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Trodelvy® (sacituzumab govitecan-hziy) Combination With Checkpoint Inhibitors in Metastatic Breast Cancer

This document is in response to your request for information about Trodelvy® (sacituzumab govitecan-hziy [SG]) in combination with checkpoint inhibitors (CPIs) in patients with metastatic breast cancer (mBC).

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Trodelvy is not indicated for use in combination with CPIs. 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 With CPIs in mBC

ASCENT-04, an ongoing, global, open label, randomized, phase 3 study compared the efficacy and safety of SG + pembro (n=221) vs chemotherapy TPC + pembro (n=222), as 1L treatment in patients with PD-L1+, inoperable, LA or mTNBC. Patients who experienced disease progression with TPC + pembro could crossover to receive 2L SG monotherapy.[1]

- SG + pembro prolonged PFS by BICR per RECIST v1.1 (primary endpoint) vs TPC + pembro (11.2 vs 7.8 mo; HR 0.65, 95% CI: 0.51–0.84; *P*<0.001), and the rates of patients alive and progression-free at 6 mo and 12 mo were 72% (95% CI: 65–77) vs 63% (95% CI: 56–69) and 48% (95% CI: 41–56) vs 33% (95% CI: 26–40), respectively. OS rates numerically favored SG + pembro; however, results for OS were immature at the time of final analysis for PFS. The safety profile of SG + pembro was consistent with the known safety profile of each agent; Grade ≥3 AEs were reported in 71% of patients in the SG + pembro arm and in 70% of patients in the TPC + pembro arm.

MORPHEUS-Pan BC is a phase 1b/2, open-label, multicenter, randomized, umbrella study in patients with inoperable, LA or mBC. Results of an 18-week interim analysis of atezo + SG (n=31) vs atezo + nab-P (n=11; control arm) in patients with 1L, PD(L)-1+ mTNBC are summarized.[2]

- The ORR with atezo + SG (n=30) vs control (n=9) was 76.7% and 66.7%, respectively. Five patients achieved a CR with atezo + SG; 6 patients achieved a PR with the control, and no CR was reported. A numerical improvement for PFS was reported with atezo + SG vs control; however, data were immature at this timepoint.[2,3] A total of 80% and 56% of patients in the atezo + SG and control arms, respectively, reported ≥1 immune-related AE. No fatal AEs were reported.[2]

Saci-IO HR+ is an open-label, randomized, phase 2 study in patients with HR+/HER2- mBC who have progressed on ≥1 line of endocrine therapy for metastatic disease, or progression on or within 12 mo of adjuvant endocrine therapy, and have received 0 to 1 prior chemotherapy regimen.[4]

- SG + pembro (n=52) vs SG (n=52) did not significantly improve median PFS (primary endpoint: 8.12 vs 6.22 mo; HR, 0.81; *P*=0.37); there was no significant difference in OS (18.52 vs 17.96 mo; HR, 0.65; *P*=0.21); however, data were immature at this timepoint. The most common Grade ≥3 TEAEs with SG + pembro included neutropenia (54%), leukopenia (23%), and lymphopenia (12%); the most common Grade ≥3 TEAEs with SG were neutropenia (44%), anemia (10%), and nausea (10%).

