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 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 (AEs). 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[2]

A phase 1, single-institution, dose-escalation study (NCT06065371) will evaluate the safety and tolerability of SG in combination with capecitabine in ≤20 patients with metastatic gastrointestinal cancers, including CRC, who progressed on standard therapy. The primary endpoint is the recommended phase 2 dose. Secondary endpoints include ORR, DOR, PFS, OS and AEs.

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.
2. Diab M, Ghosh S, Khan G, et al. Sacituzumab govitecan in combination with capecitabine for the treatment of advanced gastrointestinal cancers after progression on standard therapy [Abstract 557062]. Presented at: American Society of Clinical Oncology (ASCO) Annual Meeting; May 29-June 2, 2026; Chicago, IL.

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

Data Privacy

The Medical Information service at Gilead Sciences may collect, store and use your personal information to provide a response to your medical request. We may share your information with other Gilead Sciences colleagues to ensure that your request is addressed appropriately. If you report an adverse event or concern about the quality of a Gilead or Kite product, we will need to use the information you have given us in order to meet our regulatory requirements in relation to the safety of our medicines.

It may be necessary for us to share your information with Gilead's affiliates, business partners, service providers and regulatory authorities located in countries besides your own. Gilead Sciences has implemented measures to protect the personal information you provide. Please see the Gilead Privacy Statement (www.gilead.com/privacy-statements) for more information about how Gilead handles your personal information and your rights. If you have any further questions about the use of your personal information, please contact gilead.privacy@gilead.com.