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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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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 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 (N=443) comparing the efficacy and safety of SG + pembro vs chemotherapy TPC + pembro, as 1L treatment in patients with PD-L1+ (CPS ≥10), inoperable, locally advanced or mTNBC.[2]

PRO outcomes of 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; this data is not summarized.[3]
- Results for the physical functioning domain of EORTC QLQ-C30 were:[3]
  - Median TTD (key PRO outcome) was 3 mo for SG + pembro vs 3.5 mo for TPC + pembro (stratified HR 0.95; 95% CI 0.73–1.22). The MPWC threshold was ≥13.33-point change from BL.
  - Median TTD (pre-specified 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 MPWC threshold was ≥20-point change from BL.
  - Median TTCD (pre-specified 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 MPWC 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 MPWC threshold was ≥10-points for these domains.[3]
- Median TTCD (pre-specified 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 MPWC 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]

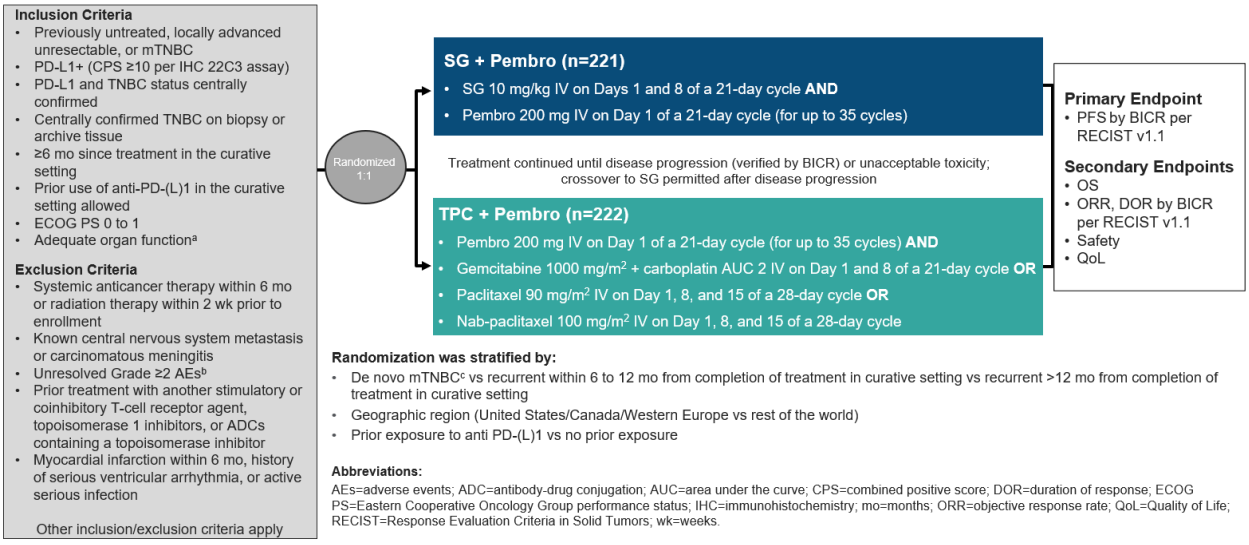
Patient-Reported Outcomes in 1L PD-L1+ mTNBC

ASCENT-04 Study

Study design and demographics

ASCENT-04 is an ongoing, global, open label, randomized, phase 3 study (N=443) that is 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, locally advanced or mTNBC (Figure 1). Patients who experienced disease progression during treatment with TPC + pembro (as verified by BICR) could crossover to receive 2L SG monotherapy.[2]

Figure 1. ASCENT-04 Study Design[2,4]



[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.

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PRO outcomes

In the statistical testing hierarchy, OS will be formally tested for significance once PFS is statistically significant, followed by objective response rate, and TTD of physical functioning (once the prior endpoint in the hierarchy was significant). Results of all PRO outcomes 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 outcomes are shown in Table 1.[3]

Table 1. 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 end point)	≥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 LSM changes from baseline in scores	Difference >0 for functioning and <0 for symptom domains favor SG + pembro

Abbreviation: LSM=least squares mean; 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 pre-specified 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]Pre-specified sensitivity analysis.
[d]Deterioration from baseline 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.

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); this data is not summarized.[3]

EORTC QLQ-C30: Physical functioning domain[3]

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 pre-specified 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 pre-specified 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).

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EORTC QLQ-C30: All domains[3]

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)

Abbreviation: QoL=quality of life.
[a]TTD or death. [b]HR <1 favors SG + pembro.

Time to confirmed deterioration

Median TTCD was assessed in a pre-specified sensitivity analysis of the EORTC QLQ-C30. The MPWC 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)

EORTC QLQ-C30 domain	Time to event,[a] median (95% CI), mo		HR (95% CI)[b]
	SG + Pembro (n=221)	TPC + Pembro (n=222)	
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[3]

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.

Table 4. Overall LSM Change 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: GHS=global health status; 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.

References

1. TRODELVY® Gilead Sciences Inc. Trodelvy (sacituzumab govitecan-hziy) for injection, for intravenous use. U.S. Prescribing Information. Foster City, CA.
2. 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.
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.
4. 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

1L=first line
2L=second line
BICR=blinded independent central review
BL=baseline
CPS=combined positive score
EORTC QLQ-C30= European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire-Core 30
LSM=least squares mean
MWPC=meaningful within patient change
NE=not estimable
OS=overall survival
pembro=pembrolizumab
PFS=progression-free survival
RECIST v1.1=Response Evaluation Criteria in Solid Tumors version 1.1
PRO=patient reported outcomes
SG=sacituzumab govitecan-hziy
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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