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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.

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

This document summarizes real-world evidence on SG in mTNBC from multiple studies, focusing on patient characteristics, line of therapy (LOT), efficacy, and safety. It is not intended to be comprehensive; additional real-world evidence summaries are available for specific topics, including antibody-drug conjugate sequencing, use in Asian patients, and neutropenia incidence and management.

Summaries of real-world studies that evaluated SG use in patients with mTNBC are shown in Table 1.[2-21]

Table 1. Real-World Studies of Patients With mTNBC[2-21]

Region and Data Source	Pt Characteristics	SG Setting/ Prior LOT	Effectiveness Outcomes	Safety Outcomes
Retrospective cohort database study[2] England; Cancer Analysis System database (data sources: Systemic Anti-Cancer Therapy database, Cancer Outcomes and Services Dataset, and Office of National Statistics)	N=980; female, 100% 2L cohort (n=606) • Age, mean ± SD: 2L, 53.7±11.9 y; 3L, 53.1±11.4 y • ECOG PS 0 and 1,[a] n (%): 2L, 177 (29) and 276 (46), respectively; 3L, 67 (11) and 115 (19) 3L cohort (n=374) • Age, mean ± SD: 2L 55±12.6 y; 3L, 55.4±12.7 y • ECOG PS 0 and 1,[a] n (%): 2L, 140 (37) and 168 (45), respectively; 3L, 106 (28) and 171 (46)	SG LOT: 2L, n=606 3L, n=374 3L was composed of two subcohorts: $3L_a$ (Stage I or II, or resectable Stage III TNBC) and $3L_m$ (unresectable Stage III or de novo Stage IV TNBC)	mPFS (95% CI), mo: 2L, 2.53 (2.3–2.76) 3L, 2.43 (2.2–2.76) mOS (95% CI), mo: 2L, 6.7 (6.14–7.62) 3L, 5.54 (4.9–6.14) Results are available for 3L subcohorts	Safety data not reported
Retrospective, observational, multicenter study[3,4] Canada; pt support program	N=453 • Age, mean (IQR): 57 (49–66) y	SG LOT: 2L, 29.4% 3L, 42.8% 4L, 16.6% 5L+, 11.3%	Treatment duration, median (95% CI), mo: 4.2 (3.7–4.9) Effectiveness data not reported	Treatment modifications: • Treatment delays, 78.4% • Number of delays, median (range): 3 (1–18) • Duration of delays (n=355), median (IQR): 23 (9–49) d • ≥1 dose reduction, 55% SG DCs (including DCs due to AEs), n (%): Pt decision, 12 (3.7); Physician decision, 10 (3.1)

