Gilead Sciences, Inc. is providing this document to you, a US Healthcare Professional, in response to your unsolicited request for medical information.

GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Use in Combination With Pembrolizumab 1L in Patients With PD-L1+ mTNBC: Efficacy by HER2 Status

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and its use in combination with pembrolizumab (pembro) first-line (1L) in patients with programmed death-ligand 1 positive (PD-L1+) metastatic triple-negative breast cancer (mTNBC) and efficacy by human epidermal growth factor receptor 2 (HER2) status.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

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 whose tumors express PD-L1 (combined positive score [CPS] ≥10) as determined by an FDA-authorized test.

Clinical Data on SG + Pembro Efficacy by HER2 Status in 1L PD-L1+ mTNBC

ASCENT-04 is an ongoing, global, open-label, randomized, phase 3 study in SG + pembro (n=221) vs treatment of physician's choice (TPC) + pembro (n=222) as 1L treatment in patients with PD-L1+, inoperable, locally advanced or mTNBC. A prespecified retrospective exploratory analysis evaluated the impact of HER2 status on the efficacy of SG + pembro vs TPC + pembro.[2,3]

- Median progression-free survival (mPFS) results in the HER2 biomarker analysis set (BAS) were consistent with those in the ITT population.[2,3]
  - In the ITT population, mPFS (95% CI) for SG and TPC groups were as follows: 11.2 (9.3–16.7) mo and 7.8 (7.3–9.3) mo, respectively (hazard ratio [HR], 0.65; 95% CI: 0.51–0.84; *P*<0.001).
  - In the HER2 BAS, mPFS (95% CI) for SG and TPC groups were as follows: 11.3 (9.3–16.7) mo and 7.8 (7.3–9.3) mo, respectively (HR, 0.66; 95% CI: 0.51–0.85).
- mPFS was longer with SG + pembro than with TPC + pembro across all HER2 subgroups. mPFS (95% CI) in the SG and TPC HER2 subgroups were as follows[3]:

- HER2 immunohistochemistry 0 (IHC 0) subgroup, 16.6 (9.1–21.2) mo vs 9 (7.2–10.8) mo, respectively (HR, 0.69; 95% CI: 0.46–1.04);
- HER2-low subgroup, 11.2 (9.1–16.6) mo vs 7.7 (7–9.4) mo (HR, 0.67; 95% CI: 0.48–0.92).

Clinical Data on SG + Pembro Efficacy by HER2 Status in 1L PD-L1+ mTNBC

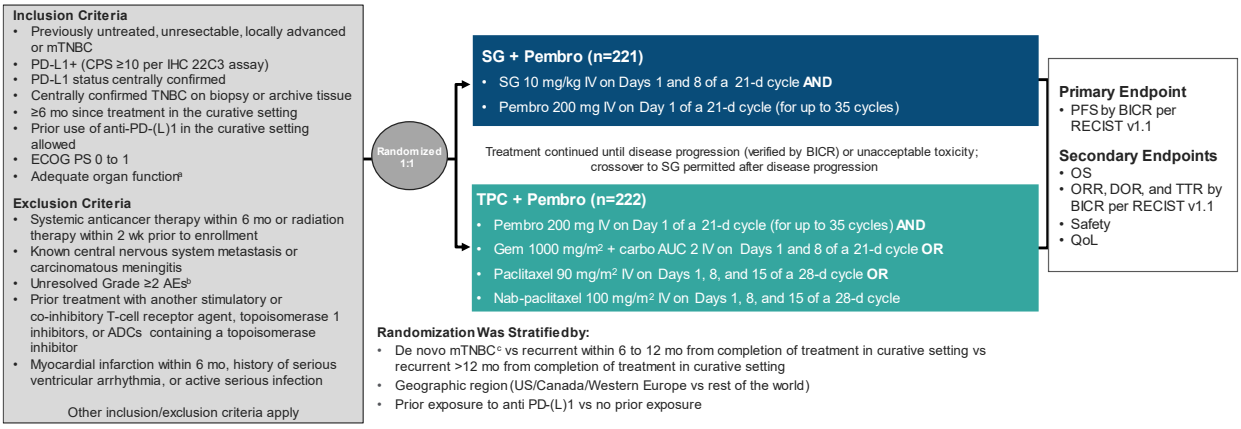
ASCENT-04 Study

Study design and demographics

ASCENT-04 is an ongoing, global, open-label, randomized, phase 3 study that is investigating 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).[2]

A total of 443 female patients were enrolled. Patients who experienced disease progression during treatment with TPC + pembro (as verified by blinded independent central review [BICR]) could cross over to receive second-line SG monotherapy.[2]

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



Abbreviations: ADC=antibody drug conjugate; AE=adverse event; AUC=area under the concentration-time curve; DOR=duration of response; ECOG=Eastern Cooperative Oncology Performance Score; IHC=immunohistochemistry; TNBC=triple-negative breast cancer; ORR=objective response rate; OS=overall survival; PFS=progression-free survival; QoL=quality of life; RECIST=response evaluation criteria in solid tumors; ULN=upper limit of normal.

[a]Hgb ≥9 g/dL, absolute neutrophil count ≥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.

