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Trodelvy® (sacituzumab govitecan-hziy) Use in 1L PD-(L)1 Inhibitor-Ineligible mTNBC

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and its use as first-line (1L) treatment in patients with locally advanced unresectable or metastatic triple-negative breast cancer (mTNBC) who are ineligible for programmed death-(ligand) 1 (PD-[L]1) inhibitors.

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Trodelvy is not indicated for use as 1L treatment in patients with PD-(L)1 inhibitor ineligible mTNBC. The full indication, important safety information, and boxed warnings for neutropenia and diarrhea are available at: www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.

Summary

Clinical Data on SG in 1L PD-(L)1 Inhibitor-Ineligible mTNBC

ASCENT-03, an ongoing, global, open-label, randomized, phase 3 study, compares the efficacy and safety of SG vs chemotherapy TPC (eg, gem + carbo, paclitaxel, or nab-paclitaxel), as 1L treatment in patients (N=558) with previously untreated, locally advanced, inoperable or mTNBC who are not candidates for PD-(L)1 inhibitor therapy.[1]

- SG prolonged PFS by BICR per RECIST v1.1 (primary endpoint) vs TPC (9.7 vs 6.9 mo; HR 0.62 [95% CI 0.5–0.77] *P*<0.001).[1]
  - A higher proportion of patients treated with SG vs TPC were alive and progression-free at 6 mo, 65% (95% CI 59–71) vs 53% (95% CI 47–59), and at 12 mo, 41% (95% CI 34–47) vs 24% (95% CI 19–30).
  - Median follow-up at the data cutoff was 13.2 mo (range, <0.1–29.2).
- Results for OS were immature at the time of the primary analysis and are descriptive only; a numerical trend in favor of SG vs PFS was observed (21.5 mo [95% CI 17.7–NR] vs 20.2 mo [18.2–NR], respectively). Further follow-up for OS is ongoing.[1] An ORR of 48% was observed in patients receiving SG vs 46% for TPC (OR 1.12; 95% CI 0.8–1.57). DOR (95% CI) with SG vs TPC was 12.2 (9.7–13.8) mo vs 7.2 (5.7–8.4) mo, respectively. Formal statistical analyses of these results were not conducted at this time.[1]
- The most common Grade ≥3 TEAEs for SG and TPC, respectively, were neutropenia (43 vs 41%), anemia (4 vs 16%), leukopenia (7 vs 13%), thrombocytopenia (1 vs 12%), and diarrhea, (9 vs 1%).[1]
- In the SG vs TPC arm, treatment-emergent SAEs were 26 vs 24%; of these SAEs, treatment-related SAEs were 17 vs 13%, respectively.[1,2]

- Incidence of TEAEs that led to treatment discontinuation was 4% with SG and 12% with TPC. Neutropenia led to treatment discontinuation in 1 and 3 patients in the SG and TPC arms, respectively; diarrhea led to treatment discontinuation in 1 patient treated with SG. No case of diarrhea led to treatment discontinuation in the TPC arm.[1]
- Primary prophylaxis of G-CSF was associated with less frequent and severe neutropenia in the SG arm.[3]
- A total of 137 and 35 patients received antidiarrheal treatment in the SG and TPC arms, respectively; loperamide was the most common treatment in both arms (SG: 90% vs TPC: 77%). For both treatments, multi-antidiarrheal regimens were used in 20% of patients that received any antidiarrheal treatment.[3]
- There were six treatment-related deaths due to infection in the SG arm; five were secondary infections due to neutropenia in patients who had risk factors for febrile neutropenia but did not receive prophylaxis with G-CSF; these events occurred early in treatment. A case of pneumonia showed no evidence of preceding or concurrent neutropenia. In the TPC arm, there was one treatment-related death due to pleural effusion.[1,3]
- Results from an exploratory safety analysis of EAIRs, which adjusted rates of TEAEs by treatment exposure, are described below.[3]
- In a post hoc analysis, the median PFS2 (95% CI) was significantly longer with SG than with TPC (18.2 [15.9–NR] mo vs 14 [12.5–17.4] mo, respectively), with a 30% reduction in the risk of a PFS2 event (stratified HR 0.7; 95% CI 0.55–0.9). For 2L therapy, most patients in the SG arm received chemotherapy, including PLT agents and taxanes, and most patients in the TPC arm received SG. Patients who received SG had a longer median TFST than those who received TPC (stratified HR 0.61; 95% CI 0.5–0.75); however, the median TSST was similar between treatment arms (stratified HR 0.82; 95% CI: 0.64–1.05).[4]

