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) Use in 1L Post-Endocrine Therapy in HR+/HER2- mBC

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and its use as first line (1L) post-endocrine therapy (ET) in hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) metastatic breast cancer (mBC).

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 as 1L post-ET in HR+/HER2- mBC. 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 Use in 1L Post-ET in HR+/HER2- mBC

The ASCENT-07 study is an ongoing, global, randomized, open-label, phase 3 study (N=690) that is investigating the efficacy and safety of SG vs chemotherapy treatment of physician's choice (capecitabine, paclitaxel, or nab-paclitaxel) in patients with HR+/HER2- (IHC 0, IHC 1+, IHC 2+/ISH-) LA, inoperable, or mBC.[1]

- Eligible adults with HR+/HER2- mBC had previously received ET and were eligible for 1L chemotherapy in the advanced or metastatic setting.
- At the primary analysis, after a median follow-up of 15.4 mo, the study did not meet its primary endpoint of PFS by BICR according to RECIST v1.1. mPFS (95% CI) was 8.3 mo (8.1–10.3) with SG vs 8.3 mo (6.9–10) with TPC; HR (95% CI), 0.85 (0.69–1.05); *P*=0.13.
  - mPFS (95% CI) per INV, a secondary endpoint, showed a numerical improvement with SG vs TPC: 8.4 mo (8.2–9.7) vs 6.4 mo (6–8.1), HR 0.78 (95% CI 0.64–0.93) nominal *P*=0.008.
- Formal statistical testing was not conducted for subsequent endpoints in the statistical hierarchy as PFS by BICR was not statistically significant, results of these endpoints are descriptive only.
  - Results for mOS were immature (27% maturity) at the time of the primary PFS analysis; an early trend favoring SG over TPC was observed: HR 0.72 (95% CI 0.54–0.97), nominal *P*=0.029.
  - ORR per BICR (95% CI) was similar between treatment arms: 37% (32–42) with SG vs 33% (27–39) with TPC, OR 1.2 (95% CI 0.86–1.69).

- The most common Grade ≥3 TEAEs for SG and TPC, respectively, were neutropenia (56% vs 21%), leukopenia (14% vs 7%), and anemia (10% vs 5%).
- Rates of dose reduction were similar in both treatment arms (SG: 39%; TPC: 38%) and the treatment discontinuation rate was lower for SG (3% vs 7%).
- There were 6 TRAEs which led to death in the SG arm and 2 in the TPC arm.

An exploratory analysis, at a median follow-up of 15.4 mo, assessed outcomes in patients with HER2 IHC 0 expression status (SG, n=192 and TPC, n=100); results of this analysis are descriptive only.[2]

- For SG and TPC, respectively, mPFS by BICR was 9.2 vs 8.1 mo, HR 0.75 (95% CI 0.55–1.02; nominal *P*=0.0601); mPFS by INV was 8.5 vs 6.1 mo, HR 0.66 (95% CI 0.5–0.86; nominal *P*=0.0024).
- The most common Grade ≥3 TEAEs for SG and TPC, respectively, were neutropenia (54% vs 21%), leukopenia (12% vs 7%), and anemia (11% vs 5%).
- Rates of TEAE-related treatment discontinuation for SG vs TPC were 2% vs 7%, respectively.