Clinical Data on SG Use With CPIs in mBC

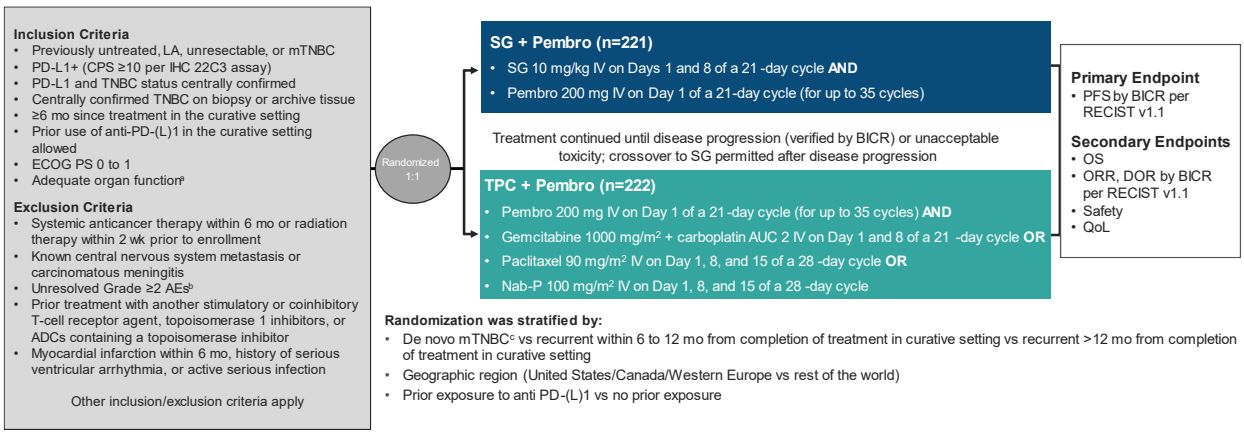
ASCENT-04 Study

Study design and demographics

ASCENT-04 is an ongoing, global, open label, randomized, phase 3 study that is being conducted to investigate the efficacy and safety of SG + pembro vs TPC + pembro, as 1L treatment in patients with PD-L1+ (CPS ≥10), inoperable, LA or mTNBC (Figure 1).[1]

A total of 443 female patients were enrolled. Patients who experienced disease progression during treatment with TPC + pembro (as verified by BICR) could crossover to receive 2L SG monotherapy.[1]

Figure 1. ASCENT-04 Study Design[1,5]



Abbreviations: AUC=area under the curve; QoL=quality of life; ULN=upper limit of normal.
[a]Hgb ≥9 g/dL, ANC ≥1500/mm^3; platelets ≥100,000/mcL, bilirubin ≤1.5 × ULN, AST/ALT ≤2.5 × ULN or ≤5 × ULN with known liver metastases, serum albumin >3 g/dL, and CrCl ≥30 mL/min.
[b]Unresolved Grade ≤2 neuropathy, endocrine-related AEs, and any-grade alopecia were allowed.
[c]Up to 35% of patients with de novo mTNBC were eligible.

At baseline, the three most common sites of metastasis were lymph node (72%), lung (50%), and bone (28%) in the SG + pembro arm and lymph node (69%), lung (43%), and liver (26%) in the TPC + pembro arm. See Table 1 for baseline characteristics.[1]

Table 1. ASCENT-04: Baseline Demographics and Disease Characteristics[1]

Key Demographics and Characteristics		SG + Pembro (n=221)	TPC + Pembro (n=222)
Age, median (range), y		54 (23–88)	55 (27–82)
≥65 y, n (%)		58 (26)	57 (26)
Race or ethnic group,[a] n (%)	White/Black/Asian	139 (63)/13 (6)/43 (19)	118 (53)/11 (5)/63 (28)
	Other or not specified	26 (12)	30 (14)
ECOG PS,[b] n (%)	0/1	156 (71)/65 (29)	154 (69)/67 (30)
Curative treatment-free interval, n (%)	De novo	75 (34)	75 (34)
	Recurrent within 6–12 mo	40 (18)	40 (18)
	Recurrent >12 mo	106 (48)	107 (48)
Chemo selected prior to randomization,[c] n (%)	Taxane	116 (52)	114 (51)
	Gemcitabine or carboplatin	105 (48)	108 (49)
Prior anti-PD-(L)1 therapy,[d] n (%)		9 (4)	11 (5)

[a]As reported by patients; other includes American Indian or Alaska Native and not permitted.
[b]One patient in the TPC + pembro group had an ECOG PS ≥2.
[c]Actual chemo received was consistent with what was selected prior to randomization; however, 2 patients were randomized but did not receive treatment.
[d]While 20 patients were included in the stratified subgroup of prior exposure to anti-PD-(L)1 therapy (yes) per the interactive response technology system, only 6 patients received prior treatment with anti-PD-(L)1 agents per the clinical database.

Efficacy[1]

Primary endpoint

SG + pembro significantly improved PFS vs TPC + pembro, and a numerically higher proportion of patients were alive and progression-free at the 6- and 12-mo timepoints (Table 2). The median duration of follow-up at the time of the final PFS analysis was 14 (range, 0.1–28.6) mo. At data cutoff, 43% (n=95) and 23% (n=52) of patients in the SG + pembro arm and in the TPC + pembro arm, respectively, remained on treatment.

