GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Order of SG and Pembrolizumab Administration in ASCENT-04

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and the order of administration with pembrolizumab (pembro) as first-line (1L) treatment in patients with programmed death ligand-1 positive (PD-L1+) metastatic triple-negative breast cancer (mTNBC).

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

Relevant Product Labeling

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.[1]

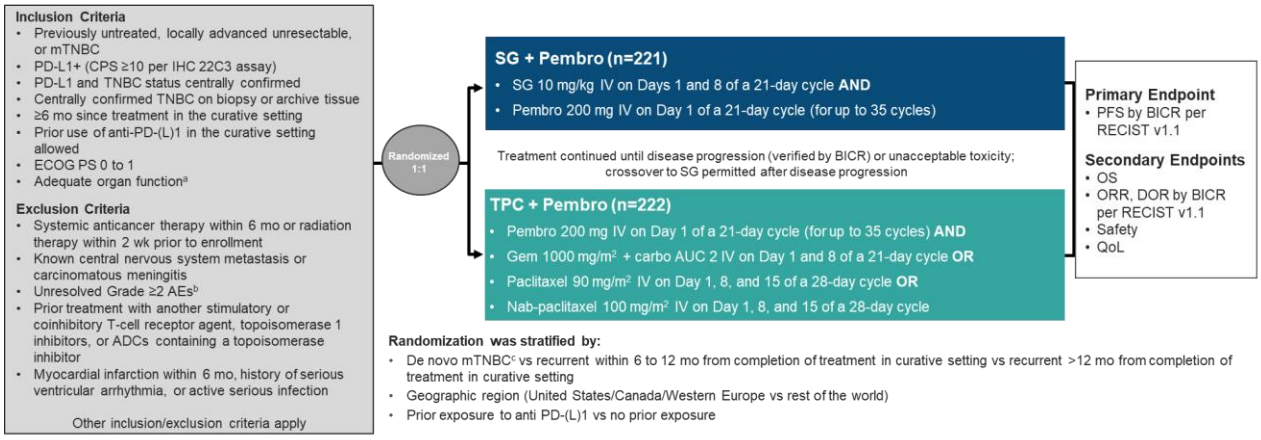
No information about the order of SG and pembro administration is available in the US FDA-approved SG Prescribing Information.

Use of SG in Combination With Pembro in 1L PD-L1+ mTNBC

Study design[2]

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 chemotherapy treatment of physicians' choice (TPC) + pembro as 1L treatment in patients with PD-L1+ (CPS ≥10), inoperable, locally advanced or mTNBC (Figure 1). A total of 443 female patients were enrolled.

Figure 1. ASCENT-04: Study Design[2,3]



Abbreviations: ADCs=antibody-drug conjugates; AEs=adverse events; AUC=area under the curve; BICR=blinded independent central review; carbo=carboplatin; DOR=duration of response; ECOG PS=Eastern Cooperative Oncology Group Performance Status; gem=gemcitabine; IHC=immunohistochemistry; OS=overall survival; ORR=objective response rate; PD-(L)1=programmed death (ligand) 1; PD-L1=programmed death ligand-1; PFS=progression-free survival; QoL=quality of life; RECIST=Response Evaluation Criteria in Solid Tumors; TNBC=triple-negative breast cancer; ULN=upper limit of normal.
[a]Hgb ≥9 g/dL, ANC ≥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.

Order of SG and Pembro Administration

According to the ASCENT-04 study protocol, on infusion days, SG was administered prior to pembro.[4]

No additional information is provided within the protocol about the specific timing or interval between the administration of these agents. The order reflects the study design and was prespecified within the protocol.

Gilead Sciences is unable to provide recommendations regarding the order of administration for SG and pembro. Please use clinical judgment to guide therapy according to individual patient goals.

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 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.
4. Tolaney S, De Azambuja E, Kalinsky K, et al. Sacituzumab govitecan plus pembrolizumab for advanced triple-negative breast cancer [Protocol]. *N Engl J Med.* 2026;394:354-366.

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 🖱 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

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