Trodelvy® (sacituzumab govitecan-hziy) Real-World Data in mTNBC

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and real-world data in metastatic triple-negative breast cancer (mTNBC).

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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]

SG is indicated for the treatment of adult patients with unresectable locally advanced or mTNBC who have received ≥2 prior systemic therapies, ≥1 of them for metastatic disease.

Real-World Data on SG Use in mTNBC

In a retrospective cohort database study conducted in England, PFS and OS were evaluated in patients with TNBC who progressed to 2L (n=606) and 3L (n=374) metastatic treatment.[2]

- In Cohorts 2L and 3L, the median durations of PFS (2.53 vs 2.43 months, respectively) and OS (6.7 vs 5.54 months, respectively) were numerically similar.[2]
- In the 2L cohort, survival was similar between <12 months and ≥12 months treatment-free intervals.[2]

In a retrospective, multicenter cohort study of 249 patients with mTNBC who received SG in Poland, the Czech Republic, and Slovakia, the median (IQR) PFS and OS were 4.1 (2.9–5.3) months and 10.3 (9.4–11.2) months, respectively.[3]

In a US retrospective, observational cohort study, SG use patterns and clinical outcomes in those diagnosed with mTNBC and treated with SG in 2L+ settings were included in the analysis (N=230).[4]

- Median (95% CI) OS was 10 (8.3–11.1) months for patients treated 2L+ and 13.9 (9.8–NE) months for patients treated 2L.[4]
- Median (95% CI) PFS in 2L and 3L+ patients was 4.9 (2.9–6) months and 3.5 (2.7–4.2) months, respectively.[4]

In a retrospective study of SG in patients with mBC in China (N=165; mTNBC, n=103), the median (95% CI) PFS was 5.1 (3.8–7.4) months and the median (95% CI) OS was 19.7 (17.3–not reached) months in the mTNBC cohort. In the overall patient population, any-grade and Grade ≥3 AEs occurred in 52.7% and 20% of patients, respectively.[5]

In a multicenter retrospective study of SG in patients with mTNBC in Italy (N=149), the median (95% CI) PFS and OS (by investigator assessment) were 5.75 (4.37–7.13) months and 12.8 (10.8–15.9) months, respectively. Hematological and gastrointestinal AEs were the most commonly reported TRAEs. The most common (≥50%) any-grade TRAEs were neutropenia, anemia, and nausea.[6]

A UK retrospective study of SG in patients with mTNBC (N=132) demonstrated a median PFS and median OS of 5.2 months and 8.7 months, respectively. The most common AEs were fatigue, neutropenia, diarrhea, and nausea.[7]

In a retrospective study in the US, 115 patients with mTNBC received SG. The median (95% CI) PFS and OS in the overall population were 4.8 (3.6–5.9) months and 9.6 (7.8–12.9) months, respectively. The most common (n≥10) Grade 3/4 AEs included neutropenia, anemia, fatigue, and vomiting.[8]

Within the TRACIE study of patients with advanced TNBC who received SG in Australia, at the interim analysis of data from the first 112 patients, the median (95% CI) PFS and OS were 9.5 (8.4–11.5) months and 13.1 (9.5–17.5) months, respectively. The most common AEs were diarrhea (9.8%), neutropenia (5.4%), and fatigue (4.5%).[9]

In an ambispective, bicentric cohort study of patients with mTNBC treated with SG within the French EAP (N=103), the median (95% CI) PFS and OS of the overall population were 4 (3.5–5.3) months and 9.2 (7.2–not reached) months, respectively. AEs that led to SG dose reduction were consistent with those reported in the ASCENT study.[10]

In a retrospective study of patients with HER2- mBC (N=91; mTNBC, n=53) treated with SG at Cedars-Sinai Medical Center, the median PFS was 4.2 months for those in the mTNBC cohort. The median PFS of SG as ADC1 was not significantly longer than that of SG as ADC2 among those with mTNBC (4.4 vs 3.5 months; *P*=0.87).[11]

In TROPSPAIN, a retrospective observational study in Spain, patients in Cohort 1 (N=87) initiated SG during the MSE and had an overall median (95% CI) OS and TTNTD of 9.3 (7.7–12.3) months and 4.5 (3.7–5.7) months, respectively. Any-grade diarrhea and neutropenia were reported in 46.7% and 44% of patients, respectively; most cases were Grade 1 or 2 in severity.[12]

