



# Trodelvy<sup>®</sup> (sacituzumab govitecan-hziy)

## Laboratory Evaluation of Trop-2 Expression Prior to Use in Patients with mBC

This document is in response to your request for information regarding Trodelvy<sup>®</sup> (sacituzumab govitecan-hziy [SG]) and laboratory evaluation of trophoblast cell surface antigen 2 (Trop-2) expression prior to use 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](http://www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi).**

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## Summary

### Relevant Product Labeling<sup>1</sup>

There is no requirement described or recommendation regarding the evaluation of Trop-2 expression contained in the SG US FDA-approved prescribing information.

### Clinical Data

Confirmation of Trop-2 expression, via immunohistology or other means, was not required prior to treatment with SG (10 mg/kg, administered on Days 1 and 8 of a 21 day cycle), in the mBC clinical studies (ASCENT, a study in second line or later [2L+] metastatic triple negative breast cancer [mTNBC],<sup>2</sup> TROPiCS-02, a study in pretreated hormone receptor positive/human epidermal growth factor receptor 2-negative metastatic breast cancer [HR+/HER2- mBC],<sup>3</sup> ASCENT-03, an ongoing study in first line [1L] programmed death (ligand) 1 [PD-(L)1] inhibitor ineligible mTNBC<sup>4,5</sup> and ASCENT-04, an ongoing study in 1L programmed death ligand 1 positive [PD-L1+] mTNBC<sup>6,7</sup>).

Biopsy, surgical, or tumor specimens were, however, collected during the ASCENT and TROPiCS-02 studies.<sup>8,9</sup> Specimens were also collected in ASCENT-03<sup>5</sup> and ASCENT-04,<sup>7</sup> however data is not yet available.

### Additional Information

Gilead Sciences does not provide information regarding evaluation of Trop-2 expression offered by any commercial laboratory and is unable to provide recommendations or suggestions pertaining to the use of any commercial laboratory for testing.

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## Clinical Data

In ASCENT and TROPiCS-02, Trop-2 expression level was evaluated using a validated immunohistochemistry (IHC) assay and was categorized by a histological score (H-score),

which was determined by the percentage of cells with specific staining intensity (staining intensity multiplied by proportion of cells with Trop-2 staining; scale, 0-300). Tumor samples were collected at study entry to determine membrane Trop-2 expression using an IHC assay; confirmation was not required for study participation.<sup>8,10</sup>

## ASCENT Study in 2L+ mTNBC

ASCENT, an open label, randomized, phase 3 study (N=529) compared the efficacy and safety of SG (n=267) vs chemotherapy treatment of physician's choice (TPC [n=262; eribulin, vinorelbine, gemcitabine, or capecitabine]) in patients with refractory or relapsed mTNBC who had received  $\geq 2$  prior chemotherapies for unresectable, locally advanced, or metastatic disease.<sup>2</sup>

Primary or metastatic archival biopsy or surgical specimens were requested at study entry to determine tumor Trop-2 expression; however, confirmation of Trop-2 expression was not required for study participation. Trop-2 expression was evaluated in patients who were negative for brain metastasis (BMNeg, n=468); in this population, 290 patients had Trop-2 expression data available (SG; n=151, TPC; n=139. Table 1). No data were collected on Trop-2 expression in primary vs metastatic tumors.<sup>8</sup>

**Table 1. ASCENT: Trop-2 Expression in BMNeg Population<sup>8</sup>**

		SG (n=151)	TPC (n=139)
Trop-2 Expression Data Available, n (%)	High (H-score >200 to 300)	85/151 (56)	72/139 (52)
	Medium (H-score 100 to 200)	39/151 (26)	35/139 (25)
	Low (H-score 0 to <100) <sup>a</sup>	27/151 (18)	32/139 (23)

<sup>a</sup>Seven and four patients in the SG and TPC groups, respectively, had no Trop-2 expression.