Region and Data Source	Pt Characteristics	SG Setting/ Prior LOT	Effectiveness Outcomes	Safety Outcomes
Retrospective study[5] US; Integra Connect Precision-Q database	N=409; female, 99.3% • Age, median (range): 61 (28–89) y • ECOG PS 0–1, n (%): 286 (69.9) • Metastatic sites, n (%): visceral (lung or liver), 300 (73.4); bone, 216 (52.8); brain, 87 (21.3)	SG LOT, n (%): 2L, 192 (46.9) 3L, 128 (31.3) 4+, 89 (21.8) SG used in multiple LOTs, 21 (5.1)	Follow-up, median (range), mo: 10 (0.6–51.3) mPFS (95% CI), mo: • 5 (4.4–5.5) • 3-mo rate: 66.8 (62–71.2) • 6-mo rate: 42.4 (37.5–47.2) mOS (95% CI), mo: • 11.3 (10–12.8) • 12-mo rate: 47.5% (42.4–52.4%) • 24-mo rate: 22.5% (17.8–27.5%) mTTNTD (95% CI), mo: 6 (5.3–6.6)	Most common AEs: fatigue, 47.4%; diarrhea, 38.1%; neutropenia, 34.7%; nausea, 32% Treatment modifications: • Dose reduction rate, 43.1% (no appreciable differences by LOT) • Dose delay (by ≥7 d), 65% • Time to the first dose delay, median (range) d: 13.5 (1–682) • Of pts with dose delay, 51.9%, 11.3%, 9%, and 27.8% had their first dose delay in Cycle 1, 2, 3, and 4+, respectively Neutropenia, n (%): 281 (68.7); median time to onset: 8 d G-CSF use, n (%): 247 (60.4) • Primary prophylaxis, 88 (21.5) • Secondary prophylaxis, 112 (27.4) • Treatment for neutropenia, 47 (11.5)
Retrospective, observational cohort study[6] US; Flatiron Health database	N=381; female, 99% • Age, median (IQR): 61 (52–69) y • ECOG PS 0–1, n (%): 247 (65) • Brain metastasis (of pts with ≥1 metastasis site), n/N (%): 68/291 (23)	SG LOT, n (%): 2L, 118 (31) 3L+, 263 (69)	Follow-up, median (IQR), mo: 8.7 (4.5–14.6) mOS (95% CI), mo: • 11.3 (10–12.9) • 12-mo rate: 47% (41–52%) • 24-mo rate: 19% (14–25%) mTTNTD (95% CI), mo: 5.6 (5–6.4)	Treatment modifications: Dose reductions, n/N (%): 137/308 (44) Neutropenia, n (%): • Grade 2, 94 (25); Grade 3/4, 101 (27) G-CSF use, n (%): • Any concomitant use, 225 (59) • Grade 3/4 neutropenia with G-CSF, 10% • Of pts who received G-CSF prophylaxis, Grade 3/4 neutropenia occurred in 4% with primary prophylaxis, 33% who received G-CSF as treatment, and 13% who received no G-CSF
Retrospective cohort study[7] Poland/Czech Republic/Slovakia (14 centers)	N=249; female, 100% • Age, median (IQR): 53 (46–63) y	Prior LOTs, median (IQR): 2 (1–2)	Follow-up, median (IQR), mo: 7.82 (4.29–12.01) Outcome (95% CI), mo: mPFS, 4.1 (2.9–5.3) mOS, 10.3 (9.4–11.2) ORR: 31.4%	Treatment modifications Delays, 60.2% Dose reductions, 41.5%