Clinical Data on SG in 1L PD-(L)1 Inhibitor-Ineligible mTNBC

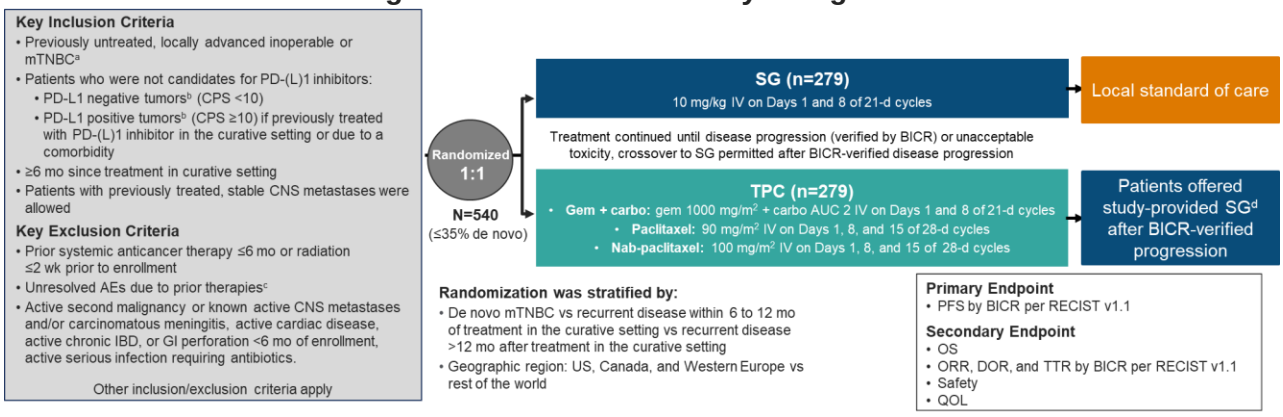
ASCENT-03 Study

Study design and demographics

ASCENT-03, an ongoing, global, open-label, randomized, phase 3 study compares the efficacy and safety of SG vs TPC as 1L treatment in patients (N=558) with previously untreated, locally advanced inoperable or mTNBC who were ineligible for PD-(L)1 inhibitor therapy (Figure 1).[1]

The study enrolled patients whose tumors did not express PD-L1 (PD-L1 negative tumors [CPS <10]) and patients who did express PD-L1 (PD-L1 positive tumors [CPS ≥10]) if they received prior PD-(L)1 inhibitor therapy in the (neo)adjuvant setting or had a comorbidity preventing treatment with a PD-(L)1 inhibitor (see Table 1 for further baseline demographics and disease characteristics). Patients must have had ≥6 mo between the completion of curative intent systemic treatment in the (neo)adjuvant setting and first documented local or distant disease recurrence. The primary endpoint is PFS by BICR per RECIST v1.1.[1]

Figure 1. ASCENT-03: Study Design[1,2,4,5]



Abbreviations: AUC=area under the concentration-time curve; CNS=central nervous system; GI=gastrointestinal; IBD=inflammatory bowel disease; TTR=time to onset of response.
[a]Centrally confirmed and determined according to American Society of Clinical Oncology–College of American Pathologists criteria.
[b]PD-L1 (IHC 22C3 assay) and triple-negative breast cancer status centrally confirmed.
[c]Any-grade neuropathy and alopecia were allowed.
[d]Patients were permitted to receive commercial SG or other treatments in later lines.

