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GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Combination With CPIs in mBC

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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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

Relevant Product Labeling[1]

SG, in combination with pembro or pembro and berahyaluronidase alfa-pmph, is indicated for the 1L treatment of adult patients with unresectable LA or mTNBC in patients whose tumors express PD-L1 (CPS ≥10) as determined by an FDA-authorized test.

SG Clinical Data on Use With CPIs in mBC

ASCENT-04, an ongoing, global, open-label, randomized, phase 3 study is comparing the efficacy and safety of SG + pembro (n=221) vs chemo TPC + pembro (n=222) as 1L treatment in patients with PD-L1+ (CPS ≥10), inoperable, LA or mTNBC. Patients who experienced disease progression with TPC + pembro could cross over to receive second-line SG monotherapy.[2]

- After a median (range) follow-up of 14 (0.1–28.6) mo, significantly longer mPFS (95% CI) was observed in patients treated with SG + pembro (11.2 [9.3–16.7] mo) vs TPC + pembro (7.8 [7.3–9.3] mo; HR, 0.65; 95% CI: 0.51–0.84; *P*<0.001).[2]
- Descriptive OS, ORR, and DOR results were reported. OS data were immature at the time of the primary analysis, and OS was not reached in both treatment arms (HR, 0.89; 95% CI: 0.62–1.29).[2,3] ORR (95% CI) was 60% (53%–66%) with SG + pembro vs 53% (46%–60%) with TPC + pembro (OR, 1.3; 95% CI: 0.9–1.9), and median DOR (95% CI) was 16.5 (12.7–19.5) mo vs 9.2 (7.6–11.3) mo, respectively.[2]
- The safety profile of SG + pembro was consistent with the known safety profile of each agent.[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 who have progressed on or within 12 mo of adjuvant endocrine therapy, and who have received 0 to 1 prior chemotherapy regimen.[4]

- At the primary analysis, after a median follow-up of 15.5 mo, SG + pembro (n=52) vs SG (n=52) did not significantly improve mPFS (primary endpoint: 8.4 vs 6.7 mo; HR, 0.76; *P*=0.12) or mOS (20 vs 18 mo; HR, 0.74; *P*=0.18).[4]
- At the primary analysis, the most common TEAEs (>40% incidence) with SG + pembro or SG were neutropenia (69.2% vs 61.5%) and alopecia (44.2% vs 38.5%). TEAEs that led to treatment discontinuation occurred in 3.8% of patients treated with SG + pembro and in 1.9% of patients treated with SG.[4]
- At the final analysis, after a median follow-up of 34.6 mo, SG + pembro did not significantly improve mPFS (8.4 vs 6.7 mo; HR, 0.78; *P*=0.12) or mOS (22.2 vs 22.1 mo; HR, 0.97; *P*=0.46) vs SG.
- At the final analysis, mPFS (95% CI) was 9.7 (4.2–15.7) mo in PD-L1+ patients treated with SG + pembro (n=19), vs 5.6 (2.5–8.7) mo in patients who were PD-L1+ treated with SG (n=20; HR, 0.56; 95% CI: 0.28–1.14; *P*=0.11). mOS was 24.3 (17–not reached) mo vs 17.7 (12.4–33) mo, respectively (HR, 0.69; 95% CI: 0.32–1.48; *P*=0.34).[5]
- The safety profile of SG + pembro was consistent with the known safety profiles of each agent.[5]

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-wk interim analysis of atezo + SG (n=31) vs atezo + nab-P (n=11; control arm) in patients with 1L, PD-L1+ mTNBC are summarized.[6]

- 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 mPFS (95% CI) was reported with atezo + SG vs control: 12.2 (7.4—NE) mo vs 5.9 (4.1—8.7) mo, respectively; however, data were immature at this timepoint.[6,7]
- 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.[6]