Clinical Data on SG Use in 1L Post-ET in HR+/HER2- mBC

ASCENT-07 Study

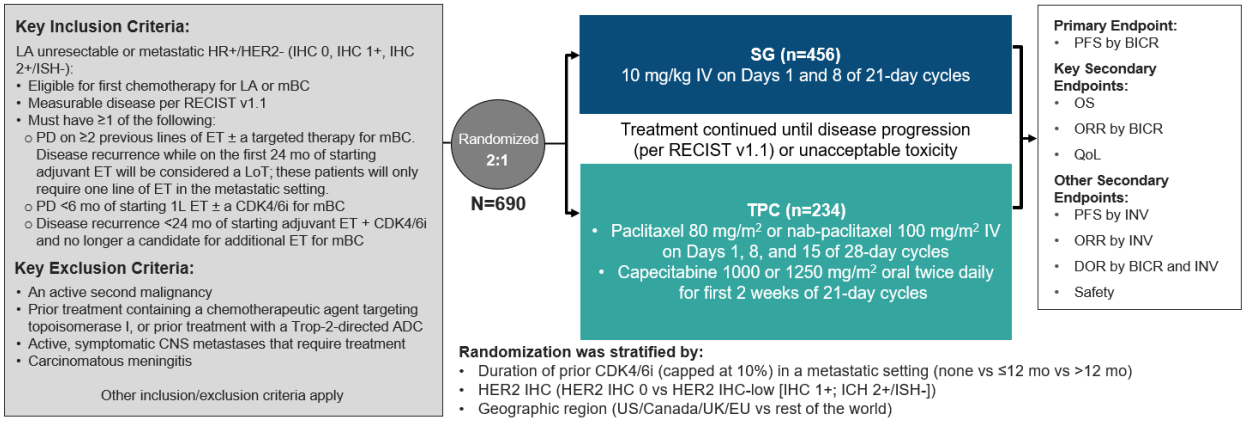
Study design and demographics

ASCENT-07, an ongoing, global, randomized, open-label, phase 3 study, is investigating the efficacy and safety of SG vs TPC (capecitabine, paclitaxel, or nab-paclitaxel) in 690 patients (99% female) with HR+/HER2- LA, inoperable, or mBC (Figure 1). Eligible adults with HR+/HER2- mBC had previously received ET and were eligible for 1L chemotherapy in the advanced or metastatic setting and met ≥1 of the following criteria[1]:

- PD in the metastatic setting after ≥2 lines of ET ± targeted therapy. Only one line of ET in the metastatic setting was required if disease recurrence occurred while on the first 24 mo after starting adjuvant ET
- PD <6 mo of starting 1L ET ± CDK4/6i for mBC
- Disease recurrence <24 mo of starting adjuvant ET + CDK4/6i and not a candidate for further ET for mBC.

See Table 1 for baseline demographics and disease characteristics.

Figure 1. ASCENT-07 Study Design[1,3]



Abbreviations: QoL=quality of life.

Table 1. ASCENT-07: Baseline Demographics and Disease Characteristics[1]

Select Demographics and Characteristics		SG (n=456)	TPC (n=234)
Age, median (range), y		57 (29–88)	58 (27–80)
Age ≥65, n (%)		106 (23)	74 (32)
Race or ethnic group,[a] n (%)	White/Asian/Black	227 (50)/ 176 (39)/ 10 (2)	106 (45)/ 95(41)/ 3 (1)
	Other or not specified	43 (9)	30 (13)
Geographic region,[b] n (%)	US/Canada/Europe	181 (40)	93 (40)
	Rest of the world	275 (60)	141 (60)
ECOG PS, n (%)	0/1	269 (59)/ 187 (41)	145 (62)/ 89 (38)
ER/PR status,[c] n (%)	ER+ and PR+	286 (63)	165 (71)
	ER+ and PR-	164 (36)	66 (28)
	ER- and PR+	2 (<1)	2 (1)
HER2 expression,[c,d] n (%)	IHC0	192 (42)	100 (43)
	HER2 low (IHC 1+; IHC 2+/ISH-)	264 (58)	134 (57)
Primary endocrine resistance,[e] n (%)		143 (31)	62 (26)
Time since metastatic diagnosis to randomization, median (range), mo		23.9 (0.5–192)	26.2 (0.3–152.1)
De novo metastatic disease at diagnosis, n (%)		111 (24)	48 (21)
Visceral disease, n (%)		407 (89)	205 (88)
Metastatic sites, n (%)	Liver	320 (70)	156 (67)
	Brain	18 (4)	14 (6)
Bone disease, n (%)		18 (4)	11 (5)

[a]Patient reported. Other/Not specified: American Indian or Alaska Native, other races, and not provided or collection not permitted.
[b]Europe: Austria, Belgium, Czech Republic, France, Germany, Greece, Hungary, Italy, Poland, Portugal, and Spain. Rest of the world: Argentina, Australia, Brazil, Chile, China, Hong Kong, Israel, Japan, Malaysia, Mexico, Republic of Korea, Singapore, South Africa, and Taiwan.
[c]Per local testing.
[d]Per interactive response technology.
[e]Defined as relapse that had occurred during the first 2 y of adjuvant ET or PD that had occurred during the first 6 mo of 1L ET for mBC.