In a multicenter retrospective study of heavily pretreated patients with mBC, including mTNBC (n=43), treated with SG in China, the overall median PFS was 3.9 months. The median PFS was 4.2 among those with mTNBC, and 6.34 months among those with brain metastases (n=13). Overall, the most common Grade ≥3 AEs were neutropenia (17.2%) and diarrhea (6.9%); febrile neutropenia occurred in 3.5% of patients.[13]

Real-World Data on SG Use in mTNBC

Outcomes in 2L and 3L SG Treatment in England[2]

A retrospective cohort database study utilized the Cancer Analysis System database (data sources: Systemic Anti-Cancer Therapy database, Cancer Outcomes and Services Dataset, and Office of National Statistics) to determine treatment outcomes in patients across 2L and 3L treatments for mTNBC. Patients with an initial BC diagnosis between January 1, 2012, and December 31, 2018, were identified; treatment follow-up continued through June 30, 2020, and follow-up for OS continued through June 30, 2021. Patients were indexed at the start of 2L or 3L therapies.

Several subcohorts were also assessed: Cohorts 2L and 3L, including Cohorts $3L_a$ and $3L_m$. Cohort 2L included patients who had progressed to 2L metastatic treatment and were diagnosed with Stage I, II, or resectable Stage III TNBC. Cohort 3L included patients who had progressed to 3L metastatic treatment. Cohort $3L_a$ included patients who were diagnosed with Stage I, II, or resectable Stage III TNBC. Cohort $3L_m$ included patients who were diagnosed with unresectable Stage III or de novo Stage IV TNBC.

Table 1. Outcomes in 2L and 3L Treatment of mTNBC in England: Baseline Demographics and Disease Characteristics[2]

Key Demographics and Characteristics			Cohort 2L (n=606)	Cohort 3L		
				Cohort 3L Combined (n=374)	Cohort $3L_a$ (n=302)	Cohort $3L_m$ (n=72)
Age at BC diagnosis/at initiation of 2L/at initiation of 3L, mean (SD), years			50.6 (11.7)/ 53.7 (11.9)/ 53.1 (11.4)	52.1 (12.5)/ 55 (12.6)/ 55.4 (12.7)	51.3 (12.2)/ 54.5 (12.4)/ 54.9 (12.4)	55.5 (13.3)/ 57.2 (13.4)/ 57.6 (13.4)
Race, White/Asian/Black/other, n (%)			524 (86)/33 (5)/ 29 (5)/9 (1)	334 (89)/17 (5)/ 14 (4)/–	267 (88)/–/ –/–	67 (93)/–/ –/–
Stage at diagnosis, n (%)	Stage I		76 (13)	49 (13)	49 (16)	0
	Stage II		362 (60)	182 (49)	182 (60)	0
	Stage III resectable		168 (24)	71 (19)	71 (24)	0
	Stage III unresectable		–	11 (3)	–	11 (15)
	Stage IV		–	61 (16)	–	61 (85)
Brain metastasis at any point after BC diagnosis, n (%)			195 (32)	117 (31)	91 (30)	26 (36)
ECOG PS,[a] n (%)	0	At BC diagnosis	208 (34)	104 (28)	79 (26)	25 (35)
		At initiation of 2L	177 (29)	140 (37)	114 (38)	26 (36)
		At initiation of 3L	67 (11)	106 (28)	81 (27)	25 (35)
	1	At BC diagnosis	19 (3)	12 (3)	–	–
		At initiation of 2L	276 (46)	168 (45)	136 (45)	32 (44)
		At initiation of 3L	115 (19)	171 (46)	144 (48)	27 (38)
	2	At BC diagnosis	–	–	–	–
		At initiation of 2L	65 (11)	21 (6)	–	–
		At initiation of 3L	–	47 (13)	–	–

[a]ECOG PS was missing/unknown at BC diagnosis in 377, 254, 211, and 43 patients within the 2L, 3L combined, $3L_a$, and $3L_m$ cohorts, respectively; at initiation in 78 and 45 patients within the 2L and 3L combined cohorts; and at initiation of 3L in 394 patients within the 2L cohort.
Note: All patients were female, and study investigators censored counts <5.

Results

The anti-cancer treatment regimens used in Cohort 2L included capecitabine (32%), eribulin (16%), carboplatin and gemcitabine (12%), and paclitaxel (10%); in Cohort 3L, eribulin (38%), capecitabine (16%), and paclitaxel (13%) were used. See Table 2 for efficacy outcomes. Real-world safety data were not reported.

