GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Use in Patients With HER2+ BC

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and its use in patients with human epidermal growth factor receptor 2-positive breast cancer (HER2+ BC; defined as immunohistochemistry 3 positive [IHC3+] or immunohistochemistry 2 positive/in situ hybridization positive [IHC 2+/ISH+]).[1,2]

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.

Trodelvy is not indicated for use in patients with HER2+ BC. 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[3]

SG is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer who have received ≥2 prior systemic therapies, ≥1 of them for metastatic disease.

SG is indicated for the treatment of adult patients with unresectable locally advanced or metastatic hormone receptor-positive, human epidermal growth factor receptor 2-negative (IHC 0, IHC 1+ or IHC 2+/ISH-negative) breast cancer who have received endocrine-based therapy and ≥2 additional systemic therapies in the metastatic setting.

Clinical Data

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 2018 and 23 October 2025 using the search terms sacituzumab govitecan, human epidermal growth factor receptor 2-positive breast cancer, HER2+, IHC3+, or IHC2+/ISH+, and related search terms. No relevant data were identified.

Ongoing Study in HER2+ mBC

The SATEEN study is a phase 2, open-label, multi-center, single-arm study (NCT06100874) evaluating the safety and efficacy of SG and trastuzumab in patients with HER2+ metastatic breast cancer (HER2+ mBC) that were previously treated with a taxane, trastuzumab, and T-DXd.

References

1. Wolff A, Hammond M, Allison K, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. *J Clin Oncol.* 2018;36:2105-2122.
2. Wolff A, Somerfield M, Dowsett M, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer. American Society of Clinical Oncology–College of American Pathologists Guideline Update. *Arch Pathol Lab Med.* 2023;147:993–1000.
3. TRODELVY® Gilead Sciences Inc. Trodelvy (sacituzumab govitecan-hziy) for injection, for intravenous use. U.S. Prescribing Information. Foster City, CA.

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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