Region and Data Source	Pt Characteristics	SG Setting/ Prior LOT	Effectiveness Outcomes	Safety Outcomes
Retrospective, observational cohort study[8] US; ConcertAI Patient 360™ and physician notes	N=230; female, 100% • Age, median (IQR): 60 (49–69) y • ECOG PS 0–1, n (%): 162 (70) • Metastatic sites, n (%): visceral, 167 (73); brain, 17 (7)	SG LOT: 2L, 33% 3L+, 67%	Follow-up, median: 7.2 mo mOS (95% CI), mo: • 2L+, 10 (8.3–11.1) • 2L, 13.9 (9.8–NE) • 3L+, 8.4 (7.7–10.3) mPFS (95% CI) mo: • 2L+, 3.8 (3.1–4.3) • 2L, 4.9 (2.9–6) • 3L+, 3.5 (2.7–4.2) mTTNTD (95% CI), mo: • 2L+, 4.6 (3.9–5.3) • 2L, 4.8 (3.2–6.9) • 3L+, 4.4 (3.8–5.5)	Toxicities: Fatigue, 45%; neutropenia, 33%; and diarrhea, 30% Toxicity led to, n (%): SG DC, 17 (7); SG dose reduction, 59 (26); SG treatment interruption, 89 (39) G-CSF use, n (%): • Prior to SG treatment, 99 (43) • First use during SG treatment, 35 (15) Time from SG initiation to G-CSF use (among pts receiving G-CSF during SG use), median (IQR): 8.5 (8–29) d
Retrospective, observational, SACISUR study[9,21] Spain (18 hospitals)	N=159; female, 100% • Age, median (IQR): 53 (21–77) y • Metastatic sites, n (%): visceral, 120 (76.9); CNS, 22 (13.8)	Previous LOT, median (range): 3 (2–8) SG LOT: 1L, 3.8% 2L, 41.5% 3L+, 54.1%	Follow-up, median: 11.6 mo Outcome (95% CI), mo: mPFS, 4.6 (3.7–6.3) mOS, 10.9 (7.6–14.2) ORR (CR or PR): 31.2% DCR: 68.9% Results are available for BMPos cohort	Most common AEs (Grade 3/4): • Neutropenia, 59.4% (30.4%) • Diarrhea, 49% (8.2%) • Nausea, 45.3% (0.6%) • ALT/AST elevation, 24.5% (1.9%) AEs led to: • ≥1 SG dose reduction: 43.4% • SG DC: 5.7% G-CSF use: • Primary prophylaxis, 29.6% • Secondary prophylaxis, 17.6%
Retrospective study[10,11] Italy (11 centers)	N=149; female, 100% • Age, median (range): 53 (26–80) y • ECOG PS 0–1: 96% • Metastatic sites, n (%): lymph nodes, 97 (65.1); lung, 75 (50.3); bone, 74 (49.7)	Prior anticancer regimens in metastatic setting median (range): 2 (0–7)	Follow-up, median: 18.2 mo Outcome (95% CI) mo: mPFS, 5.75 (4.37–7.13) mOS, 12.8 (10.8–15.9) ORR: 40% (all were PR)	Select TRAEs, any grade (Grade 3/4): • Neutropenia, 53% (26.2%) • Anemia, 50.3% (0.7%) • Nausea, 50.3% (0%) • Diarrhea, 40.9% (3.4%) SG dose decreased, 34.9% SG DC, 4%

Region and Data Source	Pt Characteristics	SG Setting/ Prior LOT	Effectiveness Outcomes	Safety Outcomes
Retrospective study[12] UK (16 centers)	N=132; female, 99.2% • Age, median (range): 56 (28–91) y • ECOG PS 0–1, n (%): 115 (87.5) • Metastatic sites, n (%): nodal, 102 (77); visceral, 99 (75); bone, 63 (48); liver, 61 (46); CNS, 24 (18)	Prior LOT in metastatic setting, median: 2 SG LOT: 2L, 28% 3L 31% 3L+, 41%	Survival analysis population, n=126 mPFS (95% CI) mo: • 5.2 (4.5–6.6) • 1L/2L, 5.3 (4.4–7) • 3L+, 5 (3.7–6.4) mOS (95% CI), mo: • 8.7 (6.8–NA) • 1L/2L, NR • 3L+, 8.7 (6.8–11.2)	Most common AEs, all grade (Grade 3/4): • Fatigue, 82% (14%) • Neutropenia, 55% (29%) • Diarrhea, 58% (15%) • Nausea, 38% (3%) Treatment modifications due to AEs led to SG dose reduction, 54% SG DC, 5%
Retrospective and prospective, observational SARELIFE study[13] Italy (30 centers)	N=128; female, 100% • Age median (range): 58 (30–86) y • ECOG PS, n (%): 0, 78 (60.9); 1, 37 (28.9) • Metastases at diagnosis, n (%): overall, 32 (25); lymph nodes, 89 (69.5); bone, 54 (42.2); lung, 54 (42.2); liver, 37 (28.9); CNS, 16 (12.5); pleura, 15 (11.7)	Prior LOT, median (range): 2 (0–9) 1 or 2 prior LOTs: 67.2% >2 prior LOTs: 32.8%	Follow-up, median: 12.7 mo Outcome (95%CI), mo: mPFS, 5.9 (4.5–6.8) mOS, 14.6 (11.7–17) ORR: 31.9% Best response (evaluable, n=116): CR, 0.9%; PR, 31%; SD, 38.8%; PD, 29.3%	Most common AEs (safety analysis, n=122): • Neutropenia, 51.2% • Fatigue, 47.6% • Nausea, 43.9% • Diarrhea, 34.1% • Anemia, 28% • Febrile neutropenia, 6.1% Grade 3 pneumonitis, n=1 Dose reductions, n=46 AEs led to SG DC, n=4 Time to first dose reduction, median (range): 32 (7–205) d
Retrospective study[14,15] France (8 centers)	N=127 • Age, median (range) at metastasis (n=117): 53 (25–80) y • Visceral metastases, n (%): 77 (60.6)	Prior LOT in metastatic setting, median (range): 2 (0–11)	Follow-up, median (95% CI), mo: 10.4 (8.3–11.2) Outcome (95% CI), mo: mPFS, 4.1 (3.7–4.7) mOS, 9.7 (7.1–12.2) Best response (n=116): CR, 2.6%; PR, 33.6%; SD ≥6 mo, 39.7%; PD, 24.1%	Safety data not reported

