GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Washout Period Prior to Starting Treatment in mBC

This document is in response to your request for information about a washout period prior to starting treatment with Trodelvy® (sacituzumab govitecan-hziy [SG]) in patients with metastatic breast cancer (mBC).

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[1]

There is no recommendation of a washout period described in the SG prescribing information.

Washout Periods in SG mBC Montherapy Studies

ASCENT-03 Study in 1L PD-(L)1 Inhibitor Ineligible mTNBC

ASCENT-03 is an ongoing, phase 3 study of first-line (1L) SG in patients with locally advanced unresectable or metastatic triple-negative breast cancer (mTNBC) who are not candidates for programmed death-(ligand) 1 inhibitor therapy (PD-[L]1).[2] In this study, eligible patients were required to have a washout period of ≥6 mo from other previous systemic anticancer treatment (with the exception of endocrine therapy [ET]) and from radiation therapy for ≥2 wk prior to enrollment. Additionally, all adverse events (AEs) due to previously administered agents were required to have resolved to Grade ≤2. Exceptions to recovery requirements included any-grade neuropathy or alopecia.[3]

ASCENT Study in 2L+ mTNBC

In ASCENT, a phase 3 study of second-line or later (2L+) SG in patients with refractory/relapsed mTNBC, eligible patients were required to have a washout period of ≥2 wk from high-dose systemic corticosteroids and all prior cancer treatment, including chemotherapy, ET, radiotherapy, and major surgery.[4,5] Prior antibody treatment had to be completed ≥3 wk before randomization. Patients who received low-dose corticosteroids (≤20 mg prednisone daily or equivalent) were eligible if the dose was stable for 4 wk. Individuals were not eligible for this study if they had an infection that required antibiotic use within 1 wk of randomization. Additionally, all acute toxicities were required to have

recovered to Grade ≤1. Exceptions to recovery requirements included alopecia and peripheral neuropathy, which could be Grade ≤2.[5]

TROPiCS-02 Study in Pretreated HR+/HER2- mBC

In TROPiCS-02, a phase 3 study of SG in pretreated hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) mBC, eligible patients were required to have a washout period of ≥2 wk from prior chemotherapy, radiation, or small molecule targeted therapy and ≥4 wk from biologic therapy.[6,7] High-dose systemic corticosteroids were prohibited within 2 wk of randomization. Low, stable doses of corticosteroids that were equivalent to ≤20 mg of prednisone daily were allowed if the patient entered the study on low-dose steroids for their treated brain metastasis or if they were medically indicated as part of their infusion pre-medications. Topical steroids and corticosteroid inhalers were permitted. Additionally, resolution of all systemic anticancer therapy-related or radiation-related toxicities to Grade ≤1, except for neuropathy (Grade ≤2) and alopecia, were required at randomization.[7]

IMMU-132-01 Study in Metastatic Epithelial Cancers

In IMMU-132-01, a phase 1/2 study in patients with previously treated advanced epithelial cancers (including patients with mTNBC treated in the 2L+ setting and patients with pretreated HR+/HER2- mBC), eligible patients were required to have a washout period of ≥2 wk from high dose systemic corticosteroids or prior treatment with chemotherapy, immunotherapy, ET, investigational drugs, and/or radiation therapy, or major surgery.[8-11] Patients who were receiving low-dose corticosteroids (<20 mg prednisone daily or equivalent) were eligible. Individuals were not eligible for this study if they had an infection that required IV antibiotic use within 1 wk of randomization. Additionally, all acute toxicities except for alopecia were required to have recovered to Grade ≤1.[9]

Washout Period in SG mBC Combination Study

ASCENT-04 Study: SG Use in Combination With Pembro in 1L PD-L1+ mTNBC

ASCENT-04 is an ongoing, randomized, phase 3 study of SG + pembrolizumab (pembro) as 1L treatment in patients with programmed death ligand 1 positive (PD-L1+), locally advanced unresectable, or mTNBC.[12] In this study, eligible patients were required to have a washout period from other previous systemic anticancer treatment (with the exception of ET) of ≥6 mo and from radiation therapy of ≥2 wk prior to enrollment. Additionally, all AEs due to previously administered agents were required to have resolved to Grade ≤1 or baseline. Exceptions to recovery requirements included Grade ≤2 neuropathy or any-grade alopecia. Patients with Grade ≤2 endocrine-related AEs that require treatment or hormone replacement may be eligible.[13]

References

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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4. Bardia A, Hurvitz SA, Tolaney SM, et al. Sacituzumab govitecan in metastatic triple-negative breast cancer. *N Engl J Med.* 2021;384(16):1529-1541.
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9. Immunomedics Inc. Protocol IMMU-132-01. A phase I/II study of IMMU-132 (hRS7-SN38 antibody drug conjugate) in patients with epithelial cancer. Available at: https://www.clinicaltrials.gov/ProvidedDocs/52/NCT01631552/Prot_000.pdf.
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12. Tolaney SM, de Azambuja E, Kalinsky K, et al. Sacituzumab govitecan plus pembrolizumab for advanced triple-negative breast cancer. *N Engl J Med.* 2026;394(4):354-366.
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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.

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

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