, n (%)	Overall (n=30)		Treated/Stable BrM (n=16)		Active BrM (n=7)		LMD (n=7)	
	CNS	Extra-CNS[a]	CNS	Extra-CNS[b]	CNS	Extra-CNS	CNS	Extra-CNS
Response[c]	4 (13.3)	1 (3.4)	2[d] (12.5)	0	0	0	2 (28.6)	1 (14.3)
SD	16 (53.3)	12 (41.4)	10 (62.5)	6 (40)	3 (42.9)	4 (57.1)	3 (42.9)	2 (28.6)
PD	10 (33.3)	16 (55.2)	4 (25)	9 (60)	4 (57.1)	3 (42.9)	2 (28.6)	4 (57.1)
DCR	20 (66.7)	13 (44.8)	12 (75)	6 (40)	3 (42.9)	4 (57.1)	5 (71.4)	3 (42.9)
CBR at 6 mo	8 (26.7)	4 (13.8)	6 (37.5)	2 (13.3)	1 (14.3)	1 (14.3)	1 (14.3)	1 (14.3)
PFS,[e] median (95% CI), mo	2.9 (2–4.3)	2.6 (1.9–4)	3.4 (2.2–10)	2.7 (1.9–4.2)	1.9 (1.2–16.5)	1.9 (1.5–10.1)	2.1 (0.4–7.7)	2 (0.4–6.9)
OS, median (95% CI), mo	6.9 (3.1–10.2)		10 (4.3–15.9)		3.1 (1.9–21.6)		3.8 (1.7–11.9)	

Abbreviations: DCR=disease control rate; PD=progressive disease; SD=stable disease.
[a]n=29. [b]n=15. [c]CR or PR for CNS response. [d]Both received RT <2 mo before SG began.
[e]Bicompartmental median (95% CI) PFS by subgroup was as follows: overall, 2.6 (1.9–4) mo; treated/stable BrM, 2.7 (1.9–4.1) mo; active BrM, 1.8 (1.5–10.1) mo, LMD, 2.4 (0.4–5.1) mo.

Overall, 32 patients discontinued treatment due to disease progression (53.1% had both CNS and extra-CNS progression), and 1 discontinued SG due to toxicity; 5 patients died during SG treatment.

Three patients had bicompartmental PFS that was >10 mo; each had surgery and brain RT. Two of these patients had TNBC with stable BrM and received SG early (≤2 prior therapies); the third patient with HR+/HER2- mBC had 95 mo between BrM diagnosis and SG initiation.

No safety data were reported.

Retrospective, Multicenter Cohort Study[8]

A retrospective, multicenter cohort study assessed the efficacy and safety of SG and concurrent (sequential or simultaneous) palliative RT in female patients with TNBC (N=17). The median (range) patient age was 48 (33–73) y, and most had an ECOG PS of 0 to 1. Patients had previously received a median (range) of 2.5 (1–6) prior lines of treatment and a median (range) of 5 (2–26.5) treatment cycles of SG, which was mostly administered using a dose of 10 mg/kg. The median (range) total dose and dose per fraction of RT was 36 (8–50.4) Gy and 3 (1.8–20) Gy, respectively. See Table 3 for further treatment characteristics.

Table 3. RT Treatment Characteristics (N=17; Krug et al)[8]

RT Technique,[a] n (%)	Patients	RT Target Volume,[a] n or n (%)	Targets
Intensity-modulated RT	13 (38.2)	Lymph node metastases	9 (26.5)
Electrons	8 (23.5)	Brain metastases	8 (23.5)
SRT	7 (20.6)	Skin metastases	8 (23.5)
3D-conformal RT	4 (11.8)	Bone metastases	6 (17.6)
Unknown	2 (5.9)	Breast/thoracic wall	2 (5.9)
		Lung metastasis	1 (2.9)
		Target volumes with re-irradiation[b]	12

[a]Individual RT courses and target volumes.
[b]Targets that had partial overlap of irradiated volumes.

