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Trodelvy® (sacituzumab govitecan-hziy) Patient-Reported Outcomes in 1L PD-L1+ mTNBC

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) + pembrolizumab (pembro) and patient-reported outcomes (PRO) in first-line (1L) programmed death ligand-1 positive (PD-L1+) metastatic triple-negative breast cancer (mTNBC).

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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 locally advanced or mTNBC in patients whose tumors express PD-L1 (CPS ≥10) as determined by an FDA-authorized test.

Patient-Reported Outcomes in 1L PD-L1+ mTNBC

ASCENT-04, an ongoing, global, open-label, randomized, phase 3 study, is comparing the efficacy and safety of SG + pembro vs chemotherapy TPC + pembro as 1L treatment in patients (N=443) with PD-L1+ (CPS ≥10), inoperable, locally advanced or mTNBC.[2]

PROs, assessed using the EORTC QLQ-C30 questionnaire, were compared between treatment arms in the ITT population.[3] At the time of the primary analysis, no formal statistical analyses were conducted; these results are descriptive only.[2,3]

- At BL, PRO scores for EORTC QLQ-C30 domains were generally comparable between treatment arms and general population norms; these data are not summarized.[3]
- Results for the physical functioning domain of EORTC QLQ-C30 were:[3]
  - Median TTD (key PRO endpoint) was 3 mo for SG + pembro vs 3.5 mo for TPC + pembro (stratified HR 0.95; 95% CI 0.73–1.22). The MWPC threshold was ≥13.33-point change from BL.
  - Median TTD (prespecified sensitivity analysis) was 9.3 mo for SG + pembro vs 6.9 mo for TPC + pembro (stratified HR 0.82; 95% CI 0.60–1.11). The MWPC threshold was ≥20-point change from BL.
  - Median TTCD (prespecified sensitivity analysis) was 8.8 mo for SG + pembro vs 5.7 mo for TPC + pembro (HR 0.84; 95% CI 0.62–1.12). The MWPC threshold was ≥13.33-point change from BL.

- Median TTD was longer with SG + pembro vs TPC + pembro for emotional functioning (9.3 vs 4.9 mo) and pain (4.3 vs 3.2 mo). Median TTD was shorter with SG + pembro vs TPC + pembro for nausea/vomiting (1.5 vs 3.5 mo) and diarrhea (1.4 vs 5.3 mo). The MWPC threshold was ≥10-points for these domains.[3]
- Median TTCD (prespecified sensitivity analysis) was longer with SG + pembro vs TPC + pembro for emotional functioning (21.9 vs 8.3 mo) and pain (12.5 vs 5.8 mo). Median TTCD was shorter for nausea/vomiting (4.4 vs 8.1 mo) and diarrhea (3.5 vs 13.9 mo). The MWPC threshold was ≥10-points for these domains.[3]
- LSM changes from BL for EORTC QLQ-C30 domains were greater for SG + pembro vs TPC + pembro in emotional functioning, pain, and insomnia. Less deterioration from BL was seen with SG + pembro vs TPC + pembro in role functioning and physical functioning, however, symptoms of nausea/vomiting and diarrhea worsened.[3]

In a post hoc analysis using pooled data from both treatment arms (N=443), associations between disease control and LSM change from BL through Week 55 in five EORTC QLQ-C30 domains were evaluated; *P*-values were nominal and results are descriptive only.[4]

- PD was associated with worsening from BL in GHS/QoL (-3.52), physical functioning (-2.51), role functioning (-3.14), pain (5.51), and fatigue (3.26).
- OR (complete or partial response) was associated with improvements from BL in role functioning (2.11) and pain (-3.86).
- Compared with PD, OR (complete or partial response) was associated with more favorable changes from BL in all five domains assessed (GHS/QoL, physical functioning, role functioning, pain, and fatigue; each, nominal $P<0.001$).
- Incremental improvement in PROs was not observed as DOR increased (all five domains; each, nominal $P\geq0.192$).