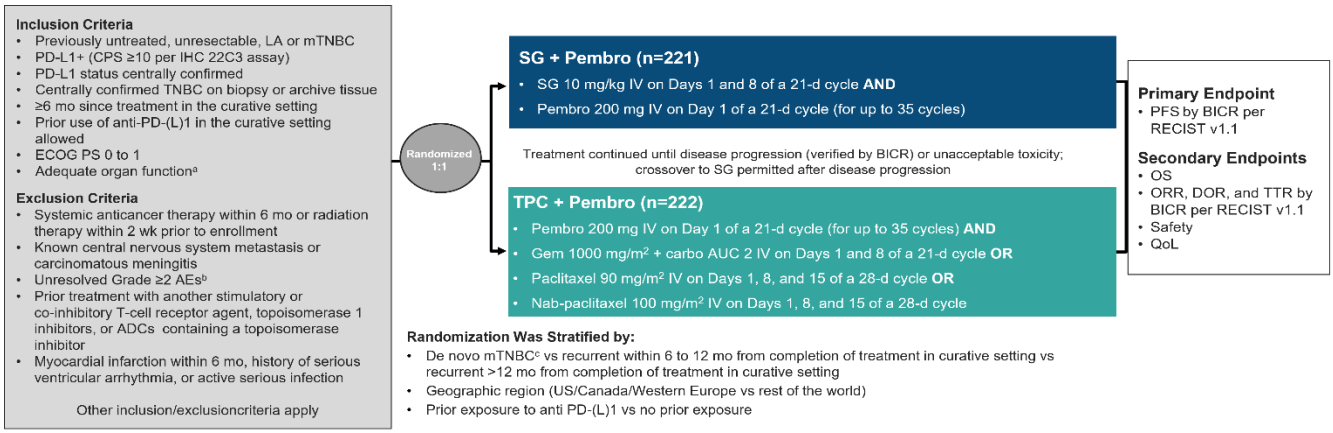
SG Clinical Data on Use With CPIs in mBC

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).[2]

Figure 1. ASCENT-04: Study Design[8]



Abbreviations: ANC=absolute neutrophil count; AUC=area under the curve; QoL=quality of life; ULN=upper limit of normal.
[a]Hgb ≥9 g/dL, ANC ≥1500/mm3, 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.

In the SG + pembro arm, a taxane was previously administered in 116 patients (52%) and gem or carbo was administered in 105 (48%); in the TPC + pembro arm, a taxane was administered in 114 patients (51%), and gem or carbo was administered in 108 patients (49%).[2] See Table 1 for baseline characteristics.

Table 1. ASCENT-04: Select Baseline Demographics and Disease Characteristics[2]

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, n (%)	White	139 (63)	118 (53)
	Asian	43 (19)	63 (28)
	American Indian or Alaska Native	14 (6)	13 (6)
	Black	13 (6)	11 (5)
	Other or not specified	12 (5)	17 (8)
ECOG PS,[a] 0/1, n (%)		156 (71)/65 (29)	154 (69)/67 (30)
Metastatic sites, n (%)	Lymph nodes	159 (72)	154 (69)
	Lung	111 (50)	95 (43)
	Bone	61 (28)	45 (20)
	Liver	55 (25)	57 (26)
	Brain	8 (4)	6 (3)
	Other[b]	81 (37)	71 (32)
Disease status, n (%)	Metastatic at initial diagnosis	75 (34)	75 (34)
	Recurrent within 6–12 mo	40 (18)	40 (18)
	Recurrent >12 mo	106 (48)	107 (48)
Prior anti-PD-(L)1 therapy,[c] n (%)		9 (4)	11 (5)

[a]One patient in the TPC + pembro group had an ECOG PS of 2.
[b]Included pleura, pleural effusion, skin, soft tissue, chest wall, and muscle.
[c]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.

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Efficacy

At data cutoff, 95 (43%) and 52 (23%) patients in the SG + pembro and TPC + pembro arms, respectively, remained on treatment. Among 119 patients who received subsequent treatment after discontinuing TPC + pembro, 96 (81%) crossed over to receive SG.[2]

After a median (range) follow-up of 14 (0.1–28.6) mo, mPFS was significantly longer in patients treated with SG + pembro vs TPC + pembro (Table 2). In the SG + pembro arm, 6- and 12-mo PFS (95% CI) rates were 72% (65–77%) and 48% (41–56%), respectively, vs 63% (56–69%) and 33% (26–40%) in the TPC + pembro arm.[2]