Table 2. ASCENT-04: PFS by BICR and Investigator Assessment[1]

			SG + Pembro (n=221)	TPC + Pembro (n=222)	Stratified HR (95% CI); *P*-Value[a]
BICR analysis	Number of PFS events		109	140	0.65 (0.51–0.84); <0.001
	PFS, median (95% CI), mo		11.2 (9.3–16.7)	7.8 (7.3–9.3)	
	PFS rate, % (95% CI)	6-mo	72 (65–77)	63 (56–69)	-
		12-mo	48 (41–56)	33 (26–40)	-
Investigator assessment	Number of PFS events		111	142	0.67 (0.52–0.87); 0.002
	PFS, median (95% CI), mo		11.3 (9.2–14.6)	8.3 (7.3–9.3)	
	PFS rate, % (95% CI)	6-mo	75 (68–80)	61 (54–68)	-
		12-mo	48 (41–56)	36 (29–42)	-

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

Secondary endpoints

At the data cut-off for the final PFS analysis, results for OS were immature (26% maturity rate), results for OS are, therefore, descriptive; a numerical trend in favor of SG + pembro was observed (HR, 0.89; 95% CI: 0.62–1.29). A total of 77 patients who progressed on TPC + pembro crossed over to receive 2L SG monotherapy per protocol.

Statistical testing was not conducted for subsequent endpoints in the statistical hierarchy as the statistical boundary for OS was not crossed; therefore, these results are descriptive only. ORR (95% CI) was 60% (52.9–66.3) with SG + pembro vs 53% (46.4–59.9) with TPC

+ pembro (OR, 1.3, 95% CI: 0.9–1.9). Median DOR (95% CI) was 16.5 (12.7–19.5) mo vs 9.2 (7.6–11.3) mo with SG + pembro vs TPC + pembro, respectively.

Safety[1]

Overall, the safety profile of SG + pembro was consistent with the known safety profile of each agent, with no additive toxicity observed. The rate of SAEs was higher with SG + pembro vs TPC + pembro; however, the rate of TEAEs that led to treatment discontinuation was lower with SG + pembro (Table 3). TEAEs that led to death occurred in 7 patients (3%) in the SG + pembro arm (3 were deemed treatment related) and in 6 patients (3%) in the TPC + pembro arm (1 was deemed treatment related). TEAEs that led to death with SG + pembro were pneumonia, sepsis, neutropenic sepsis, pulmonary embolism, and suicide (each, n=1); there were 2 deaths of unknown cause. TEAEs that led to death with TPC + pembro were cardiac arrest, large intestine perforation, pneumonia, sepsis, post-procedural complication, and death of unknown cause (each, n=1).

Table 3. ASCENT-04: Safety Summary[1]

AEs, n (%)	SG + Pembro (n=221)	TPC + Pembro (n=220)
Any TEAE	220 (>99)	219 (>99)
Grade ≥3	158 (71)	154 (70)
Treatment-emergent SAE	84 (38)	68 (31)
Treatment-related	61 (28)	42 (19)
TEAEs that led to treatment discontinuation[a]	26 (12)	68 (31)
TEAEs that led lead to dose interruption	171 (77)	162 (74)
TEAEs that led to dose reduction[b]	78 (35)	96 (44)

[a]The most common any-grade TEAEs that led to treatment discontinuation were pneumonitis (1%) for SG + pembro and peripheral neuropathy (5%), pneumonitis (3%), and thrombocytopenia (3%) for TPC + pembro.
[b]There was no dose reduction for pembro per the protocol.

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

Table 4. ASCENT-04: Most Common (≥20%) TEAEs[1a]

TEAEs, %	SG + Pembro (n=221)		TPC + Pembro (n=220)	
	Any-Grade	Grade ≥3	Any-Grade	Grade ≥3
Diarrhea	70	10	29	2
Nausea	68	3	38	2
Neutropenia	63	43	59	45
Fatigue	58	8	56	3
Alopecia	52	N/A	32	N/A
Constipation	41	1	35	1
Anemia	37	7	51	16
Vomiting	29	1	14	2
Headache	25	1	17	0
Rash	21	1	20	1
ALT increased	20	4	30	6
Leukopenia	19	3	21	9
AST increased	16	3	25	4

TEAEs, %	SG + Pembro (n=221)		TPC + Pembro (n=220)	
	Any-Grade	Grade ≥3	Any-Grade	Grade ≥3
Peripheral neuropathy	7	1	21	3
Thrombocytopenia	5	1	29	14

[a]Defined as any AEs that began or worsened on or after the first dose of study drug ≤30 d (or ≤90 d for SAEs) after the last dose of study drug or initiation of subsequent anticancer therapy (including crossover treatment).
Note: Combined preferred terms of neutropenia included neutrophil count decreased, leukopenia includes WBC decreased, anemia includes Hgb decreased and RBC count decreased, thrombocytopenia included platelet count decreased, fatigue includes asthenia.

