GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Use in Patients With Ovarian Cancer

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

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Trodelvy is not indicated for use in patients with ovarian 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.

Clinical Study of SG use in Ovarian Cancer

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

Study design

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

In the EOC cohort (n=8), 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.

Efficacy endpoints in the overall basket study included the following: objective response rate (ORR; defined as both partial response [PR] and complete response [CR] confirmed by investigator's assessment per Response Evaluation Criteria in Solid Tumors version 1.1), duration of response (DOR), clinical benefit rate (CBR; defined as CR + PR + stable disease ≥6 months), progression-free survival (PFS), and overall survival (OS).

Efficacy

The ORR in patients with EOC was 0%. Stable disease was achieved by 2 patients (25% of patients with EOC). The median DOR, median OS, median PFS, and CBR were not provided due to the small sample size.

Safety

Safety data specific to patients with EOC were not reported.

In the overall safety population (n=495), 41 patients (8.3%) permanently discontinued treatment due to adverse events. The most common treatment-related adverse events (TRAEs) were nausea (62.6%), neutropenia (57.8%), diarrhea (56.2%), fatigue (48.3%), and

alopecia (40.4%). Grade ≥3 neutropenia and febrile neutropenia occurred in 42.4% and 5.3% of patients, respectively.

Real-World Study

SG Use in Platinum-Resistant EOC[2]

A retrospective analysis evaluated the efficacy and safety of SG in patients with recurrent breast cancer (n=24) or platinum-resistant EOC (n=10). Data for the 10 patients with platinum-resistant EOC is presented here. All patients with EOC were heavily pretreated, with a median (range) of 4.5 (4–7) prior lines of systemic therapy. Patients received a median of 2.5 treatment cycles. ORR was 0%, disease control rate (DCR) was 40%, median PFS was 2.5 months and the 6-month PFS rate was 20%. Grade ≥3 TRAEs occurred in 9 (90%) patients and included Grade 4 neutropenia (n=6 [60%]), with a median onset of 13.5 days after treatment cycle initiation, and Grade 4 diarrhea (n=3 [30%]), with a median onset of 13 days.

Case Report of SG use in HGSOC

There are limitations in the interpretation of case reports. Case reports cannot be generalized. Unlike controlled clinical trials, causality cannot be inferred based on uncontrolled observational data. In addition, incidence or prevalence cannot be estimated due to the lack of a representative population sample. Other limitations of case reports include the retrospective design and publication bias.[3]

A 69-year-old female patient with recurrent, metastatic, platinum-resistant high grade serous ovarian cancer (HGSOC) received multiple lines of chemotherapy and targeted treatments over approximately the previous 10 years. The tumor was known to overexpress Trop-2, and she was initiated on SG 10 mg/kg on days 1 and 8 of 21-day cycles. Following initiation of SG, CA-125 serum value dropped from 342 to 109 units/mL and continued to decline over time. CT scans showed regression of metastatic sites, and her umbilical lesion decreased in size. Adenopathy improved, a pancreatic tail mass decreased in size and numerous hepatic metastases also decreased in size with no new lesions reported. At the time of publication, she had received 8 cycles of SG; intermittent gastrointestinal symptoms were reported, with no need for dose reductions.[4]

Ongoing Clinical Studies

An open-label, non-randomized, phase 2 study (NCT06028932) is evaluating the efficacy and safety of SG in patients with recurrent or persistent platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancers.

An open label, non-randomized, single-arm, phase 2 pilot study (NCT06865677) is evaluating the efficacy and safety of SG in patients with relapsed ovarian, endometrial, and cervical carcinomas (3 separate cohorts). In the ovarian cancer cohort, patients must have recurrent platinum-resistant epithelial (i.e., high grade serous, endometrioid, low grade serous, or clear cell) ovarian carcinoma that is refractory to standard treatment.

An open-label, phase 1 study (NCT06040970) is evaluating the efficacy and safety of SG in combination with cisplatin, in platinum sensitive recurrent ovarian and endometrial cancer, conducted in two separate disease groups; the primary objective of the study is to determine the optimal dose of SG in combination with cisplatin for treatment of epithelial ovarian and endometrial cancers.

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. Prast I, Marth C, Zeimet AG, Tsibulak I. Sacituzumab Govitecan In Platinum-Resistant Epithelial Ovarian Cancer In A Real-Life Clinical Setting. Presented at: European Society of Gynaecological Oncology (ESGO); February 20-23, 2025; Rome, Italy.
3. Nissen T, Wynn R. The clinical case report: a review of its merits and limitations. *BMC Res Notes.* 2014;7:264. https://www.ncbi.nlm.nih.gov/pubmed/24758689
4. Greenman M, Bellone S, Demirkiran C, Hartwich TMP, Santin AD. Sacituzumab govitecan in heavily pretreated, platinum-resistant high grade serous ovarian cancer. *Gynecologic Oncology Reports.* 2024;54:101459.

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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