Table 2. ASCENT-04: PFS by BICR[2]

Efficacy Outcome	SG + Pembro (n=221)	TPC + Pembro (n=222)	Stratified HR (95% CI); *P*-Value
PFS events, n	109	140	0.65 (0.51–0.84); *P*<0.001[a]
mPFS, (95% CI), mo	11.2 (9.3–16.7)	7.8 (7.3–9.3)	

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

OS, ORR, and DOR results were descriptive only, as formal hypothesis testing of secondary efficacy endpoints was not conducted.[2] Data on OS were immature at the time of the primary analysis, and OS was not reached in either treatment arm (HR, 0.89; 95% CI: 0.62–1.29).[2,3] SG + pembro demonstrated higher ORR and longer median DOR vs TPC + pembro (Table 3).

Table 3. ASCENT-04: Response Rates[2]

Efficacy Outcome	SG + Pembro (n=221)	TPC + Pembro (n=222)
ORR, % (95% CI)	60 (53–66)	53 (46–60)
Median DOR, (95% CI), mo	16.5 (12.7–19.5)	9.2 (7.6–11.3)

Safety[2]

Overall, the safety profile of SG + pembro was consistent with the known safety profile of each agent. See Table 4 for an overall safety summary.

Table 4. ASCENT-04: Safety Summary[2]

TEAEs, n (%)	SG + Pembro (n=221)	TPC + Pembro (n=220)
Any TEAEs	220 (>99)	219 (>99)
Grade ≥3	158 (71)	154 (70)
TRAEs	218 (99)	215 (98)
SAEs	84 (38)	68 (31)
TEAEs that led to dose reduction[a]	78 (35)	96 (44)
TEAEs that led lead to dose interruption	171 (77)	162 (74)
TEAEs that led to treatment discontinuation of SG or TPC	16 (7)	50 (23)
TEAEs that led to treatment discontinuation of pembro	19 (9)	29 (13)
AEs that led to death	7 (3)[b]	6 (3)[c]

[a]There was no dose reduction for pembro per the protocol.
[b]Two deaths were due to unknown causes, and 1 death each was due to pneumonia, sepsis, neutropenic sepsis, suicide, and pulmonary embolism. Three deaths (each, n=1: neutropenic sepsis, pneumonia, and pulmonary embolism) were deemed treatment-related.
[c]One death each was due to cardiac arrest, large-intestine perforation, unknown cause, pneumonia, sepsis, and a postprocedural complication. One death due to pneumonia was deemed related to trial treatment.

The most common any-grade and Grade ≥3 TEAEs are presented in Table 5.

Table 5. ASCENT-04: Most Common Any-Grade (≥20%) and Grade ≥3 (≥5%) TEAEs[2a]

TEAEs, n (%)	SG + Pembro (n=221)		TPC + Pembro (n=220)	
	Any-Grade	Grade ≥3	Any-Grade	Grade ≥3
Diarrhea	155 (70)	22 (10)	63 (29)	5 (2)
Nausea	150 (68)	7 (3)	83 (38)	4 (2)
Neutropenia	139 (63)	95 (43)	130 (59)	98 (45)
Fatigue	129 (58)	18 (8)	123 (56)	7 (3)
Alopecia	114 (52)	-	71 (32)	-
Constipation	90 (41)	1 (<1)	76 (35)	1 (<1)
Anemia	81 (37)	16 (7)	112 (51)	35 (16)
Vomiting	65 (29)	2 (1)	31 (14)	4 (2)
Headache	55 (25)	1 (<1)	38 (17)	0
Rash	47 (21)	2 (1)	44 (20)	3 (1)
ALT increased	44 (20)	8 (4)	66 (30)	13 (6)
Leukopenia	42 (19)	7 (3)	46 (21)	19 (9)
AST increased	35 (16)	7 (3)	56 (25)	8 (4)
Febrile neutropenia	17 (8)	17 (8)	4 (2)	4 (2)
Peripheral neuropathy	15 (7)	1 (<1)	46 (21)	7 (3)
Thrombocytopenia	10 (5)	1 (<1)	63 (29)	30 (14)