AESIs are presented in Table 5; these events were consistent with the known safety profiles of each agent. No new safety concerns were observed.

Table 5. ASCENT-04: AESIs[1]

AESIs,[a] n (%)		SG + Pembro (n=221)		TPC + Pembro (n=220)	
		Any-Grade	Grade ≥3	Any-Grade	Grade ≥3
SG AESIs	Neutropenia[b]	143 (65)	104 (47)	132 (60)	100 (45)
	Hypersensitivity[b]	43 (19)	4 (2)	51 (23)	5 (2)
	Serious infections secondary to neutropenia[b]	6 (3)	5 (2)	3 (1)	3 (1)
	Grade ≥3 diarrhea	N/A	22 (10)	N/A	5 (2)
Pembro AESIs	Overall	30 (14)	9 (4)	56 (26)	16 (7)
	Infusion reactions (not immune-mediated)[a]	11 (5)	3 (1)	19 (9)	5 (2)
	Pneumonitis[b]	5 (2)	3 (1)	10 (5)	2 (1)
	Colitis[b]	4 (2)	1 (<1)	1 (<1)	1 (<1)
	Hypothyroidism[b]	4 (2)	0	19 (9)	0
	Hypophysitis[b]	2 (1)	0	2 (1)	0
	Hyperthyroidism[b]	2 (1)	0	5 (2)	0
	Severe skin reactions,[b] including SJS and TEN	2 (1)	2 (1)	2 (1)	2 (1)
	Hepatitis[b]	1 (<1)	0	2 (1)	2 (1)
	Adrenal insufficiency[b]	1 (<1)	0	2 (1)	1 (<1)
	Pancreatitis[b]	0	0	2 (1)	2 (1)

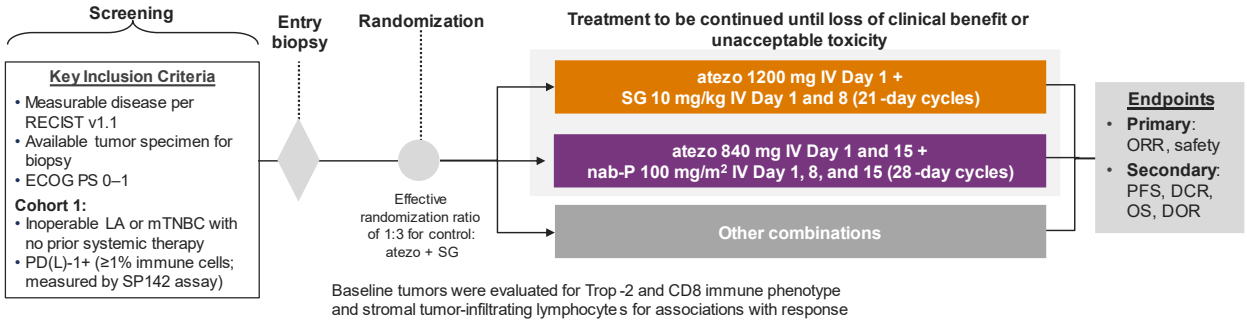
Abbreviations: SJS=Stevens-Johnson syndrome; TEN=toxic epidermal necrolysis.
[a]AESIs observed in ≥1% of patients in either group. [b]Grouped term.

MORPHEUS-Pan BC Study

Study design and demographics[2]

MORPHEUS-Pan BC is a phase 1b/2, open-label, multicenter, randomized, umbrella study that is evaluating multiple treatment combinations in patients with inoperable LA or mBC (Figure 2). Interim analysis results for atezo + SG vs atezo + nab-P (control) in patients with no prior systemic treatment for PD(L)-1+ and inoperable, LA or mTNBC are summarized.

Figure 2. MORPHEUS-Pan BC Study Design[2]



Abbreviations: CD8=cluster of differentiation 8; Trop-2=trophoblast cell surface antigen 2.

Patients were female, and most were <65 y (84% and 64% in the atezo + SG and control arm, respectively). The most common sites of metastasis at enrollment in the atezo + SG and atezo + nab-P arms were lymph node (67.7% and 54.5%, respectively), lung (51.6% and 45.5%), and bone (35.5% and 36.4%). See Table 6 for key demographics and characteristics.

