A retrospectIve observational multicenter study on SacItuzumab Govitecan in mTNBC treated in ≥2L setting post NHIA reimbursement in Taiwan (inSiGht)- An interim analysis

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inSiGht

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Conclusions

- Sacituzumab govitecan (SG) demonstrated real-world effectiveness in Taiwanese patients with mTNBC treated in the ≥2L setting, with a median rwPFS of 5 months and a 9-month OS rate of 73%. Notably, among patients who received SG as 2L therapy, the median rwPFS reached 9 months, indicating greater benefit when used earlier.
- Clinical benefit and response were higher in the 2L setting (PR 53.8%, CBR 76.9%) compared with later lines (≥3L: PR 25.0%, CBR 55.0%), with manageable toxicity and few discontinuations due to AEs.
- These findings are consistent with the ASCENT trial, confirming reproducibility of SG efficacy and tolerability in an Asian population.
- The results highlight SG's clinical value and the need for region-specific real-world data to inform optimal treatment sequencing in mTNBC.

Plain Language Summary

This study evaluated sacituzumab govitecan (SG) treatment in Taiwanese women with advanced triple-negative breast cancer who had received several prior treatments. Registry data from 42 patients were reviewed. Patients who received SG earlier tended to have longer disease control. Overall, SG was associated with extended survival and side effects that were generally manageable, supporting its role in real-world clinical practice.

References: **1**. Bardia A, et al. J Clin Oncol. 2024 May 20;42(15):1738-1744. **2**. Yap YS. ESMO Open. 2023 Jun;8(3):101564. **3**. Chuang E, et al. J Immigr Minor Health. 2012 Oct;14(5):754-8. **4**. Bardia A, et al. N Engl J Med. 2021 Apr 22;384(16):1529-1541. **5**. Di Maio M, et al. Oncologist. 2020 May;25(5):e746-e752. **6**. Reinisch M, et al. Ther Adv Med Oncol. 2023 Sep 28;15:17588359231200454. **7**. Kalinsky K, et al. Breast Cancer Res Treat. 2024 Nov;208(1):203-214.

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Introduction

- In the pivotal ASCENT trial, sacituzumab govitecan (SG) significantly improved progression-free survival (PFS; median 4.8 vs 1.7 months) and overall survival (OS; 11.8 vs 6.9 months) versus physician's choice chemotherapy in heavily pretreated metastatic triple-negative breast cancer (mTNBC) patients. However, the trial population consisted mainly of Western (non-Asian) patients, limiting the generalizability of findings to Asian populations. Regional differences in disease characteristics and treatment patterns further highlight the need for real-world evidence in this population.
- Although SG is globally approved and increasingly used in clinical practice, real-world data in Asian populations remain scarce. Such evidence is crucial, as real-world patients often present with more diverse clinical features, comorbidities, and prior treatment histories than those enrolled in trials. SG was approved in Taiwan in November 2022 and reimbursed in February 2024, providing a timely opportunity to evaluate its real-world effectiveness and safety in Asian mTNBC patients under routine practice conditions.
- The study objective is to evaluate the real-world effectiveness and safety of sacituzumab govitecan in Taiwanese patients with mTNBC treated in the second-line (2L) or later setting after National Health Insurance reimbursement.

Methods

- Data Source: Data were retrospectively obtained from the Chang Gung Memorial Hospital (CGMH) Breast Cancer Registry (Taipei, Linkou, and Tucheng sites), which includes demographic, clinical, treatment, and outcome information.
- Participants: Eligible patients were women with mTNBC who received SG in the 2L or later setting between February 2024 and April 2025.
- Study Design: Secondary data analysis of the CGMH Breast Cancer Registry. The index date was the date of first SG administration. A 6-month pre-index period was used to capture baseline characteristics and prior treatments. Patients were followed until death, or data cutoff (June 2025), whichever occurred first.
- Outcomes: Clinical characteristics, treatment patterns, real-world progression-free survival (rwPFS), overall survival (OS), treatment response, and safety.
- Statistical Analysis: Kaplan–Meier methods were used for time-to-event analyses. Subgroup analyses were performed by treatment line (2L vs ≥3L).

Results

- A total of 42 patients were included (2L: n=15; ≥3L: n=27). Most initiated SG in 2024 (88.0%). The mean (SD) age was 57 (9) years, and the mean (SD) BMI was 23.1 (4.2) kg/m². Overall, 61.9% were postmenopausal, with a higher proportion in ≥3L (74.0%) versus 2L (40.0%). The mean (SD) time from metastatic diagnosis to SG initiation was 15.4 (14.0) months, longer in ≥3L (17.7 months) than 2L (10.6 months) (**Table 1**).
- Of all patients, 52.4% were HER2-negative and 47.6% HER2-low. ECOG performance status 0–1 was observed in 90.5%. Prior PD-(L)1 inhibitor exposure occurred in 28.6%. Visceral metastases were present in 90.5% and brain metastases in 21.4% (**Table 2**).
- Among 33 evaluable patients, partial response (PR) was observed in 36.4%, stable disease (SD) in 27.3%, and progression in 36.4%. The PR rate was higher in 2L (53.8%) than ≥3L (25.0%). Corresponding clinical benefit rates (CBR; PR+SD) were 76.9% and 55.0%, respectively (**Figure 1**).
- Median rwPFS was 5.0 months (95% CI: 2.6–8.8) overall. By line of therapy, median rwPFS was 9.0 months (95% CI: 2.6–NR) in 2L and 3.8 months (95% CI: 2.3–NR) in ≥3L. Median follow-up was 9.0 months (IQR: 6.4–13.8). The 9-month OS rate (95% CI) was 73% (59–89%) overall, with higher survival in 2L (92% [79–100%]) versus ≥3L (61% [43–85%]) (**Figure 2**).

