Title: Real-world use patterns, effectiveness, and tolerability of sacituzumab govitecan for second-line and later treatment of metastatic triple-negative breast cancer

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Background: Sacituzumab govitecan (SG) is a Trop-2–directed antibody-drug conjugate approved in multiple countries for patients with metastatic triple-negative breast cancer (mTNBC) after ≥2 prior systemic therapies (≥1 for metastatic disease). In the ASCENT study (NCT02574455), SG had superior efficacy vs single-agent chemotherapy as well as a manageable safety profile in patients with mTNBC. This study describes real-world (RW) SG dosing and clinical outcomes in patients with mTNBC treated with SG in the second-line (2L) and later (3L+) in the US.

Methods: This retrospective cohort study used deidentified US electronic health records in the ConcertAI database of patients (≥18 years of age) with mTNBC treated with SG in the 2L and 3L+ from April 2020 to May 2022 to allow for a 3-month minimum data accrual. Clinical outcomes (RW overall survival, time to next treatment or death, and RW progression-free survival) from start of SG (index date) were estimated by Kaplan-Meier methods.

Results: Female patients (N = 230; median age of 60 years; 26% Black; 17% Eastern Cooperative Oncology Group performance status ≥2, 66% treated in community settings) were included in the analysis. Median follow-up was 7.2 months (IQR, 3.9–11.1). RW outcomes of SG for all patients and by SG line (2L and 3L+) are shown in the table. Clinical outcomes were similar for all patients and stratified analyses (by race, concomitant granulocyte colony-stimulating factor [G-CSF] use, and treatment-free interval duration). Of the 134 patients (58%) who received G-CSF during SG treatment, 99 (74%) previously received G-CSF. Median time from SG start to G-CSF use was 8.5 days (IQR, 8–29). SG was discontinued due to toxicity in 17 patients (7%).

Conclusions: This RW analysis included patients with mTNBC treated with SG in the 2L and 3L+ settings since the approval of SG in the US. SG showed a survival benefit in this broad patient population. The follow-up duration was short for some patients in this analysis. As data will continue to mature over time, they will provide more insight into the RW effectiveness of SG.

	2L mTNBC SG n = 77	**3L+ mTNBC SG n = 153**	**2L+ mTNBC SG N = 230**
Median rwOS (95% CI), months[a,b]	13.9 (9.8–NE)	8.4 (7.4–10.3)	10.0 (8.3–11.1)
rwOS rate (95% CI), %			
12 months	51 (37–64)	35 (26–44)	40 (33–48)
24 months	32 (13–54)	20 (11–29)	23 (15–32)
Median TTNTD (95% CI), months[b]	4.8 (3.2–6.9)	4.4 (3.8–5.5)	4.6 (3.9–5.3)
Median rwPFS (95% CI), months[b]	4.9 (2.9–6.0)	3.5 (2.7–4.2)	3.8 (3.1–4.3)

[a]Kalinsky, et al. ASCO 2023 abstract e18879. [b]Measured from index date.

2L, second line; 2L+, second line and later lines; 3L+, third line and later lines; mTNBC, metastatic triple-negative breast cancer; NE, not estimable; rwOS, real-world overall survival; rwPFS, real-world progression-free survival; SG, sacituzumab govitecan; TTNTD, time to next treatment or death.