Table 2. Outcomes in 2L and 3L Treatment of mTNBC in England: PFS and OS According to Cohort[2]

			Cohort 2L	Cohort 3L Combined
PFS (time to death or discontinuation)	Median (95% CI), months		2.53 (2.3–2.76)	2.43 (2.2–2.76)
	PFS by treatment-free interval	<12 months, median (95% CI), months	2.3 (2.07–2.76)	–
		≥12 months, median (95% CI), months	2.76 (2.46–2.96)	–
		Log-rank *P*-value	0.30706	N/A
OS	Median (95% CI), months		6.7 (6.14–7.62)	5.54 (4.9–6.14)
	OS by treatment-free interval	<12 months, median (95% CI), months	5.72 (5.06–6.64)	–
		≥12 months, median (95% CI), months	7.49 (6.74–8.31)	–
		Log-rank *P*-value	0.10359	N/A

Multicenter, Retrospective Study in Poland, the Czech Republic, and Slovakia[3]

A retrospective, multicenter cohort study used hospital records to assess the effectiveness of SG in 249 patients with mTNBC who initiated SG between November 2022 and January 2025 across 14 oncology centers in Poland, the Czech Republic, and Slovakia. The median (IQR) age was 53 (46–63) years, the median (IQR) number of prior systemic lines of therapy was 2 (1–2), and the median (IQR) SG exposure was 4 (2–7) cycles. Treatment delays and dose reductions occurred in 60.2% and 41.5%, respectively. At data cutoff (April 30, 2025), 35 patients (14.1%) remained on SG. At a median (IQR) follow-up of 7.82 (4.29–12.01) months, the ORR was 31.4%. The median (95% CI) PFS and OS were 4.1 (2.9–5.3) months and 10.3 (9.4–11.2) months, respectively. Safety data were not reported.

Outcomes in 2L+ SG Treatment in the US[4]

A US retrospective, observational cohort study was conducted using the ConcertAI Patient360™ database to assess SG use patterns and clinical outcomes in adult females diagnosed with mTNBC who initiated SG as 2L+ treatment between April 2020 and May 2022. A total of 230 patients were included in the analysis (Table 3); 33% and 67% of patients received SG in 2L and 3L+, respectively.

Table 3. Outcomes in 2L+ SG Treatment of mTNBC in the US: Baseline Demographics and Disease Characteristics[4]

Key Demographics and Characteristics	2L+ (N=230)
Age, median (IQR), years	60 (49–69)
Race, White/Black/Asian/other/unknown, %	63/26/4/7
ECOG PS, ≤1/≥2/unknown, %	70/17/12
Baseline metastases, visceral/brain, %	73/7
Time from mBC diagnosis to SG initiation, median (IQR), months	11.8 (7.6–19.2)
Prior number of therapies in metastatic setting,[a] median (IQR)	2 (1–3)

[a]Forty-four percent (101/230) of patients had received prior (neo)adjuvant anti-cancer therapy; median (IQR) number of prior anti-cancer regimens in both settings was 4 (2–5).

Results

Prior anti-cancer regimens used included taxanes (65%), carboplatin (42%), capecitabine (41%), anthracyclines (11%), and cyclophosphamide (7%). Among all patients, the median

(IQR) treatment duration was 3.8 (2.1–7) months, and the maximum duration was 25.8 months. A total of 21 (9%) patients were still receiving SG at the end of the study period. Efficacy outcomes are shown in Table 4.

Table 4. Outcomes in 2L+ SG Treatment of mTNBC in the US: Efficacy[4]

		2L+ (N=230)	2L (n=77)	3L+ (n=153)
OS	Median (95% CI), months	10 (8.3–11.1)	13.9 (9.8–NE)	8.4 (7.7–10.3)
	12-month survival rate, % (95% CI)	40 (33–48)	51 (37–64)	35 (26–44)
	24-month survival rate, % (95% CI)	23 (15–32)	32 (13–54)	20 (11–29)
PFS, median (95% CI), months		3.8 (3.1–4.3)	4.9 (2.9–6)	3.5 (2.7–4.2)

Safety

Neutropenia was reported in 77 patients (33%), diarrhea in 70 patients (30%), and fatigue in 104 patients (45%). Dose modifications, discontinuation, and G-CSF usage results are reported in Table 5.