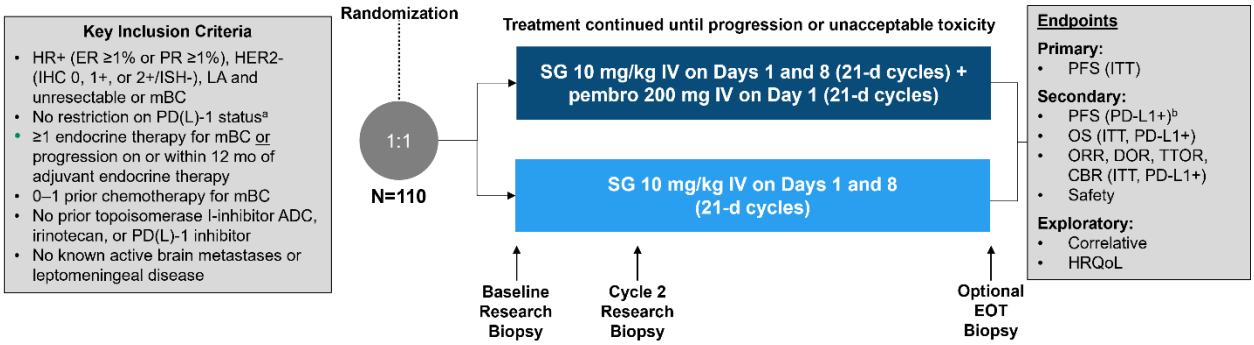
[a]Defined as any AEs that began or worsened on or after the first dose of study drug ≤30 d after the last dose of study drug or initiation of subsequent anticancer therapy (including crossover treatment).
Note: Combined preferred terms of neutropenia included neutropenia and neutrophil count decreased; fatigue included fatigue and asthenia; anemia included anemia, Hgb decreased, and red-cell count decreased; leukopenia included leukopenia and white-cell count decreased; thrombocytopenia included thrombocytopenia and platelet count decreased. All alopecia events were Grade 1 or 2 according to the National Cancer Institute Common Terminology Criteria for Adverse Events.

Saci-IO HR+ Study

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 2).[4,9]

Figure 2. Saci-IO HR+ Study Design[9]



Abbreviations: EOT=end of treatment; HRQoL=health-related quality of life; IHC=immunohistochemistry; ISH=in situ hybridization.
[a]Protocol amendment was activated in January 2022 to allow patients with any PD-L1 status to enroll.
[b]Central PD-L1 testing was performed with the PharmDx 22C3 assay; PD-L1+, CPS ≥1.

See Table 6 for select baseline demographics and characteristics.[4]

Table 6. Saci-IO HR+: Select 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)
Sex assigned at birth, female/male, n (%)		50 (96.2)/2 (3.8)	52 (100)/0
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 (%)		51 (98.1)/1 (1.9)/0	50 (96.2)/1 (1.9)/1 (1.9)
PD-L1 status,[b] negative/CPS ≥1, n (%)		22 (53.7) 19 (46.3)	27 (57.4)/ 20 (42.6)
Presentation at mBC diagnosis, de novo/recurrent mBC, n (%)		13 (25)/39 (75)	13 (25)/39 (75)
Liver metastasis, n (%)		40 (76.9)	41 (78.8)
Brain metastasis, n (%)		5 (9.6)	5 (9.6)
Prior (neo)adjuvant chemotherapy,[c] yes/no, n (%)		30 (76.9)/9 (23.1)	29 (74.4)/10 (25.6)
Prior CDK4/6i, yes/no, n (%)		49 (94.2)/3 (5.8)	49 (94.2)/3 (5.8)
Number of prior chemotherapy regimens for mBC, 0/1, n (%)		25 (48.1)/27 (51.9)	24 (46.2)/28 (53.8)

Abbreviation: CDK4/6i=cyclin-dependent 4/6 inhibitor.
[a]ER in the most recent available tumor sample prior to study registration. ER+ (% unknown in 1 patient).
[b]Central PD-L1 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=13; SG, n=13) were excluded from denominator.