Prior to treatment, patients in the SG and TPC arms had a median of 2 lines of therapy in a metastatic setting; see Table 2 for additional details of prior therapies.[1]

Table 2. ASCENT-07: Prior Therapies[1]

		SG (n=456)	TPC (n=234)
Metastatic setting			
Number of lines, median (range)		2 (0–8)	2 (0–4)
Lines of ET, n (%)	None	8 (2)	1 (<1)
	1	122 (27)	63 (27)
	2	263 (58)	139 (59)
	≥3	63 (14)	31 (13)
Previous endocrine-based therapies,[a] n (%)	ET with CDK4/6i	416 (91)	216 (92)
	ET with CDK4/6i ≤6 mo[b]	74 (16)	35 (15)
	ET monotherapy	182 (40)	95 (41)
	ET with other targeted therapy[c]	160 (35)	74 (32)
(Neo)adjuvant setting[a], n (%)			
ET[e]		295 (65)	158 (68)
ET with CDK4/6i		17 (4)	8 (3)
Chemotherapy		260 (57)	140 (60)
Taxane		211 (46)	115 (49)
Anthracycline		217 (48)	118 (50)
Prior CDK4/6i use in metastatic setting, n (%)			
None		32 (7)	19 (8)
≤12 mo		197 (43)	98 (42)
>12 mo		227 (50)	117 (50)

[a]Therapies reported are not mutually exclusive.
[b]In first line.
[c]Other targeted therapies in the SG and TPC arms included everolimus (25% and 22%), alpelisib (5% and 3%), and olaparib (2% and 3%).
[d]Some patients had unknown adjuvant therapy history.
[e]ET includes ET monotherapy and combination therapy.

Efficacy[1]

Primary endpoint

At the primary analysis, after a median follow-up of 15.4 mo, the study did not meet statistical significance for the primary endpoint of PFS per BICR with SG vs TPC (Table 3). Formal statistical testing was not conducted for subsequent endpoints in the statistical hierarchy as PFS by BICR was not statistically significant, results of these endpoints are, therefore, descriptive only.

Table 3. ASCENT-07: PFS per BICR at Primary Analysis[1]

		SG (n=456)	TPC (n=234)
mPFS (95% CI), mo		8.3 (8.1–10.3)	8.3 (6.9–10)
Stratified HR (95% CI), *P*-value[a]		0.85 (0.69–1.05), 0.13	
PFS rate, % (95% CI)	6-mo	71 (66–75)	64 (57–71)
	12-mo	40 (35–45)	37 (29–44)

[a]Two-sided *P*-value from stratified log-rank test.

Secondary endpoints

PFS per INV showed a numerical improvement with SG vs TPC (Table 4). Results for OS were immature (27% maturity rate) at the time of the primary PFS analysis and are descriptive only; an early trend favoring SG over TPC was observed. The study will continue to further assess OS.

Table 4. ASCENT-07: PFS per INV and OS at Primary Analysis[1]

		SG (n=456)	TPC (n=234)
mPFS (95% CI), mo		8.4 (8.2–9.7)	6.4 (6–8.1)
Stratified HR (95% CI), nominal *P*-value[a]		0.78 (0.64–0.93), 0.008	
PFS rate, % (95% CI)	6 mo	69 (64–73)	58 (51–64)
	12 mo	36 (32–41)	30 (24–36)
mOS (95% CI), mo		NR (NR–NR)	NR (19.7–NR)
HR (95% CI), nominal *P*-value		0.72 (0.54-0.97), 0.029	

[a]Two-sided *P*-value from stratified log-rank test.

A total of 32% and 61% of patients in the SG and TPC arms, respectively, received an ADC following treatment discontinuation (Table 5). Other subsequent anticancer therapies are shown in Table 5.

Table 5. ASCENT-07: Subsequent Anticancer Therapy[1]

n, (%)	SG (n=348)	TPC (n=203)
Patients without subsequent anticancer therapy[a]	66 (19)	43 (21)
Patients with any subsequent anticancer therapy[b]	282 (81)	160 (79)
ADC	91 (32)	97 (61)
Trastuzumab deruxtecan	83 (29)	66 (41)
SG	1 (0.4)	29 (18)
Datopotamab deruxtecan	0	3 (2)
Other ADC	8 (3)	7 (4)
Chemotherapy	238 (84)	106 (66)
Targeted therapy	65 (23)	24 (15)
Endocrine therapy	42 (15)	24 (15)
Immunotherapy	10 (4)	3 (2)
Other	5 (2)	3 (2)

[a]Due to death or due to no subsequent treatment data available.
[b]Patients could have received more than 1 treatment type across subsequent lines of treatment.
[c]Included poly-adenosine diphosphate-ribose polymerase inhibitor, bevacizumab, mammalian target of rapamycin inhibitor, protein kinase B inhibitor, phosphatidylinositol 3-kinase inhibitor, CDK4/6i, other.