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

TROPiCS-02, an open-label, randomized, multicenter, phase 3 study (N=543) compared the efficacy and safety of SG (n=272) vs TPC (n=271; eribulin, gemcitabine, capecitabine, or vinorelbine) in patients with HR+/HER2- mBC who were previously treated with  $\geq 1$  taxane,  $\geq 1$  endocrine therapy, and  $\geq 1$  cyclin-dependent kinase 4/6 inhibitor therapy in any setting, and who had received  $\geq 2$  and  $\leq 4$  prior chemotherapy regimens for metastatic disease.<sup>3</sup>

Primary or metastatic archival tumor tissue was requested at study entry to determine tumor Trop-2 expression; however, confirmation of Trop-2 expression was not required for study participation. In this exploratory analysis, 238 patients (88%) in the SG group, and 224 patients (83%) in the TPC group had samples evaluable for Trop-2 expression (Table 2). Trop-2 expression was observed in  $\sim 95\%$  of patients with evaluable samples; 25 patients (5%) had a H-score of 0 (SG; n=10).<sup>10</sup>

**Table 2. TROPiCS-02: Trop-2 Expression in Tumor Tissue Samples<sup>10</sup>**

		Total (n=462) n (%)	SG (n=238) n	TPC (n=224) n
Trop-2 Expression	H-score $\geq 100$	270 (58)	142	128
	H-score >10 to <100	113 (24)	62	51
	H-score >0 to $\leq 10$	54 (12)	34	45

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

ASCENT-03, an ongoing, global, open-label, randomized, phase 3 study (N=558), is comparing the efficacy and safety of SG (n=279) vs TPC (n=279; gemcitabine + carboplatin, paclitaxel, or nab-paclitaxel), as 1L treatment in patients with previously untreated, locally advanced, inoperable or mTNBC who are not candidates for PD-(L)1 inhibitor therapy.<sup>4</sup>

Optional biopsy assessment included collection of fresh or archival tumor tissue which will be analyzed retrospectively for Trop-2 levels;<sup>5</sup> however, this data is not yet available.

## ASCENT-04 Study in 1L PD-L1+ mTNBC

ASCENT-04, an ongoing, global, open-label, randomized, phase 3 study (N=443), is comparing the efficacy and safety of SG + pembrolizumab (n=221) vs TPC (gemcitabine + carboplatin, paclitaxel, or nab-paclitaxel) + pembrolizumab (n=222), as 1L treatment in patients with PD-L1+ (combined positive score  $\geq 10$ ) inoperable, locally advanced or mTNBC.<sup>6</sup>

Biopsy assessment included collection of fresh or archival tumor tissue which will be analyzed retrospectively for Trop-2 levels;<sup>7</sup> however, this data is not yet available.

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## References

1. TRODELVY® Gilead Sciences Inc. Trodelvy (sacituzumab govitecan-hziy) for injection, for intravenous use. U.S. Prescribing Information. Foster City, CA.
2. 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.
3. Rugo HS, Bardia A, Marme F, et al. Sacituzumab govitecan in hormone receptor-positive/human epidermal growth factor receptor 2-negative metastatic breast cancer. *J Clin Oncol*. 2022;40(29):3365-3376.
4. Cortés J, Punie K, Barrios C, et al. Sacituzumab govitecan in untreated, advanced triple-negative breast cancer. *N Engl J Med*. 2025;393(19):1912-1925.
5. Cortés J, Punie K, Barrios C, et al. Sacituzumab govitecan in untreated, advanced triple-negative breast cancer [Protocol]. *N Engl J Med*. 2025;393(19):1912-1925.
6. 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.
7. 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.
8. Bardia A, Tolaney SM, Punie K, et al. Biomarker analyses in the phase III ASCENT study of sacituzumab govitecan versus chemotherapy in patients with metastatic triple-negative breast cancer. *Ann Oncol*. 2021;32(9):1148-1156.
9. Rugo HS, Bardia A, Marme F, et al. Sacituzumab govitecan in hormone receptor-positive/human epidermal growth factor receptor 2-negative metastatic breast cancer [Protocol]. *J Clin Oncol*. 2022;40(29):3365-3376.
10. Rugo H, Bardia A, Marmé F, et al. Sacituzumab govitecan vs treatment of physician's choice: efficacy by Trop-2 expression in the TROPiCS-02 study of patients with HR+/HER2- metastatic breast cancer. Presented at: SABCS; December 6-10, 2022; San Antonio, TX.

Gilead Sciences, Inc. is providing this document to you, a US Healthcare Professional, in response to your unsolicited request for medical information.

## 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:

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FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🌐 [www.accessdata.fda.gov/scripts/medwatch](http://www.accessdata.fda.gov/scripts/medwatch)

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