In the statistical testing hierarchy, OS will be formally tested for significance once PFS is statistically significant, followed by ORR and QOL endpoints (once the prior endpoint in the hierarchy was significant).[2]

Table 1. ASCENT-03: Baseline Demographics and Disease Characteristics[1]

Select Demographics and Characteristics		SG (n=279)	TPC (n=279)
Age, median (range), y		56 (28-84)	54 (23-86)
Age ≥65, n (%)		65 (23)	78 (28)
Sex, n (%)	Female	278 (>99)	277 (99)
Race or ethnic group, n (%)[a]	White/Asian/Black	178 (64)/66 (24)/10 (4)	178 (64)/65 (23)/7 (3)
	Other or not specified	25 (9)	29 (10)
Geographic region, n (%)[b]	US/Canada/Western Europe	89 (32)	89 (32)
	Rest of the world	190 (68)	190 (68)
ECOG PS, n (%)	0/1	183 (66)/96 (34)	187 (67)/92 (33)
PD-L1 negative status, n (%)[c]		277 (99)	278 (>99)
Disease status, n (%)[d]	Metastatic at initial diagnosis	87 (31)	88 (32)
	Recurrent within 6–12 mo[e]	58 (21)	57 (20)
	Recurrent >12 mo[e]	134 (48)	134 (48)
Metastatic sites, n (%)	Lymph node	179 (64)	180 (65)
	Lung	166 (59)	170 (61)
	Bone	95 (34)	87 (31)
	Liver	81 (29)	72 (26)
	Brain	15 (5)	14 (5)
	Other	98 (35)	84 (30)
Prior (neo)adjuvant therapies, n (%)	Taxane	162 (58)	162 (58)
	PLT agents	51 (18)	49 (18)
	Cape	50 (18)	57 (20)
	PD-(L)1 inhibitors	13 (5)	11 (4)

Select Demographics and Characteristics	SG (n=279)	TPC (n=279)
Time since diagnosis of metastatic or LA unresectable disease to randomization, median (range), mo	1.9 (0.4–26.7)	1.9 (0.1–18.9)

Abbreviations: ECOG PS=Eastern Cooperative Oncology Group Performance Status; LA=locally advanced.
[a]Patient reported. [b]Western Europe: Austria, Belgium, France, Germany, Italy, Netherlands, Spain, Switzerland, and United Kingdom. Rest of the world: Argentina, Australia, Brazil, Chile, China, Czech Republic, Hong Kong, Hungary, Israel, Japan, Malaysia, Mexico, Poland, South Korea, Romania, Slovakia, South Africa, Taiwan, and Turkey.
[c]PD-L1 status assessed using the PD-L1 IHC 22C3 assay (Dako, Agilent Technologies) at the time of enrollment; one patient in each treatment arm was considered PD-L1 positive. One patient in the SG arm had PD-L1 CPS missing.
[d]From completion of treatment in the curative setting.
[e]Corresponding numbers: SG: 86 de novo, 59 recurrent disease within 6 to 12 mo, 134 recurrent disease >12 mo; TPC: 83 de novo, 62 recurrent disease within 6 to 12 mo, 134 recurrent disease >12 mo.

Efficacy

Primary endpoint

A total of 349 PFS events were observed at the at the time of the primary analysis. SG significantly improved median PFS vs TPC with a 38% reduction in the risk of disease progression or death, and a higher proportion of patients alive and progression-free at the 6- and 12-mo timepoints (Table 2).[1]

Table 2. ASCENT-03: Primary Endpoint[1]

			SG (n=279)	TPC (n=279)
BICR	PFS, median (95% CI), mo		9.7 (8.1–11.1)	6.9 (5.6–8.2)
	Stratified HR (95% CI); *P*-value		0.62 (0.5–0.77); <0.001	
	PFS rate, % (95% CI)	6-mo	65 (59–71)	53 (47–59)
		12-mo	41 (34–47)	24 (19–30)

Secondary endpoints

At the data cutoff for the final PFS analysis, results for OS were immature and are descriptive only; a numerical trend in favor of SG vs TPC was observed (21.5 mo [17.7–NR] vs 20.2 mo [18.2–NR], respectively).[1]

Statistical testing was not conducted for subsequent endpoints in the statistical hierarchy, as the statistical boundary for OS was not crossed, results of these endpoints can therefore only be described descriptively. ORR (95% CI) was 48% (42–54) with SG vs 46% (40–52) with TPC (OR, 1.12; 95% CI: 0.8–1.57). DOR (95% CI) was 12.2 (9.7–13.8) mo vs 7.2 (5.7–8.4) mo with SG vs TPC, respectively.[1]