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

Select 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)

Select Demographics and Characteristics		SG + Pembro (n=221)	TPC + Pembro (n=222)
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)
Geography, n (%)	US/Canada/Western Europe	85 (38)	85 (38)
	Rest of the world[b]	136 (62)	137 (62)
ECOG PS,[c] 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 in >12 mo	106 (48)	107 (48)
Metastatic sites, n (%)	Lymph node	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[d]	81 (37)	71 (32)
Chemo selected prior to randomization,[e] n (%)	Taxane	116 (52)	114 (51)
	Gemcitabine/carboplatin	105 (48)	108 (49)
Prior anti-PD-(L)1 therapy,[f] n (%)		9 (4)	11 (5)

[a]As reported by patients; other included American Indian or Alaska Native and not permitted.
[b]Included Argentina, Australia, Brazil, Chile, Czech Republic, Hong Kong, Hungary, Israel, Japan, Malaysia, Mexico, Poland, Singapore, South Africa, South Korea, Taiwan, and Turkey.
[c]One patient in the TPC + pembro arm had an ECOG PS ≥2.
[d]Other metastatic sites included pleura, pleural effusion, skin, soft tissue, chest wall, and muscle.
[e]Actual chemotherapy received was consistent with what was selected prior to randomization; however, 2 patients were randomized but did not receive treatment.
[f]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 by HER2 status

A prespecified retrospective exploratory analysis evaluated the impact of HER2 expression on the efficacy of SG + pembro vs TPC + pembro. Biomarker status was analyzed descriptively for association with PFS by BICR; patients who had received ≥1 dose of study treatment and had ≥1 evaluable post-baseline biomarker measurement were included in the BAS. HER2 expression was measured by in situ hybridization (ISH) and IHC, and patients were categorized as HER2 IHC 0 or HER2 low (IHC 1+ or IHC 2+/ISH-).[3]

At the primary data cutoff, the median (range) follow-up was 14 (0.1–28.6) mo. mPFS results in the HER2 BAS were consistent with those in the ITT population (Table 2). mPFS was longer with SG + pembro than with TPC + pembro across all HER2 subgroups (Table 2). Results should be interpreted with caution due to the small sample size and the descriptive nature of the analysis.[3]

Gilead Sciences, Inc. is providing this document to you, a US Healthcare Professional, in response to your unsolicited request for medical information.

Table 2. ASCENT-04 Subgroup Analysis: Efficacy in ITT Population and by HER2 Status[2,3]

Subgroup		SG + Pembro			TPC + Pembro			HR (95% CI)
		n	Events	mPFS (95% CI), Mo	n	Events	mPFS (95% CI), Mo	
ITT population		221	109	11.2 (9.3–16.7)	222	140	7.8 (7.3–9.3)	0.65 (0.51–0.84)[a]; *P*<0.001
HER2 BAS		217	–	11.3 (9.3–16.7)	218	–	7.8 (7.3–9.3)	0.66 (0.51–0.85)
HER2 subgroup	HER2 IHC 0	84	42	16.6 (9.1–21.2)	82	54	9 (7.2–10.8)	0.69 (0.46–1.04)
	HER2 low	133	65	11.2 (9.1–16.6)	136	83	7.7 (7–9.4)	0.67 (0.48–0.92)

[a]Stratified HR.
Note: An HR <1 indicated treatment with SG + pembro was favorable to treatment with TPC + 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 S, De Azambuja E, Kalinsky K, et al. Sacituzumab govitecan plus pembrolizumab for advanced triple-negative breast cancer. *N Engl J Med.* 2026;394:354-366.
3. Tolaney SM, Schmid P, de Azambuja E, et al. ASCENT-04: analysis of efficacy by biomarker subgroups with sacituzumab govitecan plus pembrolizumab vs chemotherapy plus pembrolizumab in participantts with previously untreated PD-L1 positive metastatic triple-negative breast cancer [Oral 1013]. Presented at: American Society of Clinical Oncology (ASCO); May 29-June 2, 2026; Chicago, IL.
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.

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.

Follow-Up

For any additional questions, please contact Trodelvy Medical Information at:

☎1-888-983-4668 or www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or https://www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or www.accessdata.fda.gov/scripts/medwatch

Data Privacy

The Medical Information service at Gilead Sciences may collect, store, and use your personal information to provide a response to your medical request. We may share your information with other Gilead Sciences colleagues to ensure that your request is addressed appropriately. If you report an adverse event or concern about the quality of a Gilead or Kite product, we will need to use the information you have given us in order to meet our regulatory requirements in relation to the safety of our medicines.

It may be necessary for us to share your information with Gilead's affiliates, business partners, service providers, and regulatory authorities located in countries besides your own. Gilead Sciences has implemented measures to protect the personal information you provide. Please see the Gilead Privacy Statement (www.gilead.com/privacy-statements) for more information about how Gilead handles your personal information and your rights. If you have any further questions about the use of your personal information, please contact gilead.privacy@gilead.com.

TRODELVY, GILEAD, and the GILEAD logo are registered trademarks of Gilead Sciences, Inc., or its related companies.
© 2026 Gilead Sciences, Inc.