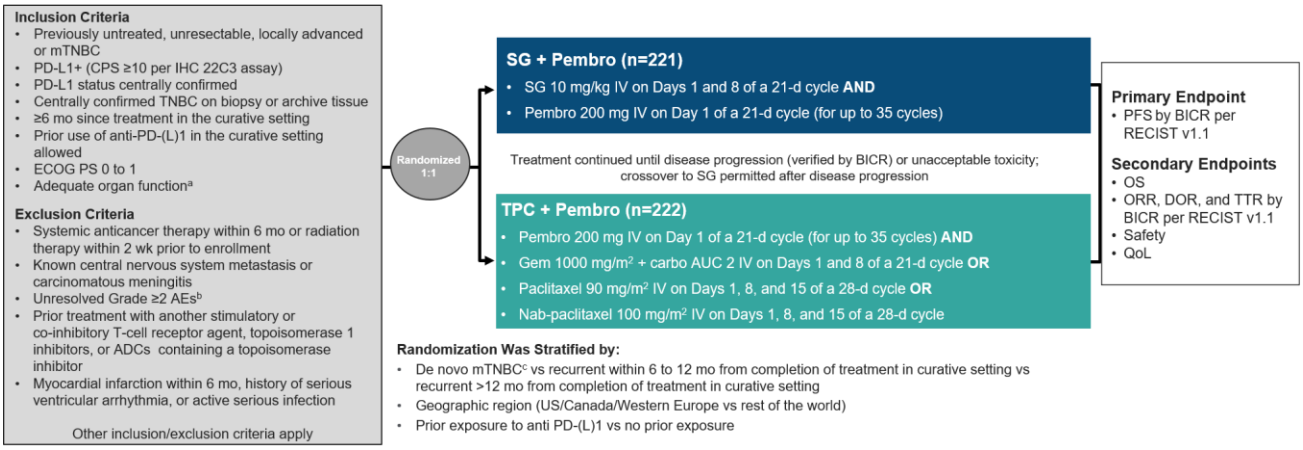
Patient-Reported Outcomes in 1L PD-L1+ mTNBC

ASCENT-04 Study

Study design and demographics

ASCENT-04 is an ongoing, global, open-label, randomized, phase 3 study (N=443) that is comparing the efficacy and safety of SG + pembro vs TPC + pembro as 1L treatment in patients with PD-L1+ (CPS ≥10), inoperable, locally advanced or mTNBC (Figure 1). Patients who experienced disease progression during treatment with TPC + pembro (as verified by BICR) could cross over to receive 2L SG monotherapy.[2]

Figure 1. ASCENT-04: Study Design[2,5]



Abbreviations: ADC=antibody drug conjugate; AE=adverse event; ANC=absolute neutrophil count; AUC=area under the concentration-time curve; carbo=carboplatin; ECOG PS=Eastern Cooperative Oncology Group Performance Status; gem=gemcitabine; IHC=immunohistochemistry; ORR=objective response rate; OS=overall survival; PFS=progression-free survival; RECIST=response evaluation criteria in solid tumors; TNBC=triple-negative breast cancer; TTR=time to response; ULN=upper limit of normal.
[a]Hemoglobin ≥9 g/dL, ANC ≥1500/mm^3; platelets ≥100,000/μL, 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.

PRO endpoints and results

PFS was the primary endpoint and served as the gatekeeper for formal testing of OS, followed by ORR and TTD of physical functioning (once the prior endpoint in the hierarchy was significant). Results of all PRO endpoints can, therefore, only be described descriptively as statistical testing was not conducted.[2,3]

The assessment schedule for PRO was BL, Day 1 of Cycle 1, and Day 1 of all subsequent cycles until end of treatment. The analyses and clinically meaningful thresholds for all PRO endpoints are shown in Table 1.[3]

Table 1. ASCENT-04: EORTC QLQ-C30 Outcomes and Clinically Meaningful Thresholds[3]

Outcome using the EORTC QLQ-C30 questionnaire	Clinically meaningful threshold (MWPC change from baseline)
TTD[a] in physical functioning (key secondary endpoint)	≥13.33-points[b]
TTD[a] in all remaining domains	≥10-points
TTD[a] in physical functioning at a higher threshold[c]	≥20-points
TTCD[c,d] in physical functioning	≥13.33-points[b]
TTCD[c,d] in all remaining domains	≥10-points
Overall least squares mean changes from baseline in scores	Difference >0 for functioning and <0 for symptom domains favor SG + pembro

Abbreviations: MWPC=meaningful within patient change; TTCD=time to confirmed deterioration.
[a]TTD in each domain defined as the time between randomization and the assessment at which a patient first experienced a prespecified MWPC from BL or death. [b]Physical functioning scores change in 6.67 increments so 13.33 is equivalent to a 10-point threshold. [c]Prespecified sensitivity analysis. [d]Deterioration from BL confirmed by a next scheduled visit or followed by missing PRO visit or death <42 days after last PRO assessment or death <42 days after randomization if BL/post-BL assessments were missing.