Table 5. Outcomes in 2L+ SG Treatment of mTNBC in the US: SG Treatment Discontinuation, Dose Modifications, and G-CSF Use[4]

Outcomes, n (%)	All Patients (N=230)
Discontinuation	209 (91)
Due to toxicity[a,b]	17 (7)
Dose reduction	79 (34)
Due to toxicity[a,b]	59 (26)
Dose interruption	133 (58)
Due to toxicity[a,b]	89 (39)
G-CSF use during SG treatment	134 (58)
G-CSF use prior to SG treatment	99 (43)
G-CSF use first time during SG treatment	35 (15)
Time from SG start date to G-CSF use,[c] median (IQR), days	8.5 (8–29)

[a]Percentages are based on total number of patients.
[b]Based on data abstracted from physicians' notes.
[c]Among patients initiating G-CSF for the first time during SG treatment.

Multicenter Retrospective Study in China[5]

A retrospective study evaluated the effectiveness and safety of SG in 165 patients with mBC, including 103 patients with TNBC, treated at 3 centers in China between June 2023 and December 2024. Among the patients with mTNBC, the median age was 51 years; 10.7% had an ECOG PS score of 2; 72.8% had visceral metastases; 13.6% had brain metastases; and the median number of prior lines of treatment for metastatic disease was 2.

As of the data cutoff date (January 21, 2025) in the mTNBC cohort, the median (95% CI) PFS was 5.1 (3.8–7.4) months, the ORR was 17.5%, the DCR was 47.6%, and the median (95% CI) OS was 19.7 (17.3–not reached) months. SG use as 1L/2L vs as ≥3L resulted in longer PFS in patients with mTNBC (*P*=0.017). SG used in combination with other agents resulted in numerically longer PFS relative to SG monotherapy among mTNBC patients (14.2 vs 4.6 months, respectively; HR: 0.51; *P*=0.115). The presence of brain metastases and previous ADC use did not decrease the effectiveness of SG.

No new safety signals were reported during the study. In the overall patient population, any-grade and Grade ≥3 AEs occurred in 52.7% and 20% of patients, respectively; 15 patients (9.1%) required a dose reduction of SG, and 14 (8.5%) discontinued SG.

Multicenter Retrospective Study in Italy

A multicenter retrospective study evaluated the effectiveness and safety of SG in 149 patients with mTNBC from 11 centers in Italy between March 2021 and December 2024. The median (range) age was 53 (26–80) years, 96% had an ECOG PS of 0 to 1; 30% previously used a PD-1 or PD-L1 inhibitor, and 7% previously used a PARP inhibitor; 9.4%, 38.2%, and 52.4% had 1, 2, and ≥3 metastatic sites, respectively. Major tumor locations were as follows: lymph nodes, 65.1%; lung, 50.3%; bone, 49.7% (bone-only disease, 4%); liver, 29.5%; and brain, 22.8% (30 patients received radiotherapy). At initial diagnosis, 74.5% had mTNBC, 30.2% had HER2-low mBC, and 8% had ER-low BC. The median (range) number of prior regimens for metastatic disease was 2 (0–7); the median (range) duration from diagnosis of metastatic disease to SG use was 17 (0–86) months. The treatment-free interval (defined as the time from the last adjuvant treatment to the onset of recurrent/metastatic disease) and disease-free interval (defined as the time from the first diagnosis to the onset of recurrent/metastatic disease) was >12 months in 42 patients (28.2%).[6]

Results[6]

After a median follow-up duration of 18.2 months, 88 patients died, and 81.8% had disease progression. The median (95% CI) PFS and OS (by investigator assessment) were 5.75 (4.37–7.13) months and 12.8 (10.8–15.9) months, respectively. The ORR was 40%, and all responses were PRs; 38 (26%) achieved SD, and 51 (34%) had PD.

Safety

Hematological and gastrointestinal AEs were the most commonly reported TRAEs. Safety data are summarized in Table 6.[6] The SG dose was decreased in 34.9% of patients, and 4% discontinued SG.[14]

Table 6. Multicenter Retrospective Study in Italy: Safety Outcomes[6]

TRAEs, n (%)	Any Grade[a]	Grade 3	Grade 4
Any TRAE	142 (95)	42 (28.2)	12 (8)
Neutropenia	79 (53)	28 (18.8)	11 (7.4)
Anemia	75 (50.3)	1 (0.7)	0
Nausea	75 (50.3)	0	0
Diarrhea	61 (40.9)	5 (3.4)	0
Asthenia	30 (20.1)	2 (1.3)	0
ALT/AST increased	25 (16.8)	3 (2)	1 (0.7)
Thrombocytopenia	24 (16.1)	0	0
Vomiting	17 (11.4)	0	0

[a]Included any-grade TRAEs that occurred in >10% of patients.