Timing of RT

Prior to SG administration, 12 patients had received RT, while 17 patients received 34 local RT series concurrently with SG; sequential and simultaneous SG and RT were administered

in 9 and 8 patients, respectively. The median (range) time between sequential SG and RT was 7 (1–33) d. SG was resumed after a median (range) of 6 (1–68) d. In most patients, concomitant RT was used to treat local progressive metastases; other reasons included palliation of symptoms or ulcerations (n=2), treatment of a local relapse or postoperative irradiation after resection of a brain metastasis (each, n=1). There was an overlap with prior RT in 12 RT courses. The median (range) time between concurrent SG and RT with prior courses of RT was 2 (1–7) y. The median (range) dose of cumulative RT was 79 (65–102) Gy.

Efficacy and safety outcomes

At the first follow-up (4–8 wk post-RT), the response rate per treatment course was 82.1%. RT response was not available in 6 lesions. After the first SG dose, OS ranged from 2.5 to 36 mo; post-RT, the OS ranged from 1.6 to 12 mo.

All patients treated with SG received granulocyte colony-stimulating factor as primary prophylaxis. Safety data were available for 15 patients; the most common AEs were neutropenia and fatigue. Other AEs included infections (enterocolitis, n=2; herpes zoster, n=1), diarrhea, abdominal pain, chest pain, and alopecia. Grade 2 fatigue was reported in 6 patients after RT.

No Grade 4 or 5 AEs were reported with SG and RT used in combination; however, 82.3% of patients experienced AEs, and fatigue and dermatitis were the most commonly reported AEs. In-field Grade 3 AEs included dermatitis (n=2) and esophagitis (n=1). Grade 3 AEs were only reported by patients with overlap of prior radiation fields. Three patients (37.5%) who received simultaneous RT and 4 patients (44.4%) who received sequential RT administration reported acute Grade 2 to 3 AEs.

Retrospective, Single-Center Study in France[9]

A retrospective, single-center study evaluated safety outcomes in patients (N=13) with mBC treated with SG and concurrent EBRT EBRT was delivered according to a conventional fractionation or stereotactic technique. Of the included patients (median [range] age of 54 [37–77] y; 12 with invasive ductal carcinoma and 1 with invasive lobular carcinoma), 8 had TNBC, and 5 had HR+/HER2-low/negative mBC. Most tumors (61.5%) were Grade 3, and there was a median (range) Ki67 index of 35% (8–90%). Patients received SG for a median (range) of 7 (2–19) mo. Of the 19 sites of metastases treated with RT, 10 were in the brain, and 9 were in bone; 4 sites in the brain had previously been surgically resected.

Ten sites (52.6%) received SBRT: 4 received 27 Gy/3 fractions; and 1 each received 30 Gy/5 fractions, 25 Gy/5 fractions, 24 Gy/3 fractions, 22 Gy/1 fraction, or 20 Gy/1 fraction. Nine sites (47.4%) received conformal VMAT: 4 each received 30 Gy/10 fractions or 20 Gy/5 fractions; 2 received 8 Gy/1 fraction; and 1 received 30 Gy/5 fractions.

Results

The median (range) duration of follow-up after completion of RT was 5 (1–19) mo. At the time of data cutoff, 9 patients died due to disease progression; the time between completion of RT and death ranged from 1 to 19 mo. The overall median OS from the completion of RT was 6 mo, and the median (95% CI) OS at Months 6 and 12 was 45.1% (22.9–88.9%) and 16.9% (3.27–87.5%), respectively.

No patients had RT-induced AEs, and none required disruption of SG. One (7.7%) Grade 3 and 1 (7.7%) Grade 4 SG-related AE of neutropenia were reported. All other SG-related AEs

were Grade 1 or 2 in severity: nausea/vomiting (Grade 1, 30.8%); asthenia (Grade 1, 23.1%; Grade 2, 15.4%); alopecia (Grade 1, 15.4%; Grade 2, 23.1%); diarrhea (each, Grade 1 and 2, 15.4%); anemia (Grade 1, 15.4%); and neutropenia (Grade 2, 7.7%).

Retrospective Real-World Study in UK[10]

A UK retrospective, real-world study evaluated safety and efficacy in patients with mTNBC who had received ≥1 dose of SG following ≥2 prior lines of chemotherapy, one of which could have been in the (neo)adjuvant setting. In a subgroup analysis of 24 patients with CNS disease, 11 patients received RT for BrM prior to or during SG treatment.