Results[3]

At BL, PRO scores for EORTC QLQ-C30 domains were generally comparable between treatment arms and with general population norms (reweighted by age and sex distributions of the ITT population); these data are not summarized.

EORTC QLQ-C30: physical functioning domain

TTD in the physical functioning domain of EORTC QLQ-C30 was the key PRO endpoint; two types of sensitivity analyses were also conducted for this domain.

Results showed that the median TTD (95% CI) in physical functioning was 3 (2.3–4.6) mo with SG + pembro vs 3.5 (2.9–4.2) mo for TPC + pembro (stratified HR 0.95; 95% CI 0.73–1.22).

In a prespecified sensitivity analysis of TTD, which used a higher ≥20-point MWPC threshold from BL, a numerically longer median TTD (95% CI) in physical functioning of 9.3 (6.1–NE) mo with SG + pembro vs 6.9 (5.6–8.3) mo with TPC + pembro (stratified HR 0.82; 95% CI 0.60–1.11) was observed.

A separate prespecified sensitivity analysis assessed TTCD in physical functioning. Results showed a numerically longer median TTCD (95% CI) for physical functioning of 8.8 (5.1–13.1) mo for SG + pembro vs 5.7 (4.4–7.0) mo for TPC + pembro (HR 0.84; 95% CI 0.62–1.12).

EORTC QLQ-C30: all domains

Time to deterioration

TTD in the EORTC QLQ-C30 domains other than the physical functioning domain was assessed using the threshold of ≥10-points; median TTD in most of these domains was maintained for a similar duration in both treatment arms (Table 2). Median TTD of emotional functioning and pain was numerically longer for SG + pembro, whereas TTD for nausea/vomiting and diarrhea was numerically shorter.

Table 2. ASCENT-04: TTD in EORTC QLQ-C30 Domains (ITT Population)[3]

EORTC QLQ-C30 domain	Time to event, [a] median (95% CI), mo		HR (95% CI)[b]
	SG + Pembro (n=221)	TPC + Pembro (n=222)	
Global health status/QoL	2.2 (2.1–3.3)	3.5 (2.3–4.2)	0.98 (0.75–1.27)
Physical functioning	3 (2.3–4.6)	3.5 (2.9–4.2)	0.95 (0.73–1.22)
Role functioning	1.7 (1.1–2.2)	1.5 (1.4–2.3)	1.01 (0.79–1.29)
Emotional functioning	9.3 (5.9–NE)	4.9 (3.5–6.3)	0.71 (0.53–0.96)
Cognitive functioning	2.3 (1.5–3.5)	2.9 (2.2–3.5)	0.96 (0.74–1.23)
Social functioning	1.9 (1.5–2.2)	2.2 (1.5–3.3)	1.02 (0.8–1.31)
Fatigue	1.1 (1–1.4)	1 (0.9–1.4)	0.91 (0.72–1.15)
Nausea/vomiting	1.5 (1–2.2)	3.5 (2.1–4.4)	1.38 (1.07–1.77)
Pain	4.3 (2.4–5.7)	3.2 (2.2–4.2)	0.75 (0.57–0.98)
Dyspnea	4.7 (3.1–6.7)	3.7 (2.8–5.6)	0.88 (0.67–1.16)
Insomnia	5.6 (3.7–10.8)	3.5 (2.8–4.4)	0.75 (0.56–1)
Appetite loss	2.2 (1.7–3)	4.2 (2.9–5.6)	1.25 (0.96–1.64)
Constipation	2.8 (2.1–3.5)	3.7 (2.4–5.1)	1.07 (0.82–1.39)
Diarrhea	1.4 (1–1.8)	5.3 (3.1–6.9)	1.92 (1.48–2.48)
Financial difficulties	7.6 (4.2–13.6)	9.3 (5.7–NE)	1.16 (0.85–1.59)

[a]TTD or death. [b]HR <1 favors SG + pembro.