Safety

The median duration (range) of treatment at the time of the final PFS analysis with SG, taxane, and gem + carbo was 8.3 (<0.1–28.7) mo, 6.3 (<0.1–24.2) mo, and 5.8 (<0.1–23.1) mo, respectively.[1]

The number of patients with TEAEs (any-grade, Grade ≥3, and SAEs) was similar across treatment arms (Table 3). In the SG and TPC arms, TEAEs which resulted in dose interruption, dose reduction, and those which lead to treatment discontinuation occurred in 66% vs 62%, 37% vs 45%, and 4% vs 12% of patients, respectively.[1]

In the SG arm, there were seven deaths due to TEAEs (Table 3); 6 deaths were deemed to be treatment-related (neutropenic colitis [n=1], pneumonia [n=1], and sepsis [n=4]). A single

case of acute respiratory failure was not deemed to be treatment-related. All treatment-related deaths in the SG arm were due to infections; five were due to infections secondary to neutropenia, in patients who had risk factors for febrile neutropenia but did not receive prophylaxis with G-CSF; these events occurred early in treatment (two patients on Day 26 [Cycle 2] and one patient each on days 14, 15, and 21 [Cycle 1]). A case of pneumonia showed no evidence of preceding or concurrent neutropenia. In the TPC arm, there was one death due to pleural effusion, this was deemed to be treatment-related.[1,3]

Table 3. ASCENT-03: Safety Summary[1,2]

Safety Outcomes, n (%)	SG (n=275)	TPC (n=276)
Any TEAE	273 (99)	269 (97)
Grade ≥3	181 (66)	171 (62)
Treatment-emergent SAE	71 (26)	67 (24)
Treatment-related SAE	46 (17)	37 (13)
TEAEs that led to treatment discontinuation	10 (4)	33 (12)
TEAEs that led lead to dose interruption	181 (66)	171 (62)
TEAEs that led to dose reduction	101 (37)	124 (45)
TEAEs that led to death	7 (3)	1 (<1)
Treatment-related death	6 (2)	1 (<1)

The most common any-grade and Grade ≥3 adverse events are presented in Table 4.

Table 4. ASCENT-03: Any-Grade TEAEs (≥15%) and Grade ≥3 TEAEs (≥5%)[a1]

TEAEs, n (%)	SG (n=275)		TPC (n=276)	
	Any-Grade	Grade ≥3	Any-Grade	Grade ≥3
Neutropenia[b]	183 (67)	118 (43)	157 (57)	112 (41)
Nausea	167 (61)	5 (2)	95 (34)	1 (<1)
Alopecia[c]	151 (55)	-	75 (27)	-
Diarrhea	148 (54)	25 (9)	55 (20)	2 (1)
Fatigue[d]	130 (47)	9 (3)	129 (47)	11 (4)
Anemia[e]	107 (39)	12 (4)	138 (50)	45 (16)
Constipation	104 (38)	0	68 (25)	0
Leukopenia[f]	70 (25)	20 (7)	70 (25)	35 (13)
Vomiting	69 (25)	5 (2)	35 (13)	4 (1)
ALT increased	56 (20)	9 (3)	81 (29)	17 (6)
Cough	49 (18)	0	35 (13)	1 (<1)
Decreased appetite	48 (17)	2 (1)	27 (10)	1 (<1)
AST increased	47 (17)	3 (1)	69 (25)	7 (3)
Headache	47 (17)	1 (<1)	33 (12)	0
Stomatitis	42 (15)	3 (1)	18 (7)	0
Abdominal pain	41 (15)	2 (1)	16 (6)	0
Thrombocytopenia[g]	12 (4)	2 (1)	78 (28)	33 (12)

[a]TEAEs began on or after the first dose date of study drug and ≤30 d after the last dose date of study drug (including crossover treatment if applicable) or the initiation of subsequent anticancer therapy, whichever occurred first. AEs were coded according to preferred terms in the Medical Dictionary for Regulatory Activities, v27.1, and graded for severity according to the National Cancer Institute Common Terminology Criteria for Adverse Events, version 5.0.
[b]Includes preferred terms of neutropenia and neutrophil count decreased.
[c]Is Grade 1 or 2 per National Cancer Institute Common Terminology Criteria for Adverse Events, v5.0.
[d]Includes preferred terms of fatigue and asthenia.
[e]Includes preferred terms of anemia, Hgb decreased, and RBC decreased.
[f]Includes preferred terms of leukopenia and WBC count decreased.
[g]Includes preferred terms of thrombocytopenia and platelet count decreased.