ORR per BICR was similar between treatment arms: 37% with SG vs 33% with TPC (OR 1.2), see Table 6. Numerical improvements in CBR were seen with SG vs TPC: 65% vs 53%, respectively, and median DOR was longer with SG: 12.1 vs 9.3 mo.

Table 6. ASCENT-07: Tumor Response and Duration of Response by BICR[1]

Variable		SG (n=456)	TPC (n=234)
ORR,[a] % (95% CI)		37 (32–42)	33 (27–39)
Stratified OR (95% CI)		1.2 (0.86–1.69)	
Best Overall Response, n (%)	CR	4 (1)	0
	Partial response	164 (36)	77 (33)
	SD	202 (44)	112 (48)
	SD ≥6 mo	126 (28)	48 (21)
	PD	64 (14)	33 (14)
	Not evaluable[b]	22 (5)	12 (5)
	CBR,[c] % (95% CI)	65 (60–69)	53 (47–60)
Responders		**SG (n=168)**	**TPC (n=77)**
Time To Response,[d] median (range), mo		2.3 (1.2–14.6)	2.3 (1.4–12.5)
DOR, median (95% CI), mo		12.1 (8.5–13.8)	9.3 (6.5–14.3)

[a]The proportion of patients who achieved a best overall response of CR/partial response.

[b]Patients without any evaluable post-baseline tumor assessment are included.
[c]The proportion of patients who achieved best overall response of CR/partial response or durable SD with duration ≥6 mo. The 95% CI is based on Clopper-Pearson method.
[d]Date of first documented CR or partial response - date of randomization + 1/30.4375.

Safety[1]

The median duration (range) of treatment at the time of the primary PFS analysis with SG and TPC was 8.3 mo (0–22.1) and 6.1 mo (0.3–21.1), respectively.

TEAEs which resulted in dose interruption, dose reduction, and those which lead to treatment discontinuation are shown in Table 7.

TEAEs leading to death in the SG arm were respiratory failure (n=2), febrile neutropenia, intestinal ischemia, Klebsiella bacteremia, pneumonia, and septic shock (1 each), and in the TPC arm were septic shock, sepsis, diabetic ketoacidosis, and acute kidney injury (1 each), as well as 1 death of unknown cause. A total of 1% of deaths in the SG and TPC arms were deemed to be treatment-related.

Table 7. ASCENT-07: Exposure and Safety Summary (Safety Population)[1]

Safety Outcomes, n (%)	SG (n=449)	TPC (n=232)
Duration of treatment, median (range), mo	8.3 (0–22.1)	6.1 (0.3–21.1)
Relative dose intensity,[a] median (range), %	86.2 (33.1–135.5)	93 (43.2–108.4)
Any TEAE	448 (>99)	226 (97)
Treatment-related	447 (>99)	216 (93)
Grade ≥3 TEAEs	323 (72)	112 (48)
Treatment-related	305 (68)	86 (37)
Excluding neutropenia[b]	161 (36)	64 (28)
Treatment-emergent SAE	105 (23)	35 (15)
Treatment-related	71 (16)	11 (5)
TEAEs that led to treatment discontinuation[c]	13 (3)	16 (7)
TEAEs that led to dose interruption	337 (75)	107 (46)
TEAEs that led to dose reduction	174 (39)	88 (38)
TEAEs that led to death	7 (2)	5 (2)
Treatment-related	6 (1)	2 (1)

TEAEs began on or after the first dose date of study drug up to 30 d after the last dose date of the study drug, if applicable, or the initiation of subsequent anticancer therapy, whichever occurred first.
[a]Calculated as (total amount of study drug administered/total amount of actual study drug planned by protocol)*100.
[b]Combined preferred terms includes neutrophil count decreased.
[c]The most common were pneumonia (<1%) in the SG arm and peripheral neuropathy (2%) and infusion-related reaction (<1%) in the TPC arm.