Premedication and preventative treatments were used frequently: 96.6% of patients used steroid premedication, 40.5% used a 5-HT3 receptor antagonist alone, 57.8% used a 5-HT3 and NK1 receptor antagonists before Cycle 1, 6.7% used 5-HT3 and NK1 receptor antagonists due to side effects, 8.7% used atropine before Cycle 1, and 7.4% used atropine due to side effects.[6]

Study of 2L+ SG Treatment in the UK[7]

A retrospective study in mTNBC evaluated the safety and efficacy of SG in 132 patients collected from 16 major UK cancer centers who received ≥1 dose of SG with ≥2 prior lines

of chemotherapy, one of which could have been in the (neo)adjuvant setting. The median (range) age was 56 (28–91) years, and 75% of patients had visceral metastases. Patients had an ECOG PS of 0 to 3, with 58% of patients having an ECOG PS of 1.

Median PFS and OS were 5.2 months and 8.7 months, respectively (n=126), and 6 patients were excluded due to incomplete data. Patients with central nervous system disease (n=24) had a PFS of 5.1 months (*P*=0.8), and OS was not reached. The most common AEs were fatigue, neutropenia, diarrhea, and nausea. SG dose reduction was required in 54% of patients due to AEs.

Study of mTNBC Patients in the US[8]

A retrospective study evaluated the effectiveness of SG in 115 female patients with mTNBC from four centers in the US between January 2021 and May 2023. The median (range) age at SG initiation was 60.3 (31.5–85.8) years, 73 patients (63.5%) were White, 31 (27%) were Black, and 11 (9.6%) were another race. Most (86%) had metastases to ≥2 organs, and the median (range) ECOG PS was 1 (0–2); brain metastasis was present in 25 (21.7%) patients. The median (range) number of prior lines of therapy in the metastatic setting was 2 (0–8); 29.6% had received >3 lines of therapy. Previous treatments included the following: taxane, 70.4%; PD-L1, 51.3%; capecitabine, 47.8%; carboplatin, 42.6%; anthracycline, 33%; cyclophosphamide, 20%; and PARP inhibitor, 8.7%.

Results

After a median follow-up of 16.1 months, the median (95% CI) OS and PFS in the overall population were 9.6 (7.8–12.9) months and 4.8 (3.6–5.9) months, respectively; the 1-year survival rate was 43% (95% CI: 33–52%). The presence of lung metastasis (*P*=0.042) and absence of liver metastasis (*P*=0.033) were significantly associated with a clinical benefit of SG treatment. Relative to patients who received ≤3 prior lines of therapy, those who received >3 lines of therapy had a lower ORR (*P*=0.002) and a significantly shorter median duration of response (5 vs 2 months; *P*=0.012).

Twenty-six patients (22.6%) with HER2-low BC received T-DXd after SG treatment; T-DXd was the next line of treatment initiated for 15 of the 45 patients who did not have clinical benefit from SG treatment and for 8 of the 54 patients who did have clinical benefit from SG treatment. After a median (95% CI) follow-up time of 17.5 (15.6–17.6) months, the ORR with T-DXd was 34.8% (8/26), the clinical benefit rate was 65% (n=15), and the median (95% CI) PFS was 7 (4.6–10.1) months. Three patients began T-DXd after discontinuing SG due to AEs.

The most common any-grade AEs included neutropenia, anemia, fatigue, nausea, diarrhea, febrile neutropenia, constipation, loss of appetite, thrombocytopenia, nervous system disorder, vomiting, alopecia, skin disorder, and abdominal pain. The most common (n≥10) Grade 3/4 AEs included neutropenia, anemia, fatigue, and vomiting. In general, the incidence of most any-grade AEs was higher among those aged ≤65 years than among those aged >65 years; the incidence of Grade 3/4 neutropenia, anemia, fatigue, vomiting, thrombocytopenia, and nervous system disorder was higher among those aged ≤65 years than among those aged >65 years.

Australian TRACIE Study[9]

A secondary data analysis is being performed for 150 patients with advanced TNBC who received SG in the ≥2L setting in Australia through an EAP (October 2021–April 2022) or

from a government reimbursement scheme (after May 2022). Results of an interim analysis of data from the first 112 patients were reported, with a median follow-up of 25.3 months. The median (IQR) age of patients was 54.5 (49.5–64.5) years; at initiation of SG, 71.5% had an ECOG PS of 0 to 1; of the 87.5% of patients who underwent germline testing, 11.2% had a pathogenic *BRCA1/2* variant. The most common metastatic sites were nodes (58.9%), liver (42%), and lung (29.5%); brain metastases were present in 7.1% of patients. Of the 87.5% of patients who had a biopsy in the metastatic setting, 80.6% had HR- BC, and 19.4% had ER/progesterone receptor staining <10%; 60.2% had HER2- tumors (IHC 0), and 39.8% had HER2-low tumors (IHC 1+ or IHC 2+/ISH-). Most patients (62.5%) had received ≥2 prior lines of treatment in the metastatic setting, and 25% received immunotherapy; the most common chemotherapy regimens included capecitabine (20.5%), eribulin (17%), and carboplatin + gemcitabine (15.2%).