Time to confirmed deterioration

Median TTCD was assessed in a prespecified sensitivity analysis of the EORTC QLQ-C30. The MWPC threshold was ≥13.33-points for physical functioning and ≥10-points for all other domains. Similar to the results of the TTD analysis, TTCD of emotional functioning and pain was numerically longer with SG + pembro vs TPC + pembro, however, TTCD of nausea/vomiting and diarrhea was numerically shorter (Table 3).

Table 3. ASCENT-04: TTCD in EORTC QLQ-C30 Domains (ITT Population)[3]

EORTC QLQ-C30 domain	Time to event, [a] median (95% CI), mo		HR (95% CI)[b]
	SG + Pembro (n=221)	TPC + Pembro (n=222)	
Global health status/QoL	6.9 (3.1–8.8)	5.8 (4.3–NE)	1.1 (0.82–1.48)
Physical functioning	8.8 (5.1–13.1)	5.7 (4.4–7)	0.84 (0.62–1.12)
Role functioning	3.1 (2.3–5.3)	3.5 (2.3–4.4)	0.84 (0.64–1.09)
Emotional functioning	21.9 (12.5–NE)	8.3 (5.7–12.9)	0.58 (0.41–0.83)
Cognitive functioning	5.1 (3.5–7.6)	4.9 (3.5–6.8)	0.95 (0.72–1.25)
Social functioning	4.6 (3–7)	4.2 (3.4–5.7)	0.94 (0.71–1.24)
Fatigue	2.1 (1.6–2.8)	2.1 (1–2.4)	0.8 (0.63–1.03)
Nausea/vomiting	4.4 (2.4–6.2)	8.1 (5.3–12.5)	1.4 (1.05–1.87)
Pain	12.5 (7–NE)	5.8 (4.2–8.7)	0.69 (0.5–0.94)
Dyspnea	10.9 (7.2–NE)	8.7 (6.3–NE)	0.87 (0.63–1.2)
Insomnia	15 (9.8–NE)	7.9 (5.3–NE)	0.79 (0.56–1.11)
Appetite loss	9.2 (5–NE)	7 (4.2–9.6)	0.9 (0.66–1.21)
Constipation	6.9 (4.5–NE)	7.2 (5–NE)	1.06 (0.78–1.43)
Diarrhea	3.5 (2.2–4.6)	13.9 (8.1–NE)	2.06 (1.53–2.78)
Financial difficulties	21 (11.5–NE)	NE (8.7–NE)	1.03 (0.72–1.48)

[a]TTCD or death. [b]HR <1 favors SG + pembro.

Overall LSM changes from BL in EORTC QLQ-C30 scores

Overall LSM changes from BL were evaluated for the functioning and symptom domains of the EORTC QLQ-C30. Results showed that SG + pembro demonstrated numerically greater improvements from BL vs TPC + pembro in emotional functioning, pain, and insomnia (Table 4). Numerically less deterioration from BL was seen with SG + pembro vs TPC + pembro in role functioning and physical functioning, however, symptoms of nausea/vomiting and diarrhea worsened.

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Table 4. ASCENT-04: Overall LSM Changes From BL in EORTC QLQ-C30 Scores (ITT Population)[3]

EORTC QLQ-C30 domain		Overall LSM Change from BL (95% CI)			MID
		SG + Pembro (n=221)	TPC + Pembro (n=222)	Difference (95% CI)	
Functioning domains	Emotional functioning	5.03[a]	0.97	4.07[a] (1.2 to 6.93)	7
	Role functioning	-6.4[a]	-9.74[a]	3.34[a] (0.13 to 6.55)	7.72
	Physical functioning	-2.84[a]	-5.29[a]	2.45[a] (0.09 to 4.81)	5.78
	Social functioning	-5.3[a]	-6.9[a]	1.56 (-1.15 to 4.34)	7.49
	GHS/QoL	-1.6	-2.7[a]	1.1 (-1.4 to 3.59)	6.38
	Cognitive functioning	-5.36[a]	-6.36[a]	1 (-1.63 to 3.63)	5.2
Symptom domains	Pain	-8.11[a]	-2.72[a]	-5.39[a] (-8.55 to -2.23)	8.42
	Insomnia	-6.41[a]	-1.82	-4.59[a] (-7.7 to -1.48)	8.86
	Fatigue	4.34[a]	7.09[a]	-2.75 (-5.65 to 0.15)	7
	Dyspnea	1.65	3.01[a]	-1.35 (-4.29 to 1.59)	6.91
	Appetite loss	0.16	1.28	-1.13 (-4.08 to 1.83)	7.09
	Constipation	4.95[a]	4.26[a]	0.69 (-2.79 to 4.14)	6.88
	Financial difficulties	3.28[a]	2.17	1.11 (-2.3 to 4.51)	8.73
	Nausea/vomiting	5.23[a]	2.56[a]	2.67[a] (0.73 to 4.62)	4.23
	Diarrhea	13.62[a]	3.21[a]	10.41[a] (7.53 to 13.29)	4.31