Across both treatment arms, the most common Grade ≥3 adverse events were neutropenia, leukopenia, and anemia (Table 8).[1]

Table 8. ASCENT-07: Any-Grade TEAEs (≥20%) and Grade ≥3 TEAEs[1]

TEAEs,[a] n (%)	SG (n=449)		TPC (n=232)	
	Any-Grade	Grade ≥3	Any-Grade	Grade ≥3
Neutropenia	76	56	39	21
Alopecia	61	0	36	0
Nausea	57	2	32	0
Diarrhea	54	7	31	2
Fatigue	54	5	41	3

TEAEs,[a] n (%)	SG (n=449)		TPC (n=232)	
	Any-Grade	Grade ≥3	Any-Grade	Grade ≥3
Anemia	51	10	38	5
Constipation	40	0	20	0
Leukopenia	32	14	25	7
ALT increased	22	2	19	1
Vomiting	21	1	10	1
AST increased	21	2	23	2
Decreased appetite	21	1	10	0
Hand-foot syndrome	0	1	25	5

TEAEs began on or after the first dose date of study drug up to 30 days after the last dose date of the study drug or the day before initiation of subsequent anticancer therapy, whichever occurred first. Adverse events were coded using Medical Dictionary for Regulatory Activities. Any-grade hypersensitivity was 14% with SG and 9% with TPC; Grade ≥3 was <1% in both arms. Any-grade febrile neutropenia was 8% with SG and 1% with TPC.

[a]Combined preferred terms of neutropenia includes neutrophil count decreased, fatigue includes asthenia, anemia includes hemoglobin decreased and RBC count decreased, and leukopenia includes WBC count decreased.

Use of primary and secondary G-CSF prophylaxis for neutropenia is presented in Table 9.

Table 9. ASCENT-07: Primary and Secondary G-CSF Prophylaxis[1]

G-CSF prophylaxis, n (%)	SG (n=449)	TPC (n=232)
Primary prophylaxis	89 (20)	11 (5)
Secondary prophylaxis	192 (43)	24 (10)

Exploratory analysis[2]

An exploratory analysis assessed outcomes in 292 patients with HER2 IHC 0 expression status (SG, n=192 and TPC, n=100); results of this analysis are descriptive only.

Baseline demographics and characteristics were similar to those of the overall population; median age was 58 y; 88% and 86% of patients in the SG and TPC arms, respectively, had visceral disease, and 70% and 73% of patients had liver metastasis. Most patients had received prior ET + CDK4/6i in the metastatic setting (SG, 92%; TPC, 91%).

Efficacy

Exploratory results for mPFS and mOS, at a median follow-up of 15.4 mo, are shown in Table 10.

Table 10. ASCENT-07 Exploratory Analysis: PFS and OS (HER2 IHC 0 Subgroup)[2]

		SG (n=192)	TPC (n=100)
mPFS per BICR (95% CI), mo		9.2 (8.2–10.4)	8.1 (6.3–10.4)
Unstratified HR (95% CI), nominal *P*-value[a]		0.75 (0.55–1.02), 0.0601	
PFS rate, % (95% CI)	6 mo	75 (67–80)	62 (51–71)
	12 mo	40 (32–47)	30 (20–41)
mPFS per INV, mo		8.5	6.1
HR (95% CI), nominal *P*-value		0.66 (0.5–0.86), 0.0024	
mOS (95% CI), mo[b]		NR (NE–NE)	20.2 (19.5–NE)
HR (95% CI), nominal *P*-value		0.68 (0.44–1.05), 0.0820	

Abbreviations: NE=not evaluable; NR=not reached.

[a]Two-sided *P*-value from unstratified log-rank test. [b]28% maturity.

ORR by BICR was similar for SG and TPC, and median DOR by BICR was longer for SG vs TPC (Table 11).

Table 11. ASCENT-07 Exploratory Analysis: Tumor Response and Duration of Response by BICR (HER2 IHC 0 Subgroup)[2]

Variable	SG (n=192)	TPC (n=100)
ORR, % (95% CI)	41 (34–48)	40 (30–50)
Unstratified OR (95% CI)[a]	1.03 (0.63–1.68)	
CBR, % (95% CI)	70 (63–76)	55 (45–65)
Responders	**SG (n=78)**	**TPC (n=40)**
Time To Response, median (range), mo	2.2 (1.4–10.5)	3 (1.9–10.4)
DOR, median (95% CI), mo	10.8 (6.4–12.6)	8.3 (5.5–11.2)

[a]Calculated from unstratified Mantel-Haenszel estimates without any adjustment.

