GILEAD | Medical Information

# Trodelvy® (sacituzumab govitecan-hziy) Use in Patients with Colorectal Cancer

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and its use in patients with colorectal cancer (CRC).

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 colorectal cancer. 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.**

## Summary

Clinical Study in Patients with CRC

The phase 1/2 IMMU-132-01 study investigated the efficacy and safety of SG in patients with metastatic epithelial cancers, including CRC, who had relapsed after or were refractory to ≥1 prior therapy for metastatic disease.[1]

- Patients in the CRC cohort (n=31) had an objective response rate (ORR) of 3.2%. Median progression-free survival (PFS) was 3.9 months, and the median overall survival (OS) was 14.2 months.
- Safety data specific to patients with CRC were not reported. In the overall safety population (OSP; n=495), the most common treatment-related adverse events (TRAEs) were nausea (62.6%), diarrhea (56.2%), fatigue (48.3%), alopecia (40.4%), and neutropenia (57.8%).

## Clinical Study in Patients with CRC

### IMMU-132-01 Study in Metastatic Epithelial Cancer[1]

#### Study design and demographics

IMMU-132-01, a phase 1/2, multicenter, single-arm, open-label basket study, investigated the efficacy and safety of SG in patients with metastatic epithelial cancers, including CRC, who had relapsed after or were refractory to ≥1 prior therapy for metastatic disease.

In the CRC cohort (n=31), SG 8 or 10 mg/kg IV was administered on Days 1 and 8 of a 21-day treatment cycle until disease progression or unacceptable toxicity, death, or withdrawal of consent. Of the 31 patients in the CRC cohort, 29 had prior irinotecan treatment.

Efficacy endpoints in the overall basket study included the following: ORR (defined as both partial response [PR] and complete response [CR] confirmed by investigator's assessment

per Response Evaluation Criteria in Solid Tumors [RECIST] version 1.1), duration of response (DOR), clinical benefit rate (CBR; defined as CR + PR + stable disease [SD] ≥6 months), PFS, and OS.

### Efficacy

Efficacy data for the 31 patients in the CRC cohort are presented in Table 1.

**Table 1. IMMU-132-01: Response Rates in Patients with CRC[1]**

| Patient Response Rates (n=31) | | | | | | | |
|---|---|---|---|---|---|---|---|
| ORR,% (95% CI) | CR, n (%) | PR, n (%) | SD, n (%) | DOR, median (95% CI), mo | OS, median (95% CI), mo | PFS, median (95% CI), mo | CBR, n (%) [95% CI] |
| 3.2 (0.1–16.7) | 0 | 1 (3.2) | 16 (51.6) | 9.8 (NR–NR) | 14.2 (6.8–19.1) | 3.9 (1.9–5.6) | 6 (19.4) [7.5–37.5] |

Abbreviations: NR=not reached or not calculable.

### Safety

Safety data specific to patients with CRC were not reported.

In the IMMU-132-01 study OSP (n=495), 41 patients (8.3%) permanently discontinued treatment due to adverse events. The most common TRAEs were nausea (62.6%), diarrhea (56.2%), fatigue (48.3%), alopecia (40.4%), and neutropenia (57.8%). Grade ≥3 neutropenia and febrile neutropenia occurred in 42.4% and 5.3% of patients, respectively.

## Ongoing Clinical Studies in Patients with CRC

### TROPHIT1

A phase 2/3 randomized, open label, multicenter study (NCT06243393) evaluating SG versus standard of care, in patients with metastatic colorectal cancer who are refractory to at least two lines of standard of care chemotherapy and not eligible for local therapy.

### NCT06065371

A phase 1, open-label, single institution study (NCT06065371) to evaluate the safety and tolerability of SG in combination with capecitabine for advanced gastrointestinal cancers, including colorectal cancer, after progression on standard therapy, and to assess correlation of outcomes with the biomarker Trop-2.

## References

1. Bardia A, Messersmith WA, Kio EA, et al. Sacituzumab govitecan, a Trop-2-directed antibody-drug conjugate, for patients with epithelial cancer: final safety and efficacy results from the phase I/II IMMU-132-01 basket trial. *Ann Oncol.* 2021;32(6):746-756.

## 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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