Results

The median time from the diagnosis of metastatic disease to the initiation of SG was 18.5 months, and the median (95% CI) time to next treatment was 6.2 (5.2–8) months. The median (95% CI) PFS and OS were 9.5 (8.4–11.5) months and 13.1 (9.5–17.5) months, respectively.

The most common AEs were diarrhea (9.8%), neutropenia (5.4%), and fatigue (4.5%). G-CSF was used as primary prophylaxis in 7.1% of patients and as secondary prophylaxis in 32.1% of patients. As of the data cutoff, 82.1% of patients discontinued treatment; 78.3% due to PD, 9.8% due to toxicity, 8.7% due to unspecified reasons, and 3.3% died. The most common AEs that led to SG discontinuation were nausea (4.5%), neutropenia (3.6%), and anemia, fatigue, and diarrhea (each, 2.7%); most patients experienced several AEs that led to SG discontinuation. At the initiation of SG, 92% of patients received the full dose; 23.3% required dose reductions, including 14.8% due to toxicity and 7.8% due to clinician decision.

French EAP: SG in Pretreated Patients With mTNBC[10]

An ambispective bicentric cohort study evaluated the effectiveness and safety of SG in patients treated within the French EAP between May 2021 and January 2023. PFS and OS were evaluated in the overall study cohort (N=103), in those with brain metastases (BMPos subgroup, n=32), and according to the number of prior lines of treatment (1 or 2 lines, n=65; >2 lines, n=38).

All patients were female. The median (range) age was 55 (26–89) years, and the median (range) number of prior lines of treatment in an advanced setting was 2 (1–10); 35.9% had >2 prior lines; 28.2% had previously received anti-PD-1/PD-L1 therapy, and 5.8% previously received PARP inhibitor therapy. Most patients (80.6%) had an ECOG PS of 0 to 1. Visceral metastases were present in 79.6% of patients, and liver metastases were present in 43.7% of patients; 14.6% of patients had de novo metastatic disease.

Results

Patients were followed for a median duration of 9.6 months. PFS and OS for the overall population and the BMPos subgroup are shown in Table 7. PFS and OS were not significantly different between patients with and without brain metastases (*P*=0.067 and *P*=0.14, respectively). Similarly, PFS and OS were not significantly different between patients who received 1 or 2 previous lines of therapy and those who received >2 lines (*P*=0.11 for each endpoint).

Table 7. French EAP: Effectiveness of SG in the Overall Population and the BMPos Subgroup[10]

	Overall Population (N=103)	BMPos Subgroup (n=32)
SG exposure, median (range), months	3.4 (0.3–15.4)	3.1 (0.3–9.5)
PFS, median (range), months	4 (3.5–5.3)	3.7 (2.6–6.2)
OS, median (range), months	9.2 (7.2–not reached)	6.7 (56.3–not reached)
ORR, n (%)	31 (30.1)	6 (19.8)
Complete response, n (%)	2 (1.9)	0
PR, n (%)	29 (28.2)	6 (19.8)

Multivariate analyses did not find any significant associations between PFS and various prognostic factors, including age, ECOG PS, prior systemic therapies, TNBC at diagnosis, de novo or recurrent metastatic disease, number/type of metastases, and presence of *BRCA* mutation.

At data cutoff, 78 patients had discontinued treatment. AEs that led to SG dose reduction were consistent with results from the ASCENT study (Table 8).