Primary efficacy results[4]

After a median follow-up of 15.5 mo, non-significant improvements in mPFS and mOS were reported with SG + pembro vs SG (Table 7).

Table 7. Saci-IO HR+: Primary mPFS and mOS Results (Modified ITT Population)[4]

Efficacy Outcome	SG + Pembro (n=52)	SG (n=52)	HR (95% CI); Log-Rank *P*-Value
mPFS (95% CI), mo	8.4 (4.8–11.1)	6.7 (3.9–8.7)	0.76 (0.48–1.19); 0.12
mOS (95% CI), mo	20 (16.6–NA)	18 (17.1–NA)	0.74 (0.39–1.40); 0.18

No significant differences between patients treated with SG + pembro vs patients treated with SG were observed for ORR, CBR, or median TTP (Table 8). Median DOR was longer with SG + pembro, while median TTOR was similar between groups.

Table 8. Saci-IO HR+: Secondary Endpoints[4]

Efficacy Outcome	SG + Pembro (n=52)	SG (n=52)	*P*-Value
ORR, % (95% CI)	28.8 (17.1–43.1)	19.2 (9.6–32.5)	0.36
CBR, % (95% CI)	46.2 (32.2–60.5)	36.5 (23.6–51)	0.43
Median TTP, (95% CI), mo	8.4 (5.3–12.5)	6.7 (4–8.7)	0.17
Median DOR, (95% CI), mo	12.9 (4.1–NA)	4.5 (4.5–NA)	-
Median TTOR, (95% CI), mo	4.5 (1.8–15.5)	4.2 (2–10.2)	-

Primary safety results[4]

Grade ≥2 TEAEs were reported in 51 patients (98.1%) and 50 patients (96.2%) in the SG + pembro and SG arms, respectively, and Grade ≥3 TEAEs were reported in 40 patients (76.9%) and 36 patients (69.2%), respectively; a Grade 5 event of hepatic failure occurred in 1 patient in the SG arm that was considered unlikely to be related to treatment. TEAEs that led to treatment discontinuation occurred in 3.8% of patients treated with SG + pembro and in 1.9% of patients treated with SG. See Table 9 for the most common TEAEs.

Table 9. Saci-IO HR+: Primary Safety Summary[4]

Most Common TEAEs, %	SG + Pembro (n=52)	SG (n=52)
Neutropenia	69.2	61.5
Alopecia	44.2	38.5
Fatigue	38.5	34.6
Anemia	34.6	28.8
Nausea	30.8	32.7
Leukopenia	28.8	15.4
Diarrhea	23.1	38.5

Grade 3/4 TRAEs were reported in 37 patients (71.2%) and 35 patients (67.3%) in the SG + pembro and SG arms, respectively.

The most common immune-related TRAEs attributed to pembro were hypothyroidism and increased alkaline phosphatase level (5.8% each), and increased ALT level and hypoalbuminemia (3.8% each).

In the SG + pembro and SG arms, dose modifications, delays, or omissions occurred in 45 patients (86.5%) and 44 patients (84.6%), respectively, whereas SG dose reductions occurred in 19 (36.5%) and 25 patients (48.1%), respectively. Treatment was held due to toxicity in 28 patients (53.8%) in the SG + pembro arm (SG: n=27 [51.9%]; pembro: n=16 [30.8%]) and in 25 patients (48.1%) in the SG arm.

Final efficacy results[5]

After a median follow-up of 34.6 mo, non-significant improvements in mPFS and mOS were observed with SG + pembro vs SG in the ITT population (Table 10).

Table 10. Saci-IO HR+: Final mPFS and mOS Results (ITT Population)[5]

Efficacy Outcome		SG + Pembro (n=52)	SG (n=52)	HR (95% CI); Log-Rank *P*-Value
PFS	Number of events	46	45	0.78 (0.52–1.19); 0.12
	mPFS (95% CI), mo	8.4 (4.5–12.5)	6.7 (3.8–8.7)	
OS	Number of events	37	36	0.97 (0.61–1.54); 0.46
	mOS (95% CI), mo	22.2 (17.3–31.2)	22.1 (18.0–27.4)	

Among the 19 patients with available data who were PD-L1+ and were treated with SG + pembro, mPFS (95% CI) was 9.7 (4.2–15.7) mo, vs 5.6 (2.5–8.7) mo in the 20 PD-L1+ patients who were treated with SG (HR, 0.56; 95% CI: 0.28–1.14; *P*=0.11). mOS (95% CI) was 24.3 (17–not reached) mo vs 17.7 (12.4–33) mo in the SG + pembro and SG arms, respectively (HR, 0.69; 95% CI: 0.32–1.48; *P*=0.34).

