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Trodelvy® (sacituzumab govitecan-hziy) Use in Patients With HER2+ BC

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and its use in patients with human epidermal growth factor receptor 2-positive breast cancer (HER2+ BC).

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Trodelvy is not indicated for use in patients with HER2+ BC. 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

Combination SG Study in Patients With HER2+ mBC

The phase 2 SATEEN study evaluated the efficacy and safety of SG + trastuzumab in 27 patients with HER2+ mBC who had been previously treated with a taxane, trastuzumab, and T-DXd in any setting.[1]

- ORR (95% CI) was 3.7% (0.1–19%), with 1 PR. CBR ≥18 wk (95% CI) was 14.8% (4–33%).
- Median (95% CI) PFS and median OS were 2.3 (2–3.5) mo and 9.2 (7.6–NR) mo, respectively.
- Grade ≥2 TRAEs (>20%) included anemia (59%), neutropenia (59%), diarrhea (30%), and fatigue (26%); 33% of patients required dose modifications due to AEs. One patient experienced a Grade 5 TRAE (neutropenic sepsis with multiorgan failure).

Real-World SG Monotherapy Studies in HER2+ mBC

A retrospective, observational study using Flatiron Health data evaluated 21 patients with HER2+ mBC treated with SG after T-DXd. Median PFS was 2.6 mo and 2.1 mo in patients who progressed on prior T-DXd (n≥16) or discontinued T-DXd without progression (n≤5), respectively. Safety data were not reported.[2]

A retrospective, observational single-center study included 4 patients with HER2+ mBC who initiated treatment with SG. Median (95% CI) OS was 8.3 (4.9–62.2) mo and TTNT was 4.4 (0.9–57.2) mo. Safety data were not reported in the patients with HER2+ mBC.[3]

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Combination SG Study in Patients With HER2+ mBC

SATEEN: SG + Trastuzumab in HER2+ mBC

Study design and demographics

The phase 2, single-arm, investigator-initiated, two-stage, multicenter SATEEN study evaluated the efficacy and safety of SG + trastuzumab in 27 patients with HER2+ mBC previously treated with a taxane, trastuzumab, and T-DXd in any setting.[1] HER2+ status was defined according to the ASCO/CAP 2018 guidelines; central confirmation of HER2 status was not required.[4] Patients were required to have received no prior anti-trophoblast cell surface antigen-2 ADC and ≤5 prior lines of chemo/ADC. SG 10 mg/kg IV was administered on Days 1 and 8 of a 21-d cycle + trastuzumab every 3 wk. The primary endpoint was ORR; secondary endpoints were CBR, PFS, and OS. A total of 27 patients were enrolled in Stage 1 and were included in the interim analysis (Table 1).[1]

Table 1. SATEEN: Select Baseline and Disease Characteristics[1]

Key Demographics and Characteristics		SG + Trastuzumab (N=27)
Age, median (range), y		55 (32–78)
Sex, female/male, n (%)		26 (96)/1 (4)
ER status, positive/negative, n (%)		16 (59)/11 (41)
Visceral metastases, n (%)		19 (70)
Prior T-DXd, n (%)	Yes – discontinued due to disease progression	22 (81)
	Yes – discontinued without progression[a]	4 (15)
	No – ineligible	1 (4)
Prior anti-HER2 lines for mBC, median (range)		5 (1–17)
Other prior anti-HER2 therapies in any setting, n (%)	Trastuzumab	27 (100)
	Pertuzumab	27 (100)
	T-DM1	19 (70)
	HER2 TKIs[b]	20 (74)

Abbreviations: ER=estrogen receptor; T-DM1=trastuzumab emtansine; TKI=tyrosine kinase inhibitor.
[a]Due to pneumonitis in 3 patients (75%) and cytopenia in 1 patient (25%).
[b]Tucatinib, neratinib, and lapatinib.

Efficacy[1]

The study did not meet its primary endpoint and was stopped after Stage 1; 1 confirmed PR was observed, with an ORR of 3.7% (Table 2).

Table 2. SATEEN: Primary and Secondary Efficacy Outcomes[1]

Outcome	SG + Trastuzumab (N=27)
ORR, % (95% CI)	3.7 (0.1–19)
CBR ≥18 wk, % (95% CI)	14.8 (4–33)
PFS, median (95% CI) mo	2.3 (2–3.5)
OS, median (95% CI) mo	9.2 (7.6–NR)

Safety[1]

Safety was consistent with prior trials of SG. Grade ≥2 TRAEs are summarized below (Table 3). Overall, 9 (33%) patients required dose modifications due to AEs. One patient experienced a Grade 5 TRAE (neutropenic sepsis with multiorgan failure), after which mandatory growth factor support after Day 8 (± after Day 1) was implemented.