Table 8. French EAP: Safety Results[10]

n (%) or n/N (%)	Overall Population (N=103)	BMPos Subgroup (n=32)
SG discontinued	78 (75.7)	26 (81.2)
PD	73/78 (93.6)	24/26 (92.3)
Physical deterioration	3/78 (3.8)	2/26 (7.7)
Toxicity	1/78 (1.3)	0
Patient request	1/78 (1.3)	0
SG dose reduced	19 (16.4)	4 (12.5)
Hematological toxicity	8/19 (42.1)	2/4 (50)
Gastrointestinal toxicity	6/19 (31.6)	1/4 (25)
Febrile neutropenia	3/19 (26.3)	1/4 (25)
Liver enzyme elevation	1/19 (5.3)	0
Physical deterioration	1/19 (5.3)	0
SG-related death	0	0

Retrospective Study at Cedars-Sinai Medical Center[11]

A retrospective study evaluated clinical outcomes in 91 patients with HER2- mBC who were treated with SG between 2018 and 2025 at Cedars-Sinai Medical Center. Overall, 53 patients had mTNBC; the median age was 58 years; 58.2% were White; and visceral disease and brain metastasis were present in 72.5% and 26.4% of patients, respectively. The median (range) number of prior lines of chemotherapy was 1 (0–5) for patients with mTNBC. Of the 28 patients who previously received another ADC before SG, 93% received T-DXd. Treatment post SG occurred in 53 patients and included eribulin (n=14), T-DXd (n=9), and gemcitabine + capecitabine (n=7). Next generation sequencing data were available for 54 patients; the most common mutations were *TP53* (70.4%), *PIK3CA* (33.3%), and *PTEN* (16.7%).

The median PFS was 4.2 months in the mTNBC cohort. The median PFS of SG as ADC1 was not significantly longer than that of SG as ADC2 among those with mTNBC (4.4 vs 3.5 months; *P*=0.87). In a multivariate analysis, overall, there was a trend toward improved PFS with the use of SG as ADC1 (HR: 0.42; 95% CI: 0.17–1; *P*=0.057) and the presence of a *TP53* mutation (HR: 0.46; 95% CI: 0.19–1.1; *P*=0.074). Of the 9 patients who received

T-DXd after SG, cross-resistance (defined as PD at the first restaging scan with the ADC after SG) was present in 4 patients, absent in 3 patients, and pending review in 2 patients.

TROPSPAIN Study[12]

A retrospective observational study in Spain assessed the effectiveness and safety of SG use in patients with mTNBC and unresectable, locally advanced TNBC. This interim analysis was in Cohort 1, which consisted of patients who initiated SG during the MSE (January 1, 2022–November 30, 2022). Cohort 2 included patients who received commercial use of SG (December 1, 2022–December 31, 2023). The primary objectives were OS and TTNTD; effectiveness was assessed in subgroups by age (<65 vs ≥65 years) and SG line of therapy (2 vs ≥3). Secondary outcomes include safety, duration of SG treatment, and G-CSF use.

All patients in Cohort 1 (N=87) were female; the median (IQR) age at SG treatment initiation was 51 (44–61) years, and the median (IQR) number of prior lines of treatment was 2 (1–4). SG was the 2L, 3L, and 4+L of treatment in 26.4%, 24.1%, and 49.4%, respectively. Most patients (66.7%) had an ECOG PS of 0 to 1. Sites of metastasis included lymph nodes (47.1%), bone (42.5%), lung (37.9%), liver (24.1%), and brain (6.9%); 11.5% of patients had de novo metastasis. At SG initiation, 77 patients (88.5%) had mTNBC and 10 (11.5%) had unresectable, locally advanced TNBC.

Interim results: Cohort 1

Patients in Cohort 1 received SG for a median (IQR) duration of 3.8 (2.5–6.7) months and had a median (IQR) follow-up of 9.2 (5.2–15.3) months. Overall median OS and TTNTD are shown in Table 9. In a stratified analysis by age and line of treatment, patients aged <65 years and those who received SG as 2L had numerically better OS than other subgroups; however, the associations were statistically nonsignificant (Table 9).

Table 9. TROPSPAIN Cohort 1: Effectiveness Outcomes Overall and by Subgroups[12]

Effectiveness Outcome		Cohort 1 (N=87)	*P*-Value
OS, median (95% CI), months	Overall	9.3 (7.7–12.3)	-
	Aged <65 years (n=74)	10 (7.8–13.3)	0.3016
	Aged ≥65 years (n=13)	7.7 (2.4–12.3)	
	SG as 2L (n=23)	11.5 (6.8–14.2)	0.2954
	SG as 3+L (n=64)	9 (7.2–12.3)	
TTNTD, median (95% CI), months	Overall	4.5 (3.7–5.7)	-
	Aged <65 years (n=74)	4.5 (3.7–5.9)	0.8698
	Aged ≥65 years (n=13)	5.3 (2.3–7.7)	
	SG as 2L (n=23)	5.7 (3.7–8.3)	0.1269
	SG as 3+L (n=64)	4.3 (3.4–5.3)	

Most patients (86.2%) reported any-grade AE, and most AEs of interest were Grade 1 or 2 in severity (Table 10). No deaths related to SG treatment were reported.