Time to onset and duration of neutropenia and diarrhea[3]

Median time to onset of any-grade and Grade ≥3 diarrhea was shorter for patients treated with SG vs TPC (Table 5). Median duration of diarrhea and neutropenia was generally comparable between treatment arms. These results should be interpreted with caution due to small sample sizes in the TPC arm for time to onset and duration of any-grade and Grade ≥3 diarrhea, and due to the small sample size in the SG arm for time to onset and duration of ≥3 diarrhea.

Table 5. ASCENT-03: Time to Onset and Duration of Neutropenia and Diarrhea[3]

		SG (n=275)				TPC (n=276)			
		Any-Grade		Grade ≥3		Any-Grade		Grade ≥3	
		n	Days (range)	n	Days (range)	n	Days (range)	n	Days (range)
Median time to onset[a]	Neutropenia	187	22 (6–274)	124	22 (7–720)	158	22 (6–406)	113	29 (7–295)
	Diarrhea	148	13 (1–427)	25	67 (6–356)	55	26 (1–296)	2	210 (110–310)
Median duration[b]	Neutropenia	183	9 (2–49)	122	8 (1–36)	155	14 (1–179)	112	8 (1–25)
	Diarrhea	130	6 (1–273)	24	6 (1–18)	48	6 (1–370)	2	1 (1–1)

[a]Defined as time from first dose date of study drug to onset date of first TEAE.
[b]Defined as the median duration among multiple preferred terms; within each preferred term, duration is median duration among multiple episodes (end date of TEAE – onset date of TEAE + 1 d for each episode).

Management of neutropenia[3]

The use of G-CSF as primary prophylaxis was associated with less frequent and less severe neutropenia in the SG arm (Table 6). Neutropenia led to dose reduction in 54 (20%) patients in both arms and treatment discontinuation in 1 (<1%) and 3 (1%) patients in the SG and TPC arms, respectively.

Table 6. ASCENT-03: Management of Neutropenia[3]

Neutropenia, n (%)	SG (n=275)		TPC (n=276)	
Primary G-CSF prophylaxis	Yes (n=54)	No (n=221)	Yes (n=28)	No (n=248)
Any-Grade	28 (52)	159 (72)	21 (75)	137 (55)
Grade ≥3	15 (28)	109 (49)	14 (50)	99 (40)
Secondary G-CSF prophylaxis[a]	Yes (n=81)	No (n=75)	Yes (n=51)	No (n=85)
Any-Grade	46 (57)	52 (69)	38 (75)	50 (59)
Grade ≥3	30 (37)	20 (27)	29 (57)	39 (46)

[a]Excludes patients that received primary G-CSF prophylaxis.

Management of diarrhea[3]

Across treatment arms, most cases of diarrhea were Grade 1–2 (SG: 45% vs TPC: 19%, respectively).

A total of 137 (50%) and 35 (13%) patients received antidiarrheal treatment in the SG and TPC arms, respectively; loperamide was the most common treatment in both arms (SG: 90% vs TPC: 77%). In both treatment arms, multi-antidiarrheal regimens were used in 20% of patients that received any antidiarrheal treatment. Diarrhea led to dose reduction in 15 (5%) patients and to treatment discontinuation in 1 (<1%) patient treated with SG; 3 (1%) cases led to dose reduction. No case of diarrhea led to treatment discontinuation with TPC.

Exploratory analysis: EAIRs[3]

EAIRs, defined as the number of patients with ≥1 specified TEAE per PYE, were calculated as the number of patients with a specific TEAE divided by the total PYE in each group; PYE was defined as the sum of each patient's time at risk (exposure duration) within the study. Due to the exploratory nature of this post hoc analysis, all results presented in Table 7 should be considered nominal.