Abbreviation: MID=minimally important difference.

[a] Differences in overall LSM change >0 for functioning domains and <0 for symptom domains are in favor of SG + pembro.

Association between disease control and patient-reported functioning and QoL[4]

A post hoc analysis of pooled data from both treatment arms evaluated associations between disease control and LSM change from BL in five EORTC QLQ-C30 domains in the ITT population (N=443). PD and OR were modeled as binary time-varying covariates, and DOR as a continuous time-varying covariate, using mixed models for repeated measures, with data limited to assessments through Week 55, the last time point at which model convergence was achieved. *P*-values were nominal and not adjusted for multiplicity.[4]

Results

PD was associated with worsening from BL in GHS/QoL, physical functioning, role functioning, pain, and fatigue. OR was associated with improvements from BL in role functioning and pain. Compared with PD, OR (complete or partial response) was associated with more favorable changes from BL in all five domains. Incremental improvement in PROs was not observed as DOR increased (Table 5).

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Table 5. ASCENT-04: Association Between Disease Control and LSM Change From BL in EORTC QLQ-C30 Scores Through Week 55 (Pooled ITT Population)[4]

EORTC QLQ-C30 domain		PD vs No PD		OR vs No Response		OR vs PD		DOR per Day[a]	
		Difference in LSM Change	*P*-value	Difference in LSM Change	*P*-value	Difference in LSM Change	*P*-value	Difference in LSM Change	*P*-value
Functioning domains	GHS/QoL	-3.52	<0.001	1.21	0.129	3.24	<0.001	0.005	0.558
	Physical functioning	-2.51	0.002	1.08	0.084	3.75	<0.001	0.011	0.192
	Role functioning	-3.14	0.012	2.11	0.025	3.89	<0.001	0.011	0.329
Symptom domains	Pain	5.51	<0.001	-3.86	<0.001	-5.46	<0.001	0.002	0.857
	Fatigue	3.26	0.005	-1.33	0.139	-4.17	<0.001	-0.009	0.378

[a]DOR represented cumulative days from first documented complete or partial response to PRO assessment; nonresponders were assigned a DOR of 0.

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1. TRODELVY® Gilead Sciences Inc. Trodelvy (sacituzumab govitecan-hziy) for injection, for intravenous use. U.S. Prescribing Information. Foster City, CA.
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3. De Azambuja E, Schmid P, Kalinsky K, et al. Patient-reported outcomes with sacituzumab govitecan plus pembrolizumab vs chemotherapy plus pembrolizumab in patients with previously untreated PD-L1+ metastatic triple-negative breast cancer in the phase 3 ASCENT-04/KEYNOTE-D19 study [Oral LBA22]. Presented at: European Society For Medical Oncology (ESMO) Congress; 17-21 Oct, 2025; Berlin, Germany.
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5. Tolaney S, 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

2L=second line
BICR=blinded independent central review
BL=baseline
CPS=combined positive score
DOR=duration of response
EORTC QLQ-C30=European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire-Core 30
GHS=global health status
HR=hazard ratio
LSM=least squares mean
MWPC=meaningful within patient change
NE=not estimable
OR=objective response
ORR=objective response rate
OS=overall survival
PD=progressive disease
pembro=pembrolizumab
PFS=progression-free survival
QoL=quality of life
SG=sacituzumab govitecan-hziy

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TPC=treatment of physicians' choice

TTCD=time to confirmed deterioration

TTD=time to deterioration

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.

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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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