Final safety results[5]

The safety profile of SG + pembro was consistent with the known safety profiles of each agent. See Table 11 for a summary of the most common TEAEs.

Table 11. Saci-IO HR+: Final Safety Summary (Incidence >20%)[5]

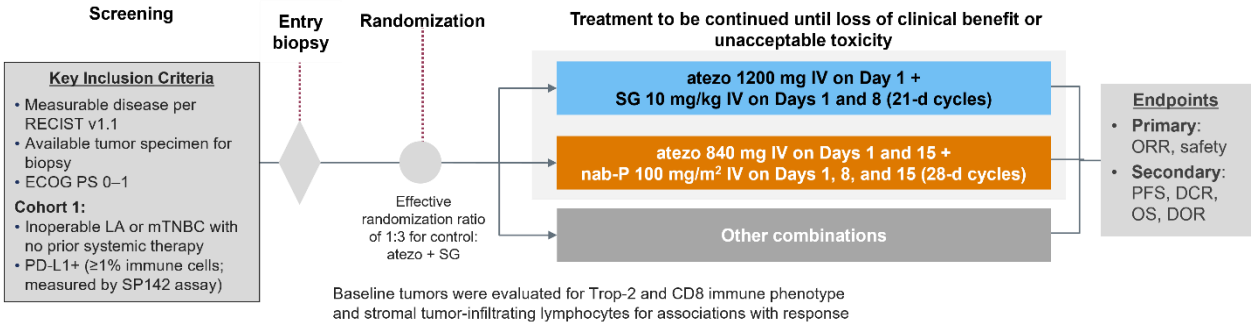
Most Common TEAEs (≥15%), n (%)	SG + Pembro (n=52)		SG (n=52)	
	Grade ≥2	Grade 3 or 4	Grade ≥2	Grade 3 or 4
Neutrophil count decreased	36 (69.2)	28 (53.8)	32 (61.5)	24 (46.2)
Alopecia	23 (44.2)	—	20 (38.5)	—
Fatigue	20 (38.5)	2 (3.8)	18 (34.6)	3 (5.8)
Anemia	19 (36.5)	4 (7.7)	15 (28.8)	5 (9.6)
Nausea	16 (30.8)	2 (3.8)	17 (32.7)	5 (9.6)
Diarrhea	13 (25)	3 (5.8)	21 (40.4)	4 (7.7)

MORPHEUS-Pan BC Study

Study design and demographics[6]

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 3). Interim analysis results for atezo + SG vs atezo + nab-P (control) in patients with no prior systemic treatment for PD-L1+ and inoperable, LA or mTNBC are summarized.

Figure 3. MORPHEUS-Pan BC Study Design[6]



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 12 for key demographics and characteristics.

Table 12. MORPHEUS-Pan BC: Baseline Demographics and Disease Characteristics[6]

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)

Key Demographics and Characteristics, n (%)	Atezo + SG (n=31)	Atezo + nab-P (n=11)
Prior treatment, taxane/capecitabine/carbo	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 13).[6,7]

Table 13. MORPHEUS-Pan BC Interim Analysis: Response Rates (Efficacy and Safety Evaluable Population)[6,7]

		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 stable disease or better for ≥12 wk.
[b]Criteria is either response and/or stable disease 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 14). Interim results of DOR showed that patients remained on treatment for longer with atezo + SG vs control.[6]

Table 14. MORPHEUS-Pan BC Interim Analysis: Secondary Endpoints[6]

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 were as follows: atezo + SG, 10.6 mo; atezo + nab-P, 11.7 mo.

Safety results[6]

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 15 for overall safety summary in the efficacy and safety evaluable population.