Any-grade EAIR (95% CI) for SG vs TPC was 40.21 (35.58–45.27) vs 21.66 (19.14–24.4), respectively. Compared with TPC, the incidence of diarrhea remained higher for SG when adjusted for treatment exposure; compared with SG, the incidence of anemia, thrombocytopenia, and peripheral neuropathy remained higher for TPC when adjusted for treatment exposure.

Table 7. ASCENT-03 Exploratory analysis: EAIRs[3]

TEAEs	SG (n=275)		TPC (n=276)		EAIR Difference (95% CI)
	n (%)	EAIR (95% CI)	n (%)	EAIR (95% CI)	
Grade ≥3	181 (66)	1.85 (1.59, 2.14)	171 (62)	2.02 (1.73, 2.35)	-0.18 (-0.59, 0.23)
SAE	71 (26)	0.4 (0.31, 0.51)	67 (24)	0.49 (0.38, 0.63)	-0.09 (-0.25, 0.06)
Led to dose interruption	181 (66)	2.05 (1.76, 2.37)	171 (62)	2.14 (1.83, 2.48)	-0.09 (-0.54, 0.36)
Led to dose reduction	101 (37)	0.68 (0.55, 0.82)	124 (45)	1.15 (0.96, 1.37)	-0.48 (-0.73, -0.23)
Led to treatment discontinuation	10 (4)	0.05 (0.02, 0.09)	33 (12)	0.22 (0.15, 0.3)	-0.17 (-0.26, -0.09)
Led to death	7 (3)	0.03 (0.01, 0.07)	1 (<1)	0.01 (0, 0.04)	0.03 (-0.01, 0.07)
Neutropenia	183 (67)	2.48 (2.13, 2.87)	157 (57)	2.01 (1.71, 2.35)	0.47 (-0.02, 0.96)
Febrile neutropenia	12 (4)	0.06 (0.03, 0.11)	3 (1)	0.02 (0, 0.06)	0.04 (0, 0.09)
Anemia	107 (39)	0.77 (0.63, 0.93)	138 (50)	1.51 (1.27, 1.78)	-0.74 (-1.05, -0.45)
Thrombocytopenia	12 (4)	0.06 (0.03, 0.11)	78 (28)	0.63 (0.5, 0.78)	-0.57 (-0.73, -0.43)
Diarrhea	148 (54)	1.42 (1.2, 1.67)	55 (20)	0.41 (0.31, 0.54)	1.01 (0.76, 1.28)
Fatigue	130 (47)	1.15 (0.96, 1.37)	129 (47)	1.24 (1.03, 1.47)	0.08 (-0.38, 0.21)
Peripheral neuropathy	12 (4)	0.06 (0.03, 0.11)	35 (13)	0.25 (0.17, 0.34)	0.18 (-0.28, -0.1)

Post hoc analysis: PFS2 and subsequent therapies[4]

A post hoc analysis evaluated PFS2 (defined as the time from randomization to first documented progression to the next line of therapy per investigator assessment or any-cause death, whichever occurred first) and subsequent therapies used following discontinuation of study treatment due to PD. At the time of data cutoff, a greater proportion of patients remained on study treatment in the SG arm vs the TPC arm: 27% vs 14%, respectively. In the SG and TPC arms, of those patients who discontinued treatment, 161/204 patients (79%) and 195/240 patients (81%), respectively, did so due to PD, and 126 (62%) and 179 (75%) received 2L+ therapy.

Treatment with SG was associated with a 30% reduction in the risk of a PFS2 event relative to TPC (Table 8).

Table 8. ASCENT-03 Post Hoc Analysis: PFS2[4]

		SG (n=279)	TPC (n=279)
PFS2	Events, n	114	143
	Median (95% CI), mo	18.2 (15.9–NR)	14 (12.5–17.4)
	Stratified HR (95% CI)	0.7 (0.55–0.9)	
PFS2 rate, % (95% CI)	12-mo	71 (65–76)	59 (53–65)
	18-mo	52 (45–59)	41 (33–48)

For 2L therapy, most patients received chemotherapy, including PLT agents and taxanes, in the SG arm and SG in the TPC arm (Table 9). The median TFST was significantly longer with SG vs TPC; however, the median TSST was similar between treatment arms (Table 9).