Table 6. MORPHEUS-Pan BC: Baseline Demographics and Disease Characteristics[2]

Key Demographics and Characteristics, n (%)	Atezo + SG (n=31)	Atezo + nab-P (n=11)
Race, White/Asian/Black or African American	20 (64.5)/10 (32.3)/1 (3.2)	7 (63.6)/4 (36.4)/0
Ethnicity, Hispanic or Latinx/ not Hispanic or Latinx/unknown	3 (9.7)/27 (87.1)/1 (3.2)	0/11 (100)/0
Prior cancer surgery/radiotherapy	25 (80.6)/24 (77.4)	6 (54.5)/4 (36.4)
Prior treatment, taxane/capecitabine/carboplatin	11 (35.5)/5 (16.1)/5 (16.1)	1 (9.1)/1 (9.1)/0
Sites of metastasis, 1/2/3/≥4	8 (25.8)/12 (38.7)/8 (25.8)/3 (9.7)	4 (36.4)/5 (45.5)/0/2 (18.2)

Efficacy results

The ORR with atezo + SG was 76.7% (n=23); 5 patients achieved a CR. Of the 6 patients (66.7%) in the control arm with an ORR, all achieved a PR (Table 7).[2,3]

Table 7. MORPHEUS-Pan BC Interim Analysis: Response Rates (Efficacy and Safety Evaluable Population)[2,3]

		Atezo + SG (n=30)	Atezo + nab-P (n=9)
Primary endpoint, n (%); [95% CI]	ORR	23 (76.7); [57.1—90.1]	6 (66.7); [29.9—92.5]
	DCR[a]	28 (93.3); [77.9—99.2]	9 (100); [66.4—100]
	CBR[b]	25 (83.3); [65.3—94.4]	6 (66.7); [29.9—92.5]

[a]Criteria is either response and/or SD or better for ≥12 wk.
[b]Criteria is either response and/or SD or better for ≥24 wk.

There was a numerical improvement with atezo + SG vs control for PFS; however, data were immature at this analysis timepoint (Table 8). Interim results of DOR showed that patients remained on treatment for longer with atezo + SG vs control.[2]

Table 8. MORPHEUS-Pan BC Interim Analysis: Secondary Endpoints[2]

Efficacy Outcome		Atezo + SG	Atezo + nab-P	HR (95% CI)
DOR	Responders, n	23	6	0.17 (0–0.7)
	Median, (95% CI), mo	14 (8.7–NE)	7.1 (2.8–NE)	
PFS[a]	Efficacy/safety evaluable population, n	30	9	0.27 (0.1–0.7)
	Median (95% CI), mo	12.2 (7.4–NE)	5.9 (4.1–8.7)	

Abbreviation: NE=not evaluable.
[a]Efficacy and safety evaluable population.
Note: Median durations of follow-up: atezo + SG, 10.6 mo; atezo + nab-P, 11.7 mo.

Safety results[2]

Safety was a co-primary endpoint. All patients reported TRAEs and any-grade TEAEs; ≥1 immune-related AEs were reported in 80% and 55.6% of patients in the atezo + SG and control arms, respectively. No fatal AEs were reported. See Table 9 for overall safety summary in the efficacy and safety evaluable population.

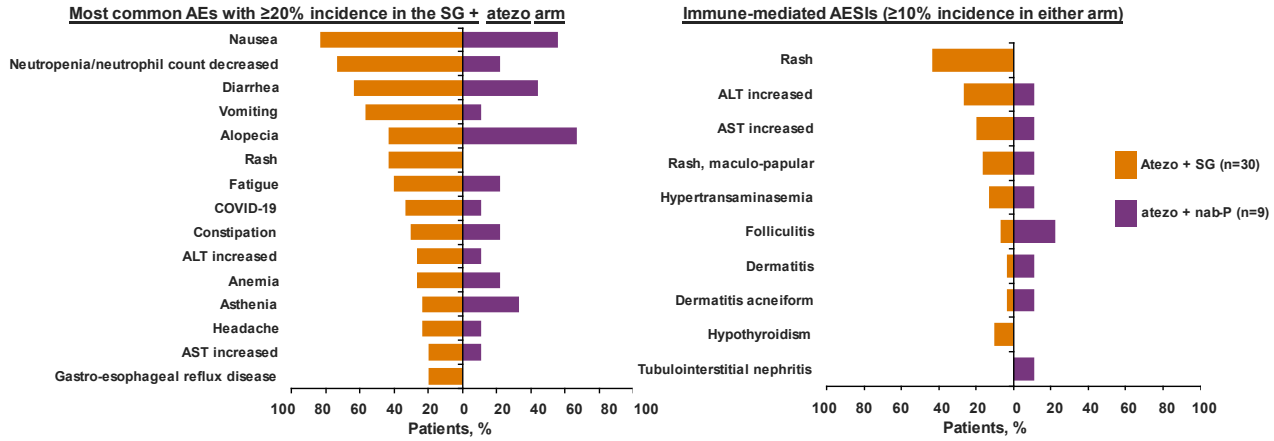
Table 9. MORPHEUS-Pan BC Interim Analysis: Overall Safety Summary[2]