Of the 126 evaluable patients, median PFS and OS were 5.2 mo and 8.7 mo, respectively. In the subgroup analysis of patients with CNS disease, PFS was 5.1 mo, which was not significantly different from that in patients without CNS disease (*P*=0.8); OS was not reached. Compared with patients with CNS disease who had not been treated with RT, PFS was significantly longer in RT-treated patients (HR, 0.27; 95% CI: 0.1–0.71; *P*=0.006). Patients with CNS disease that was untreated with RT demonstrated a PFS and OS of 1.6 and 2.6 mo, respectively. No safety data were reported in the subgroup analysis.

Retrospective Cohort Study: ADCs and SRT for BrM[11]

A US retrospective cohort study investigated whether SRT for intact BrM used concurrently with an ADC (including SG) was associated with an increased risk of SRN. Patients who had received ≥1 course of SRT for intact BrM, and ≥1 dose of ADC were identified (Table 4). Results were pooled across ADCs and were not reported separately for SG. Most patients (83.7%) were women, the median age was 55 y, and 72.4% had breast cancer as their primary diagnosis.

Table 4. ADC Received and Timing With SRT (Lebow et al)[11]

ADC Received,[a] n (%)	Concurrent ADC[b] (n=42)	No Concurrent ADC[c] (n=74)	All (N=98)
SG	7 (16.7)	23 (31.1)	26 (26.5)
Trastuzumab emtansine	21 (50)	43 (58.1)	52 (53.1)
Trastuzumab deruxtecan	14 (33.3)	42 (56.8)	50 (51)

[a]Numbers total >100% and do not total across rows because patients could have received ≥1 course of ADC.
[b]SRT was considered concurrent if delivered ≤7 d before or ≤21 d after ADC administration.
[c]ADCs given sequentially with SRT.

Results

Results showed that the median (IQR) time from SRT to last imaging was 12.4 (0–80.4) mo. Across the entire cohort, the 24-mo cumulative incidence of SRN was 8.5% (range: 6.2–11%). Concurrent ADC use was associated with a higher risk of SRN in univariable and multivariable analyses that controlled for prior RT and BrM volume (Table 5). For previously radiated lesions in patients with and without concurrent ADC therapy, the 24-mo risk of SRN was 42% and 9.4%, respectively. Among patients with BrM who were treated with concurrent ADC therapy, no ADC was associated with an increased risk of SRN (*P*=0.74). Grade 4 to 5 SRN after SRT was observed in 11 of 156 sites of metastases (7.1%) and 3 of 408 sites of metastases (0.7%) treated with and without concurrent ADC therapy, respectively.

Table 5. Risk of SRN With Concurrent ADC (n=42; Lebow et al)[11]

	Subdistribution HR (95% CI)	*P*-Value
Univariable analysis	4.01 (1.79–9.01)	<0.001
Multivariable analysis	4.31 (1.95–9.50)	<0.001
Prior RT	2.99 (1.26–7.09)	0.01
BrM volume, per cm^3	1.14 (1.09–1.19)	<0.001

Ongoing Clinical Studies: Use of SG With RT

SG and Adaptive RT Study

An ongoing single-group, open-label study (NCT05833867) in patients with localized muscle invasive bladder cancer will evaluate the safety, tolerability, and feasibility of bladder preservation treatment with concurrent SG 8 mg/kg IV and adaptive image-guided RT.

Abbreviations

ADC=antibody drug conjugate
AE=adverse event
BrM=brain metastases
CBR=clinical benefit rate
CNS=central nervous system
EBRT=external beam radiotherapy
ECOG PS=Eastern Cooperative Oncology Group Performance Status
extra-CNS=lesions or disease outside of the central nervous system
HER2=human epidermal growth factor receptor 2
HR=hazard ratio
HR+=hormone receptor-positive
IHC=immunohistochemistry
Ki-67=antigen Kiel 67
LMD=leptomeningeal disease
mBC=metastatic breast cancer
mTNBC=metastatic triple-negative breast cancer
mUC=metastatic urothelial cancer
ORR=objective response rate
OS=overall survival
PFS=progression-free survival
RT=radiation therapy
SBRT=stereotactic body radiotherapy
SG=sacituzumab govitecan-hziy
SRN=symptomatic radiation necrosis
SRT=stereotactic radiotherapy
VMAT=volumetric modulated arc therapy

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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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