Safety

TEAEs which resulted in dose interruption, dose reduction, and those which led to treatment discontinuation are shown in Table 12.

Table 12. ASCENT-07 Exploratory Analysis: Exposure and Safety Summary (HER2 IHC 0 Subgroup)[2]

Safety Outcomes, n (%)	SG (n=190)	TPC (n=100)
Duration of treatment, median (range), mo	8.3 (0–21.4)	6.1 (0.4–21.1)
Relative dose intensity, median (range), %	83.7 (33.1–127.3)	93.4 (47.5–108.4)
Any TEAE	189 (99)	97 (97)
Treatment-related	189 (99)	91 (91)
Grade ≥3 TEAEs	139 (73)	46 (46)
Treatment-related	131 (69)	35 (35)
Treatment-emergent SAE	51 (27)	13 (13)
Treatment-related	37 (20)	3 (3)
TEAEs that led to treatment discontinuation	4 (2)	7 (7)
TEAEs that led lead to dose interruption	146 (77)	44 (44)
TEAEs that led to dose reduction	83 (44)	35 (35)
TEAEs that led to death	4 (2)	3 (3)
Treatment-related	4 (2)	1 (1)

Across both treatment arms, the most common Grade ≥3 TEAEs were neutropenia, leukopenia, and anemia (Table 13).

Table 13. ASCENT-07 Exploratory Analysis: Most Common (≥20%) TEAEs (HER2 IHC 0 Subgroup)[2]

TEAEs, n (%)	SG (n=190)		TPC (n=100)	
	Any-Grade	Grade ≥3	Any-Grade	Grade ≥3
Neutropenia	77	54	40	21
Alopecia	66	0	38	0
Nausea	59	1	28	0
Fatigue	54	3	35	4
Anemia	52	11	46	5
Diarrhea	51	10	30	0
Constipation	38	0	16	0
Leukopenia	31	12	23	7
ALT increased	25	2	17	1
Vomiting	23	1	8	1
AST increased	22	3	20	2
Hand-foot syndrome	2	0	23	4

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

References

1. Jhaveri K, Park YH, Barrios C, et al. Sacituzumab govitecan vs chemotherapy as first therapy after endocrine therapy in HR+/HER2- (IHC 0, 1+, 2+/ISH-) metastatic breast cancer: primary results from ASCENT-07. Presented at: San Antonio Breast Cancer Symposium (SABCS); December 9-12, 2025; San Antonio, TX.
2. Park YH, Jhaveri K, Barrios C, et al. Subgroup analysis of participants with HER2 IHC 0 in the ASCENT-07 study of sacituzumab govitecan vs chemotherapy in HR+/ HER2- metastatic breast cancer [Poster BD179]. Presented at: American Society of Clinical Oncology (ASCO) Annual Meeting; May 29-June 2, 2026; Chicago, IL.
3. Rugo HS, Cortes J, Curigliano G, et al. ASCENT-07: a phase 3, randomized, open-label study of sacituzumab govitecan versus treatment of physician's choice in patients with HR+/HER2- inoperable, locally advanced, or metastatic breast cancer post-endocrine therapy [Poster P01-05-09]. Presented at: San Antonio Breast Cancer Symposium (SABCS); December 5-9, 2023; San Antonio, TX.

Abbreviations

ADC=antibody drug conjugate
BICR=blinded independent central review
CBR=clinical benefit rate
CR=complete response
CDK4/6i =cyclin-dependent kinase 4/6 inhibitors
DOR=duration of response
ECOG PS= Eastern Cooperative Oncology Group performance status
ER=estrogen receptor
TPC=Treatment of physician's choice
IHC=immunohistochemistry
INV=investigator assessment
ISH-=in situ hybridization negative
LA=locally advanced
mOS=median overall survival
mPFS=median progression-free survival
OR=odds ratio
ORR=objective response rate
OS=overall survival
PD=progressive disease
PFS=progression-free survival
PR=progesterone receptor
RECIST=Response Evaluation Criteria in Solid Tumors
SD=stable disease
TEAE=treatment-emergent adverse event

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 other than 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 privacy@gilead.com.

TRODELVY, GILEAD, and the GILEAD logo are registered trademarks of Gilead Sciences, Inc., or its related companies.
© 2026 Gilead Sciences, Inc.