Safety Parameters, n (%)		Atezo + SG (n=30)	Atezo + nab-P (n=9)
Patients with ≥1 AE	Worst grade: 3	14 (46.7)	4 (44.4)
	Worst grade: 4	7 (23.3)	0
AE led to treatment discontinuation[a]		1 (3.3)	1 (11.1)
AE led to dose modification/interruption		26 (86.7)	7 (77.8)
SAE		7 (23.3)	4 (44.4)
TRAEs	Led to treatment discontinuation[a]	1 (3.3)	1 (11.1)
	Led to dose modification/interruption	25 (83.3)[b]	3 (33.3)[c]

[a]Neutropenic colitis and neurotoxicity for SG + atezo and atezo + nab-P, respectively.
[b]Events with ≥10% incidence: neutrophil count decreased (n=11; 36.7%); fatigue (n=7; 23.3%); and neutropenia (n=7; 23.3%).
[c]Events with ≥10% incidence (n=1; 11.1% each): neutrophil count decreased, anemia, peripheral neuropathy, and tubulointerstitial nephritis.

See Figure 3 for the most common AEs in the atezo + SG and control arms.

Figure 3. MORPHEUS-Pan BC Interim Analysis: Most Common AEs and Immune-Mediated AESIs (Efficacy and Safety Evaluable Population)[2]

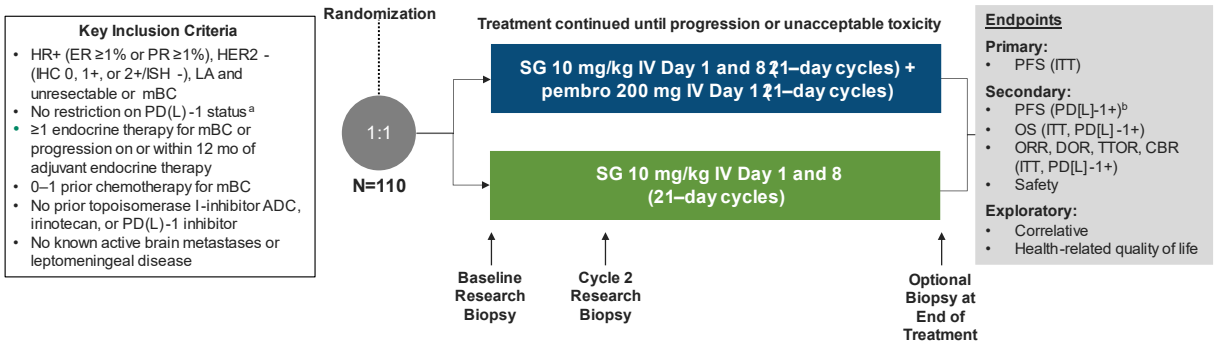


Saci-IO HR+ Study[4]

Study design and demographics

The ongoing phase 2, Saci-IO HR+ study is investigating SG + pembro vs SG in patients with HR+/HER2- mBC who have progressed on ≥1 line of endocrine therapy for metastatic disease, or have progressed on or within 12 mo of adjuvant endocrine therapy, and have received 0 or 1 prior chemotherapy regimens (Figure 4).

Figure 4. Saci-IO HR+ Study Design[4]



Abbreviations: ISH=in situ hybridization; PR=progesterone receptor.
[a]Protocol amendment was activated in January 2022 to allow patients with any PD-L1 status to enroll.
[b]Central PD(L)-1 testing was performed with the PharmDx 22C3 assay; PD(L)-1+, CPS ≥1.

Most patients were <60 y and female, with 2 male patients in the SG + pembro arm. In the SG + pembro and SG arms, 76.9% and 78.8%, respectively, had liver metastasis, and 7.7% and 9.6% had brain metastasis. See Table 10 for additional demographics and characteristics.