Region and Data Source	Pt Characteristics	SG Setting/ Prior LOT	Effectiveness Outcomes	Safety Outcomes
Retrospective, single-center study[16] US; Memorial Sloan Kettering Cancer Center	N=126; female, 99% • Age, median (range): 52 (27–86) y • Metastatic sites, n (%): visceral, 88 (70); CNS, 29 (23)	Prior LOT in metastatic setting, median (range): 2 (0–8)	Outcomes (range), mo: mPFS, 3 (0–13) mOS, 6 (0–33)	Most common AEs: • Hematologic, 18% • Gastrointestinal, 11% • Fatigue, 9% AEs led to SG dose reduction, 31%
Retrospective study[17] US (4 centers)	N=115; female, 100% • Age, median (range): 60 (31–85) y • ECOG PS, median (range): 1 (0–2) • Metastatic sites, n (%): bone, 64 (55.7); lung, 62 (53.9); liver, 58 (50.4); lymph nodes, 55 (47.8); brain, 25 (21.7)	Prior LOT in metastatic setting, n (%): ≤3L, 81 (70.4) >3L, 34 (29.6)	Follow-up, median: 16.1 mo mOS (95% CI), mo: • 9.6 (7.8–12.9) • 1-yr rate: 43% (33–52%) mPFS (95% CI), mo: 4.8 (3.6–5.9) ORR: 27.8% CR, 1%; PR, 26.8%; SD for ≥6 mo, 35%; PD, 37.1%	Most common (≥20%) any grade AEs, (Grade 3/4): • Neutropenia, 68% (41%) • Anemia, 71% (31%) • Fatigue, 57% (10%) • Nausea, 38% (8%) • Diarrhea, 38% (8%) • Febrile neutropenia, 23% (6%) • Constipation, 20% (0) AEs led to, n (%): SG dose reduction, 58 (51.3) SG DC, 15 (13.2) G-CSF use, n (%): After starting SG, 54 (47) Primary support, 26 (22.6) Secondary prophylaxis, 28 (24.3)
Multicenter TRACIE study[18] Australia EAP and reimbursed pts; interim analysis (17 sites)	N=112 • Age, median (IQR): 54.5 (49.5–64.5) y; • ECOG PS 0–1: 71.5% • Most common metastatic sites: lymph nodes, 58.9%; liver, 42%; lung, 29.5%	Prior LOT in metastatic setting: ≥2L, 62.5%	Follow-up, median: 25.3 mo Outcome (95% CI), mo: mPFS, 9.5 (8.4–11.5) mOS, 13.1 (9.5–17.5) mTTNT, 6.2 (5.2–8)	Most common AEs: • Diarrhea, 9.8% • Neutropenia, 5.4% • Fatigue, 4.5% Toxicities led to: • SG dose reduction, 23.3% • SG DC, 9.8% AEs that led to SG DC: nausea (4.5%); neutropenia (3.6%); and anemia, fatigue, and diarrhea (each, 2.7%). G-CSF use: primary prophylaxis, 7.1%; secondary prophylaxis, 32.1%