Table 15. MORPHEUS-Pan BC Interim Analysis: Overall Safety Summary[6]

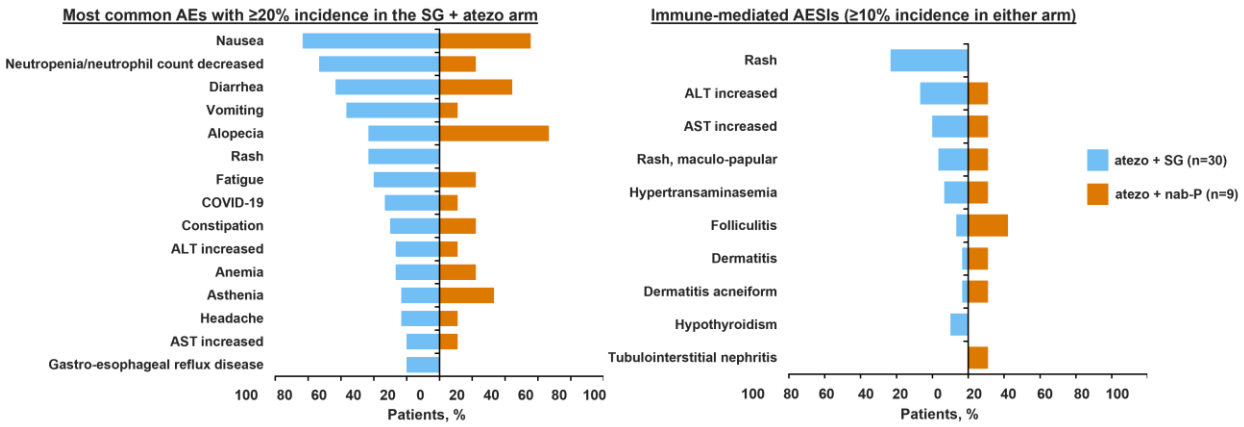
Safety Parameters, n (%)		Atezo + SG (n=30)	Atezo + nab-P (n=9)
Patients with ≥1 AE	Worst grade: 3	14 (46.7)	4 (44.4)
	Worst grade: 4	7 (23.3)	0
AEs that led to treatment discontinuation[a]		1 (3.3)	1 (11.1)
AEs that led to dose modification/interruption		26 (86.7)	7 (77.8)
SAEs		7 (23.3)	4 (44.4)

Safety Parameters, n (%)		Atezo + SG (n=30)	Atezo + nab-P (n=9)
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 4 for the most common AEs in the atezo + SG and control arms.

Figure 4. MORPHEUS-Pan BC Interim Analysis: Most Common AEs and Immune-Mediated AEs of Special Interest (Efficacy and Safety Evaluable Population)[6]



Ongoing SG Clinical Studies on 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-L1- 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 phase 2, multicenter, open-label, randomized study (NCT07040644) will investigate the efficacy and safety of SG + toripalimab vs toripalimab + nab-P in patients with previously untreated, PD-L1+, unresectable, LA or mTNBC.

A phase 2, multicenter, prospective, single-arm study (NCT06991790) will investigate the efficacy and safety of SG + toripalimab as 1L treatment in patients with advanced TNBC.

The phase 1b, randomized, open-label SIMONE study (NCT06963905) will investigate the efficacy and safety of SG + niv or SG + niv + relatlimab in second-line or later mTNBC. The primary endpoint is dose-limiting toxicities observed 3 wk after the first treatment cycle.

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Abbreviations

1L=first line
ADC=antibody-drug conjugate
AE=adverse event
atezo=atezolizumab
BC=breast cancer
BICR=blinded independent central review
carbo=carboplatin
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
gem=gemcitabine
HER2-=human epidermal growth factor receptor 2-negative
HR=hazard ratio
HR+=hormone receptor-positive
LA=locally advanced
mBC=metastatic breast cancer
mOS=median overall survival
mPFS=median progression-free survival
mTNBC=metastatic triple-negative breast cancer
NA=not available
nab-P=nab-paclitaxel
niv=nivolumab
ORR=objective response rate
OS=overall survival

PD-L1=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
TTP=time to progression

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