Table 10. Saci-IO HR+: Baseline Demographics and Disease Characteristics[4]

Key Demographics and Characteristics		SG + Pembro (n=52)	SG (n=52)
Age, median (range), y		56.5 (31–81)	57 (27–80)
Race, n (%)	White	40 (76.9)	44 (84.6)
	Black or African American	4 (7.7)	3 (5.8)
	Asian	4 (7.7)	1 (1.9)
	American Indian or Alaskan Native	1 (1.9)	0
	Other	3 (5.8)	4 (7.7)
ER status,[a] ≥10%/1–9%/unknown, n (%)		49 (94.2)/2 (3.8)/1 (1.9)	50 (96.2)/1 (1.9)/1 (1.9)
PD(L)-1 status,[b] negative/CPS ≥1, n (%)		35 (67.3)/16 (30.8)	28 (53.8)/24 (46.2)
Presentation at mBC diagnosis, de novo/recurrent mBC, n (%)		10 (19.2)/42 (80.8)	13 (25)/39 (75)
Prior (neo)adjuvant chemotherapy,[c] yes/no, n (%)		28 (66.7)/14 (33.3)	28 (71.8)/11 (28.2)
Prior CDK4/6i, yes/no, n (%)		47 (90.4)/5 (9.6)	45 (86.5)/7 (13.5)
Number of prior chemotherapy regimens for mBC, 0/1, n (%)		27 (51.9)/25 (48.1)	26 (50)/26 (50)

Abbreviation: CDK4/6i=cyclin-dependent 4/6 inhibitor.
[a]ER in the most recent available tumor sample prior to study registration. ER+ (% unknown in 2 patients).
[b]Central PD(L)-1 testing was performed on the baseline research biopsy (if not performed, testing was performed on the most recently archived tumor sample prior to study registration). Tissue was not available for testing in 1 patient.
[c]Patients with de novo Stage IV BC (SG + pembro, n=10; SG, n=13) were excluded from denominator.

Efficacy results

A non-significant improvement for PFS of 1.9 mo was reported with SG + pembro vs SG in the ITT population (Table 11). At a median follow-up of 12.5 mo, OS did not differ significantly between treatment arms; however, data were immature at this timepoint.

Table 11. Saci-IO HR+: PFS and OS Results (ITT Population)[4]

Efficacy Outcome		SG + Pembro (n=52)	SG (n=52)	HR (95% CI); Log-Rank *P*-Value
PFS	Number of events	38	38	0.81 (0.51–1.28); 0.37
	PFS median (95% CI), mo	8.12 (4.51–11.12)	6.22 (3.85–8.68)	
OS	Number of events	15	20	0.65 (0.33–1.28); 0.21
	OS median (95% CI), mo	18.52 (16.55–NA)	17.96 (12.5–NA)	

ORR, CBR, DOR, and TTOR did not differ significantly between treatment arms (*P*>0.3).

Safety results

Any-grade TEAEs were reported by 98.1% and 96.2% of patients in the SG + pembro and SG arms, respectively. Of those, 5.8% and 1.9% lead to dose discontinuation in the SG + pembro and SG arms, respectively. See Table 12 for the most common TEAEs.

Table 12. Saci-IO HR+: Safety Summary[4]

Most Common TEAEs (≥20%), n (%)	SG + Pembro (n=52)		SG (n=52)	
	Grade ≥2	Grade 3–4	Grade ≥2	Grade 3–4
Neutrophil count decreased	36 (69.2)	28 (53.8)	31 (59.6)	23 (44.2)
Alopecia	22 (42.3)	–	20 (38.5)	–
Fatigue	20 (38.5)	1 (1.9)	18 (34.6)	3 (5.8)
Anemia	18 (34.6)	3 (5.8)	14 (26.9)	5 (9.6)
Nausea	15 (28.8)	2 (3.8)	17 (32.7)	5 (9.6)
White blood cell decreased	14 (26.9)	12 (23.1)	8 (15.4)	4 (7.7)
Diarrhea	12 (23.1)	3 (5.8)	20 (38.5)	4 (7.7)

The most common immune-related TRAEs attributed to pembro were hypothyroidism (6%), hypoalbuminemia, increased ALT, and increased alkaline phosphatase (each, 4%).

Additional Studies on SG Use With CPIs in mBC

The phase 2 Saci-IO TNBC study (NCT04468061) will investigate the efficacy and safety of SG ± pembro in patients with PD(L)-1- mTNBC who have received no prior systemic therapy for mBC.