Table 1. Baseline Demographic

	Overall		2L		≥3L	
Number of patients	42		15		27	
Index year (n,%)						
2024	37	88.0%	13	87.0%	24	89.0%
2025	5	12.0%	2	13.0%	3	11.0%
Age (year)						
mean, std	57	9	55	11	57	8
median, IQR	56	50−62	53	48−63	58	51−62
BMI (kg/m²)						
mean, std	23.1	4.2	23.5	4.9	22.9	3.9
median, IQR	22.4	20.4−24.4	22.3	20.0−29.3	22.4	20.7−24.3
Menopause status (n,%)						
Yes	26	61.9%	6	40.0%	20	74.0%
No	1	2.4%	1	6.7%	0	0%
Unknown	15	35.7%	8	53.0%	7	26.0%
Time from mBC diagnosis to SG start (month)						
mean, std	15.4	14.0	11.0	10.6	17.7	15.1
median, IQR	11.0	6.0−19.8	6.2	4.0−12.8	15.0	8.4−19.8

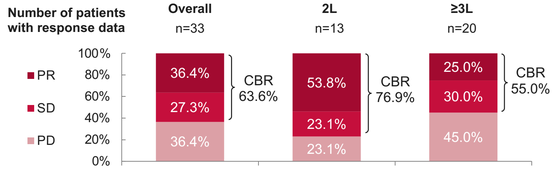
Abbreviations: 2L, second line; ≥3L, third line or later; std, standard deviation; IQR, inter quartile range; BMI, body mass index; kg, kilogram; mBC, metastatic breast cancer; SG, sacituzumab govitecan.

Table 2. Key Clinical Characteristics by Treatment Line

	Overall		2L		≥3L	
	n	%	n	%	n	%
Number of patients	42		15		27	
HER2 status						
HER2 negative	22	52.4%	7	46.7%	15	55.6%
HER2 low	20	47.6%	8	53.3%	12	44.4%
ECOG PS						
0–1	38	90.5%	13	86.7%	25	92.6%
≥2	4	9.5%	2	13.3%	2	7.4%
Prior use of PD-(L)1 inhibitors	12	28.6%	4	26.7%	8	29.6%
Visceral metastasis	38	90.5%	13	86.7%	25	92.6%
Brain metastasis	9	21.4%	4	26.7%	5	18.5%

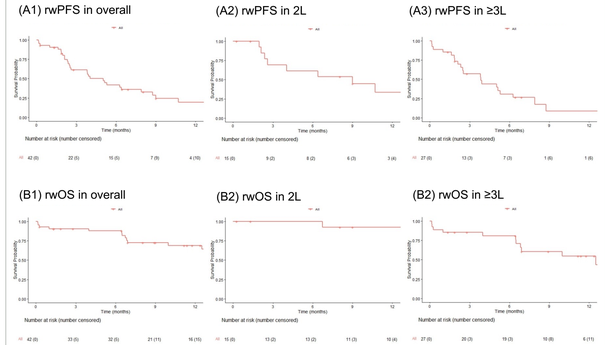
Abbreviations: 2L, second line; ≥3L, third line or later; HER2, human epidermal growth factor receptor 2; ECOG PS, Eastern Cooperative Oncology Group performance status; PD-(L)1, programmed cell death-(ligand) 1.

Figure 1. Best Treatment Response



Abbreviations: 2L, second line; ≥3L, third line or later; PR, partial response; SD, stable disease; PD, progression; CBR, clinical benefit rate. Note: Clinical benefit rate was defined as the proportion of patients achieving partial response or stable disease as their best overall response.

Figure 2. Real-World Progression-Free Survival (rwPFS) and Overall Survival (OS)



- Most patients discontinued SG due to disease progression (79.3%), followed by death (13.8%) and adverse events (AEs, 6.9%). No 2L patients discontinued because of AEs. Grade 2 diarrhea occurred in 7.1%, grade 1 in 16.7%. Grade 3–4 neutropenia occurred in 9.6% (4.8% each), and granulocyte colony-stimulating factor use was reported in 23.8% (**Table 3**).

Table 3. Treatment Discontinuation and Safety Summary

	Overall		2L		≥3L	
Number of patients	42		15		27	
SG treatment discontinuation (n,%)	29	69.0%	8	53.3%	21	77.8%
Reason for discontinuation (n,%)						
Adverse event / intolerance	2	6.9%	0	0%	2	9.5%
Disease progression	23	79.3%	8	100%	15	71.5%
Death	4	13.8%	0	0%	4	19.0%
Neutropenia (n,%)						
Grade 1–2	15	35.7%	8	53.3%	7	25.9%
Grade 3–4	4	9.6%	4	26.6%	0	0%
Diarrhea (n,%)						
Grade 1–2	10	23.8%	4	26.7%	6	22.2%
G-CSF use (n,%)	10	23.8%	5	33.3%	5	18.5%

Abbreviations: 2L, second line; ≥3L, third line or later; std, standard deviation; IQR, inter quartile range; G-CSF, granulocyte colony-stimulating factor.

Limitations

- Retrospective, single-country study with data from one institutional registry, potentially limiting generalizability
- Interim analysis with small sample size and short follow-up, restricting evaluation of long-term outcomes and infrequent toxicities