



# Trodelvy<sup>®</sup> (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<sup>®</sup> (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.

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**Trodelvy is not indicated for use as 1L treatment in patients with PD-L1+ mTNBC. 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](http://www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi).**

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## Summary

### 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.<sup>1,2</sup>

- Median progression-free survival (mPFS) results in the HER2 biomarker analysis set (BAS) were consistent with those in the ITT population.<sup>1,2</sup>
  - 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<sup>2</sup>:
  - 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

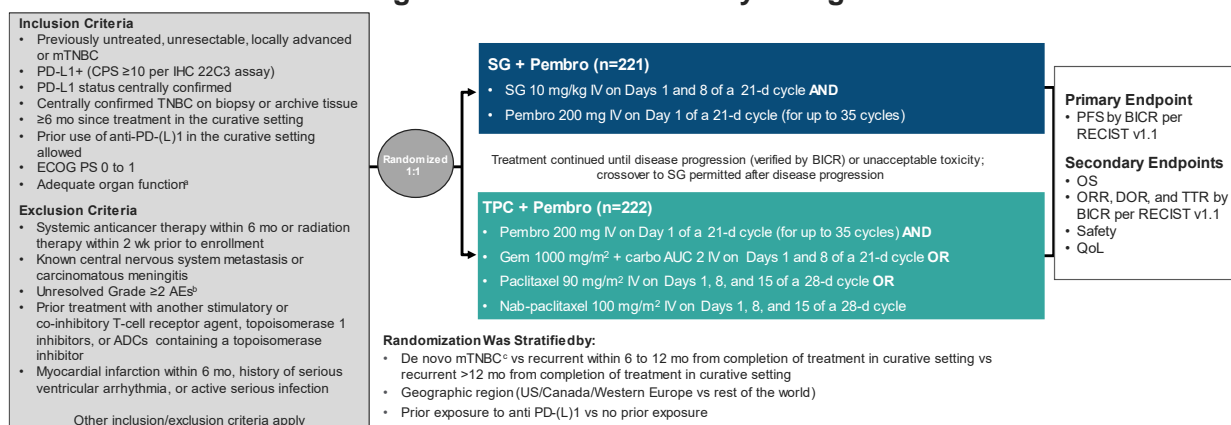
## ASCENT-04 Study

### 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+ (combined positive score [CPS]≥10) inoperable, locally advanced or mTNBC (Figure 1).<sup>1</sup>

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.<sup>1</sup>

Figure 1. ASCENT-04 Study Design<sup>1,3</sup>



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.

<sup>a</sup>Hgb ≥9 g/dL, absolute neutrophil count ≥1500/mm<sup>3</sup>; 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.

<sup>b</sup>Unresolved Grade ≤2 neuropathy, endocrine-related AEs, and any-grade alopecia were allowed.

<sup>c</sup>Up to 35% of patients with de novo mTNBC were eligible.

Table 1. ASCENT-04: Baseline Demographics and Disease Characteristics<sup>1</sup>

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)
Race or ethnic group, <sup>a</sup> n (%)	White/Black/Asian	139 (63)/13 (6)/43 (19)
	Other or not specified	26 (12)
Geography, n (%)	US/Canada/Western Europe	85 (38)
	Rest of the world <sup>b</sup>	136 (62)
ECOG PS, <sup>c</sup> n (%)	156 (71)/65 (29)	154 (69)/67 (30)

Select Demographics and Characteristics		SG + Pembro (n=221)	TPC + Pembro (n=222)
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 <sup>d</sup>	81 (37)	71 (32)
Chemo selected prior to randomization, <sup>e</sup> n (%)	Taxane	116 (52)	114 (51)
	Gemcitabine/carboplatin	105 (48)	108 (49)
Prior anti-PD-(L)1 therapy, <sup>f</sup> n (%)		9 (4)	11 (5)

<sup>a</sup>As reported by patients; other included American Indian or Alaska Native and not permitted.

<sup>b</sup>Included Argentina, Australia, Brazil, Chile, Czech Republic, Hong Kong, Hungary, Israel, Japan, Malaysia, Mexico, Poland, Singapore, South Africa, South Korea, Taiwan, and Turkey.

<sup>c</sup>One patient in the TPC + pembro arm had an ECOG PS ≥2.

<sup>d</sup>Other metastatic sites included pleura, pleural effusion, skin, soft tissue, chest wall, and muscle.

<sup>e</sup>Actual chemotherapy received was consistent with what was selected prior to randomization; however, 2 patients were randomized but did not receive treatment.

<sup>f</sup>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-).<sup>2</sup>

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.<sup>2</sup>

**Table 2. ASCENT-04 Subgroup Analysis: Efficacy in ITT Population and by HER2 Status<sup>1,2</sup>**

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) <sup>a</sup> ; 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)

<sup>a</sup>Stratified HR.

Note: An HR <1 indicated treatment with SG + pembro was favorable to treatment with TPC + pembro.

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## References

1. 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.
2. 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 participants 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.
3. 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.

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## 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](http://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](http://www.askgileadmedical.com)

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