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Table 3. SATEEN: Grade ≥2 TRAEs Occurring in >10% of Patients[1]

TRAEs, n (%)	SG + Trastuzumab (N=27)		
	Grade ≥2	Grade 3	Grade 4
Any TRAEs	23 (85)	13 (48)	7 (26)
Neutropenia	16 (59)	8 (30)	8 (30)
Anemia	16 (59)	7 (26)	-
Diarrhea	8 (30)	5 (19)	-
Fatigue	7 (26)	1 (4)	-
Thrombocytopenia	5 (19)	-	1 (4)
Alopecia	4 (15)	-	-
Nausea	3 (11)	1 (4)	-

Real-World SG Monotherapy Studies in HER2+ mBC

Retrospective, Observational Study in mBC[2]

A retrospective, observational study using Flatiron Health data evaluated the effectiveness of treatment regimens administered after T-DXd in 793 patients with mBC. Patients were considered HER2+ if ever positive prior to initiation of T-DXd, defined as FISH-positive/amplified result with any IHC status (0, 1+, 2+, 3+), IHC3+ regardless of FISH results, or HER2+ not otherwise specified.

Overall, 21 patients with HER2+ mBC received SG after T-DXd; of these 61.9% (n=13) had converted to HER2- disease by the time of SG initiation. In these 21 patients, the median (range) of prior treatment regimens before initiating SG following T-DXd was 4 (1–10).

PFS in patients with HER2+ mBC who were treated with SG is summarized below (Table 4).

Table 4. PFS in Patients With HER2+ mBC Treated With SG Post T-DXd[2]

HER2+ Patients Treated With SG	n	PFS, mo
Overall cohort	21	2.6
Patients who progressed on prior T-DXd	≥16	2.6
Patients who discontinued prior T-DXd in the absence of progression	≤5	2.1

Note: Due to Flatiron's policy, the exact number of patients who discontinued T-DXd prior to progression was not displayed when the subgroup involved ≤5 patients.

Safety data were not reported.

Retrospective, Observational Single-Center Study in mBC[3]

A retrospective, observational single-center study evaluated the effectiveness of SG monotherapy in 184 patients with mBC. HER2+ status was defined using IHC and FISH results from the last biopsy prior to SG initiation if available, using the ASCO/CAP guidelines. HER2+ patients qualified to receive SG due to prior biopsies showing HER2- disease. Overall, 3 patients (75%) had HER2+ mBC; and 1 patient had HER2- disease at the time of SG initiation. Select baseline demographics and characteristics of these patients are summarized below (Table 5).

Table 5. Select Baseline and Disease Characteristics in Patients with HER2+ mBC[3]

Key Demographics and Characteristics	SG (n=4)
Age at SG start, median (range), y	53.7 (36.3–62.6)

Key Demographics and Characteristics		SG (n=4)
White race, n (%)		4 (100)
Visceral metastases at SG start, n (%)		4 (100)
Prior therapy, n (%)	Chemo for mBC	4 (100)
	T-DXd	2 (50)
	CDK4/6 inhibitors	2 (50)
	SG administered in a clinical trial	2 (50)
	Immunotherapy	0 (0)
Prior lines of chemo, median (range)		4.5 (2–9)
Prior lines of therapy for mBC, median (range)		6.5 (3–15)

Abbreviation: CDK4/6=cyclin-dependent kinase 4/6.

Effectiveness outcomes in the patients with HER2+ mBC are summarized below (Table 6).

Table 6. Effectiveness Outcomes in HER2+ mBC[3]

Outcome, Median (95% CI), mo	SG (n=4)
OS	8.3 (4.9–62.2)
TTNT	4.4 (0.9–57.2)

Safety data were not reported in the patients with HER2+ mBC.

References

1. Tarantino P, Yu L, Faggen M, et al. Sacituzumab govitecan plus trastuzumab in patients with HER2+ metastatic breast cancer after trastuzumab deruxtecan: Results from the phase II SATEEN trial (Oral presentation). Presented at: European Society for Medical Oncology Breast Cancer (ESMO BC); 6–8 May, 2026; Berlin, Germany.
2. Tarantino P, Lee D, Foldi J, et al. Outcomes of subsequent treatment regimens after trastuzumab deruxtecan in patients with metastatic breast cancer. *Journal of the National Cancer Institute.* 2025;117(11):2327–2335.
3. Morganti S, Kusmick RJ, Hughes ME, et al. Survival outcomes and the role of DNADX ctDNA testing in patients treated with sacituzumab govitecan for metastatic breast cancer. *ESMO Open.* 2025;10(10):105828.
4. ClinicalTrials.gov. A Single-arm Phase II Trial of SAcituzumab Govitecan and Trastuzumab for HER2+ Metastatic Breast Cancer After Trastuzumab dEruxtEcaN (SATEEN). ClinicalTrials.gov Identifier: NCT06100874. Available at: https://clinicaltrials.gov/study/NCT06100874?term=NCT06100874. Last Updated: 24 February 2026.

Abbreviations

AE=adverse event
ADC=antibody-drug conjugate
ASCO=American Society of Clinical Oncology
BC=breast cancer
CAP=College of American Pathologists
CBR=clinical benefit rate
chemo=chemotherapy
FISH=fluorescence in situ hybridization
HER2+=human epidermal growth factor receptor 2-positive
HER2−=human epidermal growth factor receptor 2-negative
IHC=immunohistochemistry
mBC=metastatic breast cancer
NR=not reached
ORR=objective response rate
OS=overall survival
PFS=progression-free survival
PR=partial response
SG=sacituzumab govitecan-hziy
T-DXd=trastuzumab deruxtecan
TRAE=treatment-related adverse event
TTNT=time to next treatment

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
🖱 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

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