GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Use in 1L Post-Endocrine Therapy HR+/HER2- mBC

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and its use as first line (1L) post-endocrine therapy (ET) in hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) 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.

Trodelvy is not indicated for use as 1L post-ET in HR+/HER2- mBC. 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

Clinical Data on SG Use in 1L Post-ET HR+/HER2- mBC

ASCENT-07 Study

The ASCENT-07 study (NCT05840211) is an ongoing, global, randomized, open-label, phase 3 study that is being conducted to investigate the efficacy and safety of SG vs chemotherapy treatment of physician's choice (TPC; capecitabine, paclitaxel, or nab-paclitaxel) in 654 patients with HR+/HER2- (IHC 0, IHC 1+, IHC 2+/ISH-) locally advanced (LA), inoperable, or mBC. Eligible patients with HR+/HER2- mBC had previously received ET and were eligible for 1L chemotherapy in the advanced or metastatic setting and met ≥1 of the following criteria[1,2]:

- Progressive disease (PD) in the metastatic setting after receiving ≥2 lines of ET with or without targeted therapy. Only one line of endocrine therapy in the metastatic setting was required if disease recurrence occurred while on the first 24 months after starting adjuvant ET[1]
- PD within 6 months of starting 1L ET, with or without cyclin-dependent kinase 4/6 inhibitors (CDK4/6i) in the metastatic setting[1]
- Recurrence of disease within 24 months of starting adjuvant ET + CDK4/6i and not a candidate for further ET[1]

The primary endpoint is progression-free survival (PFS) by blinded independent central review (BICR) according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. Key secondary endpoints include overall survival (OS); objective response rate and duration of response (BICR and investigator assessed); select quality of life (QoL) measures; and safety.[1]

On November 7, 2025, Gilead announced topline results from the phase 3 ASCENT-07 study. The study did not meet the primary endpoint PFS with SG compared to physician's choice chemotherapy. At the time of the primary analysis, OS was not mature however, there was an early numerical trend favoring patients in the SG arm compared to TPC. The study will continue to further assess OS. The safety profile of SG was consistent with prior studies in mBC. Detailed results from this study will be presented at an upcoming medical conference.[3] Full press release can be found here: https://www.gilead.com/news/news-details/2025/gilead-provides-update-on-phase-3-ascent-07-study

References

1. Rugo HS, Cortes J, Curigliano G, et al. ASCENT-07: a phase 3, randomized, open-label study of sacituzumab govitecan versus treatment of physician's choice in patients with HR+/HER2- inoperable, locally advanced, or metastatic breast cancer post-endocrine therapy [Poster P01-05-09]. Paper presented at: San Antonio Breast Cancer Symposium (SABCS); December 5-9, 2023; San Antonio, TX.
2. ClinicalTrials.gov. Study of sacituzumab govitecan versus treatment of physician's choice in patients with hormone receptor-positive/human epidermal growth factor receptor 2 negative (HR+/HER2-) metastatic breast cancer who have received endocrine therapy (ASCENT-07). Available at: https://clinicaltrials.gov/study/NCT05840211. Last updated October 3, 2025.
3. Gilead Sciences, Inc. Gilead provides update on phase 3 ASCENT-07 study. [press release]. 7 November 2025.

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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