Region and Data Source	Pt Characteristics	SG Setting/ Prior LOT	Effectiveness Outcomes	Safety Outcomes
Ambispective, bicentric cohort study[19] France EAP	N=103; female, 100% • Age, median (range): 55 (26–89) y • ECOG PS 0–1, n (%): 83 (80.6) • Metastatic sites, n (%): visceral, 82 (79.6); liver, 45 (43.7); brain, 32 (31.1)	Prior LOT in advanced setting, n (%): 1–2L, 66 (64.1) >2L, 37 (35.9)	Follow-up, median: 9.6 mo Outcome (range), mo: mPFS, 4 (3.5–5.3) mOS, 9.2 (7.2–NR) ORR, n (%): 31 (30.1) • CR, 2 (1.9) • PR, 29 (28.2) Results available for BMPos pts	Toxicity led to, n/N (%): • SG DC, 1/78 (1.3) • SD dose reduction, 19/103 (16.4) Most common toxicities that led to SG dose reduction, n/N (%): • Hematological, 8/19 (42.1) • Gastrointestinal, 6/19 (31.6) • Febrile neutropenia, 3/19 (26.3)
Retrospective, observational study: TROPSPAIN[20] Spain Cohort 1 (SG in the Special Situation Medication program; 18 sites)	N=87; female, 100% • Age, median (IQR): 51 (44–61) y • ECOG PS 0–1, n (%): 58 (66.7) • Most common metastatic sites, n (%): lymph nodes, 41 (47.1); bone, 37 (42.5); lung, 33 (37.9)	SG LOT: 2L, 26.4% 3L in 24.1% ≥4L in 49.4% Number of prior LOT median (IQR): 2 (1–4).	Interim analysis Follow-up, median (IQR), mo: 9.2 (5.2–15.3) Outcome (95% CI), mo: mOS, 9.3 (7.7–12.3) mTTNTD, 4.5 (3.7–5.7)	AEs of interest, any grade (Grade 3/4): Diarrhea,[b] 46.7% (5.4%) Neutropenia, 44% (54.9%) Any-grade AE led to, n (%): • SG DC, 1 (1.3) • SG dose reduction, 24 (32) • SG treatment interruption, 26 (36.7) G-CSF use for prophylaxis, n/N (%): primary, 14/33 (42.4); secondary, 19/33 (57.6)

Abbreviations: 1L/2L/3L/4L=first-/second-/third-/fourth-line; 2L+/3L+/4L+/5L+=second-/third-/fourth-/fifth-line or later; AE=adverse event; BC=breast cancer; BMNeg=negative for brain metastases; BMPos=positive for brain metastases; CNS=central nervous system; CR=complete response; DC=discontinuation; DCR=disease control rate; EAP=Early Access Program; ECOG PS=Eastern Cooperative Oncology Group Performance Status; G-CSF=granulocyte colony-stimulating factor; HR=hazard ratio; LA=locally advanced; LOT=line of therapy; mOS=median overall survival; mPFS=median progression-free survival; mTNBC=metastatic triple-negative breast cancer; mTTNTD=median time to next treatment or death; NA=not available; NE=not estimable; NR=not reached; ORR=objective response rate; OS=overall survival; PD=progressive disease; PFS=progression-free survival; PR=partial response; SD=stable disease; pt=patient; SG=sacituzumab govitecan-hziy; TNBC=triple-negative breast cancer; TPC=treatment of physician's choice; TRAE=treatment-related adverse event.

[a]ECOG PS was missing/unknown at BC diagnosis in 377, 254, 211, and 43 pts in the 2L, 3L combined, $3L_a$, and $3L_m$ cohorts, respectively; at initiation in 78 and 45 pts in the 2L and 3L combined cohorts; and at initiation of 3L in 394 pts in the 2L cohort.

[b]Grade was unknown in 2 pts (3.6%) who reported diarrhea.

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