Table 9. ASCENT-03 Post Hoc Analysis: Subsequent 2L and 3L Therapies[4]

Subsequent Therapies		SG (n=279)	TPC (n=279)
Any subsequent therapy line, n		126	179
Subsequent therapies in the 2L	Any subsequent 2L therapy, n (%)	126 (100)	179 (100)
	PLT agents	43 (34)	4 (2)
	Taxanes	32 (25)	5 (3)
	Anthracyclines	14 (11)	3 (2)
	ADC	13 (10)	149 (83)
	T-DXd/SG	12 (10)/1 (1)	7 (4)/142 (79)[a]
	PD-(L)1 inhibitors	5 (4)	2 (1)
	PARPi	2 (2)	1 (1)
	Other	85 (67)[b]	25 (14)[c]
	TFST, median (95% CI), mo	11.2 (10–13)	7.9 (7.2–9)
	Stratified HR (95% CI)	0.61 (0.5–0.75)	
Subsequent therapies in the 3L	Any subsequent 3L therapy, n (%)	31 (25)	55 (31)
	Taxanes	6 (5)	7 (4)
	ADC	5 (4)	10 (6)
	T-DXd/SG	4 (3)/1 (1)	6 (3)/4 (2)[d]
	PLT agents	5 (4)	7 (4)
	Anthracyclines	3 (2)	8 (4)
	PD-(L)1 inhibitors	3 (2)	2 (1)
	PARPi	2 (2)	2 (1)
	Other	16 (13)[e]	36 (20)[f]
	TSST, median (95% CI), mo	17.3 (15.2–NR)	16.6 (13.6–18.5)
	Stratified HR (95% CI)	0.82 (0.64–1.05)	

Abbreviations: ADC=antibody-drug conjugate; PARPi=poly ADP-ribose polymerase inhibitor; T-DXd=trastuzumab deruxtecan.

[a]Included commercial SG use (n=28) and crossover to SG (n=114).

[b]Included gem (n=23); cape (n=18); cyclophosphamide and eribulin (each, n=13); bevacizumab (n=5); gem hypochloride, fluorouracil, and trastuzumab (each, n=3); eribulin mesylate, pertuzumab, and zoledronic acid monohydrate (each, n=2); vinorelbine tartrate, dexmedetomidine, and gimeracil-oteracil potassium-tegafur; nadunolimab, natural killer cells, Abbv 400, Azd 9574, Cln 619, investigational drug, other therapeutic products, and all other therapeutic products (each, n=1).

[c]Included cape (n=16); cyclophosphamide, gem hypochloride, and vinorelbine tartrate (each, n=2); gem, eribulin, eribulin mesylate, and larotrectinib (each, n=1).

[d]One patient received SG as treatment beyond 3L.

[e]Included eribulin mesylate (n=5), gem hypochloride (n=4), eribulin (n=3), bevacizumab (n=2), and cape and gem (each, n=1).

[f]Included cape (n=10); cyclophosphamide (n=6); eribulin (n=5); gem and eribulin mesylate (each, n=3); gem hypochloride and bevacizumab (each, n=2); and bortezomib, gimeracil/oteracil potassium/tegafur, repotrectinib, and investigational drug (each, n=1).

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Abbreviations

1L/2L/3L=first-/second-/third-line
2L+=second-line and later
AE=adverse event
BICR=blinded independent central review
cape=capecitabine
carbo=carboplatin
CPS=combined positive score
DOR=duration of response
EAIR=exposure-adjusted incidence rate
G-CSF=granulocyte-colony stimulating factor
gem=gemcitabine
HR=hazard ratio
IHC=immunohistochemistry
mTNBC=metastatic triple-negative breast cancer
NR=not reached
OR=odds ratio
ORR=objective response rate
OS=overall survival
PD-(L)1=programmed death (ligand) 1
PFS=progression-free survival
PFS2=progression-free survival 2
PLT=platinum
PYE=patient-year of exposure
QOL=quality of life
RECIST=Response Evaluation Criteria in Solid Tumors
SAE=serious adverse event
SG=sacituzumab govitecan-hziy
TEAE=treatment-emergent adverse event
TFST=time to first subsequent therapy
TPC=treatment of physicians' choice
TSST=time to second subsequent therapy

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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FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or www.accessdata.fda.gov/scripts/medwatch

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