Table 10. TROPSPAIN Cohort 1: Safety Outcomes and G-CSF Use[12]

Outcomes, n or n/N (%)	Cohort 1 (N=87)
Any-grade AE	75 (86.2)
Led to SG discontinuation	1 (1.3)
Led to SG dose reduction	24 (32)
Led to SG treatment interruption	26 (36.7)

Outcomes, n or n/N (%)		Cohort 1 (N=87)
AE of interest: diarrhea[a]	Any grade	35 (46.7)
	Grade 1	32 (57.1)
	Grade 2	19 (33.9)
	Grade 3	3 (5.4)
AE of interest: neutropenia	Any grade	33 (44)
	Grade 1	4 (7.4)
	Grade 2	19 (37.2)
	Grade 3	21 (41.2)
	Grade 4	7 (13.7)
G-CSF use during SG treatment	Primary prophylaxis	14/33 (42.4)
	Secondary prophylaxis	19/33 (57.6)

[a]Grade was unknown in 2 patients (3.6%) who reported diarrhea.
Note: AEs were defined by the Common Terminology Criteria for Adverse Events.

Multicenter Retrospective Study in China: Heavily Pretreated Patients[13]

A multicenter retrospective study in China evaluated the effectiveness and safety of SG in 58 patients with HER2- mBC treated with SG and who underwent their first radiological examination between June 2023 and October 2024. Forty-three patients (74.1%) had mTNBC. Overall, the median age was 53.4 years, and the patients had received a median (range) of 3 (1–10) prior systemic treatments for metastatic disease. Metastatic sites were as follows: liver, 55.2%; bone, 53.3%; lung, 41.4%; and brain, 22.4%.

Efficacy data are summarized in Table 11. OS data were immature at the time of publication; the Month 6 OS rate was 76.8%. Among the 4 patients with mTNBC who received SG with PD-1 inhibitors, the ORR was 50%.

Table 11. Multicenter Retrospective Study in China: Efficacy Overall and by Subgroup[13]

Efficacy Outcomes	Overall	mTNBC	Patients With Brain Metastases[a]
ORR, %	36.2	34.8[b]	30.7
DCR, %	81	79.1	–
PFS, median, months	3.9	4.2	6.3

[a]n=13. [b]Among the 4 patients with mTNBC who received PD-1 inhibitors with SG, the ORR was 50%.

Overall, the most common AEs and Grade ≥3 AEs were neutropenia in 53.5% and 17.2% of patients, respectively, and diarrhea in 22.4% and 6.9% of patients; febrile neutropenia was reported in 3.5% of patients. Prophylactic G-CSF was used in 34.5% of patients.

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Abbreviations

1L/2L/3L/4L=first-/second-/third-/fourth-line
2L+=second-line or later
3L+=third-line or later
5-HT3=5-hydroxytryptamine type-3
ADC=antibody-drug conjugate
ADC1/ADC2=first/second antibody-drug conjugate
AE=adverse event
BC=breast cancer
BMPos=positive for brain metastases
BRCA1/2=breast cancer gene 1/2
DCR=disease control rate
EAP=Early Access Program
ECOG PS=Eastern Cooperative Oncology Group Performance Status
ER=estrogen receptor
G-CSF=granulocyte colony-stimulating factor
HER2=human epidermal growth factor receptor 2
HR=hazard ratio
IHC=immunohistochemistry
ISH=in situ hybridization
mBC=metastatic breast cancer
MSE=Special Situation Medication program

mTNBC=metastatic triple-negative breast cancer
NE=not estimable
NK1=neurokinin 1
ORR=objective response rate
OS=overall survival
PARP=poly ADP (adenosine diphosphate) ribose polymerase
PD=progressive disease
PD-1=programmed death receptor-1
PD-L1=programmed death-ligand 1
PFS=progression-free survival
PIK3CA=phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit α
PR=partial response
PTEN=phosphatase and tensin homolog
SD=stable disease
SG=sacituzumab govitecan-hziy
T-DXd=trastuzumab deruxtecan
TNBC=triple-negative breast cancer
TOT2=time on treatment from the start of ADC1 to the last of ADC2 among those treated with 2 ADCs
TP53=tumor protein p53
TRAE=treatment-related adverse event
TTNTD=time to next treatment or death

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