The phase 2, single-arm BALISTA study (NCT06793332) will investigate the efficacy and safety of ivonescimab + a trophoblast cell surface antigen-2 ADC, including SG, in patients with mTNBC and brain metastases.

A multicenter, phase 2 cohort study (NCT06878625) will investigate the efficacy and safety of SG + toripalimab or + anti-angiogenesis therapy (either bevacizumab or anlotinib) as ≥2L treatment in patients with mTNBC.

The phase 1/2 TARGET-TNBC study (NCT06238921) will investigate the efficacy and safety of SG + zimberelimab with stereotactic radiation vs SG monotherapy in patients with mTNBC and brain metastases.

References

1. Tolaney SM, De Azambuja E, Kalinsky K, et al. Sacituzumab govitecan plus pembrolizumab vs chemotherapy plus pembrolizumab in patients with previously untreated, PD-L1-positive, advanced or metastatic triple-negative breast cancer: primary results from the randomized, Phase 3 ASCENT-04/KEYNOTE-D19 study [Oral]. Presented at: American Society of Clinical Oncology (ASCO) Annual Meeting; 30 May-03 June, 2025; Chicago, IL.
2. Schmid P, Loi S, Cruz-Merino L, et al. Interim analysis (IA) of the atezolizumab (atezo) + sacituzumab govitecan (SG) arm in patients (pts) with triple-negative breastcancer (TNBC) in MORPHEUS-pan BC: A phase Ib/II study of multiple treatment (tx) combinations in pts with locally advanced/metastatic BC (LA/mBC) [Oral presentation: 181O]. Presented at: European Society for Medical Oncology Breast Cancer (ESMO BC) Congress; 15-17 May, 2024; Berlin, Germany.
3. Schmid P, Loi S, Cruz Merino L, et al. Interim analysis (IA) of the atezolizumab (atezo) + sacituzumab govitecan (SG) arm in patients (pts) with triple-negative breast cancer (TNBC) in MORPHEUS-pan BC: A phase Ib/II study of multiple treatment (tx) combinations in pts with locally advanced/metastatic BC (LA/mBC) [Abstract: ID: 211]. Presented at: European Society for Medical Oncology Breast Cancer (ESMO BC) Congress; 15-17 May, 2024; Berlin, Germany.
4. Garrido-Castro AC, Kim S-E, Desrosiers J, et al. SACI-IO HR+: A randomized phase II trial of sacituzumab govitecan with or without pembrolizumab in patients with metastatic hormone receptor-positive/ HER2-negative breast cancer [Oral Presentation LBA1004]. Presented at: American Society of Clinical Oncology (ASCO) Annual Meeting; 31 May-4 June, 2024; Chicago, IL.
5. Tolaney SM, De Azambuja E, Emens LA, et al. ASCENT-04/KEYNOTE-D19: phase 3 study of sacituzumab govitecan plus pembrolizumab vs treatment of physician's choice plus pembro in first-line programmed death-ligand 1-positive metastatic triple-negative breast cancer [Poster 276TiP]. Presented at: European Society for Medical Oncology (ESMO) Congress; 9-13 September, 2022; Paris, France.

Abbreviations

1L=first line
2L=second line
ADC=antibody-drug conjugate
AE=adverse event
AESI=adverse event of special interest
atezo=atezolizumab
BC=breast cancer
BICR=blinded independent central review
CBR=clinical benefit rate
CPI=checkpoint inhibitor
CPS=combined positive score
CR=complete response
DCR=disease control rate
DOR=duration of response
ECOG PS=Eastern Cooperative Oncology Group Performance Status
ER=estrogen receptor
HR=hazard ratio
HR+=hormone receptor-positive
HER2-=human epidermal growth factor receptor 2-negative
IHC=immunohistochemistry
LA=locally advanced
mBC=metastatic breast cancer
mTNBC=metastatic triple-negative breast cancer
NA=not available
nab-P=nab-paclitaxel
ORR=objective response rate
OS=overall survival
PD=progressive disease
PD(L)-1=programmed death (ligand)-1
pembro=pembrolizumab
PFS=progression-free survival
PR=partial response
RECIST=Response Evaluation Criteria in Solid Tumors
SD=stable disease
SAE=serious adverse event
SG=sacituzumab govitecan-hziy
TEAE=treatment-emergent adverse event
TNBC=triple-negative breast cancer
TPC=treatment of physicians' choice
TRAE=treatment-related adverse event
TTOR=time to objective response

Product Label

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