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Trodelvy® (sacituzumab govitecan-hziy) Use in Patients with Recurrent GBM

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

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Trodelvy is not indicated for use in patients with rGBM. 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 Studies on SG Use in Patients With rGBM

An open-label, multicenter, single-arm, phase 2 study evaluated the use of SG in patients with IDH wild-type rGBM who have previously received standard-of-care chemoradiation. The primary endpoint was PFS with SG compared with PFS observed in a historical control group treated with lomustine.[1]

- In an interim analysis of 20 patients, mean PFS and OS were 7 mo and 2 mo, respectively. Overall, 20% of patients achieved SD as their best response, while the remaining patients experienced PD.
- Of 19 evaluable samples, 63% were positive for Trop-2 expression (defined as H-score ≥100). A post hoc analysis showed a significant correlation between OS and H-score (*P*=0.0361).
- AEs included lymphopenia (40%), neutropenia (40%), hypokalemia (35%), elevated alkaline phosphatase (30%), and anemia (30%). Grade ≥3 neutropenia deemed related to SG was reported in 4 patients.

A prospective, single-center, non-randomized, window-of-opportunity, phase 0 study evaluated the efficacy and safety (secondary endpoints) of SG in 25 patients undergoing craniotomy for BCBM or rGBM.[2,3]

- In the 12 patients with rGBM, median (range) OS was 38 (3.7–112.1) wk, and median (range) PFS was 8 (2–53) wk.[2,3]
- In an unplanned exploratory analysis (n=7), intracranial ORR was 28% (SD, 28%; PR, 28%; and CR, 0%).[2,3]
- Across the rGBM and BCBM population (N=25), most AEs were Grade 1 or 2. The most common AEs included fatigue (60%), diarrhea (52%), alopecia (44%), headache (40%), neutropenia (40%), and nausea (36%). Grade ≥3 AEs included neutropenia (28%) and hypokalemia, seizure, thromboembolic event, UTI, and lower limb muscle weakness (8% each). There was one instance of Grade 4 neutropenia. One patient in the rGBM cohort had Grade 5 pneumonia, which was assessed to be unrelated to SG.[2]

IMMU-132-01, a phase 1/2, single-arm, multicenter, basket study evaluated the efficacy and safety of SG in patients with metastatic epithelial cancers, including 3 patients with GBM, who had relapsed after or were refractory to ≥1 prior standard therapy.[4]

- No patient had a CR or PR (ORR=0%), and SD was observed in 1 patient (33.3%) in the GBM cohort. Other efficacy outcomes were not reported due to the small sample size.
- To date, safety data specific to patients with GBM have not been published.

Clinical Studies on SG Use in Patients With rGBM

Phase 2 Study in rGBM[1]

Study design and demographics

An open-label, multicenter, single-arm, phase 2 study using a two-stage adaptive Bayesian design evaluated the use of SG 10 mg/kg IV on Days 1 and 8 of a 21-d treatment cycle in patients with IDH wild-type rGBM who had previously received standard-of-care chemoradiation. The primary endpoint was PFS with SG compared with PFS observed in a historical control group treated with lomustine. Efficacy outcomes were assessed using RANO criteria, and safety was assessed using CTCAE v5.

At the interim analysis cutoff, 20 patients were enrolled. The average age was 58.8 y and 65% were male.

Efficacy

Mean PFS and OS were 7 mo and 2 mo, respectively. Overall, 20% of patients achieved SD as their best response, while the remaining patients experienced PD.

Of 19 evaluable samples, 63% were positive for Trop-2 expression (defined as H-score ≥100), with a mean H-score of 123.6. A post hoc analysis of OS log survival time compared with H-score using an accelerated failure time model showed a significant correlation between OS and H-score (P=0.0361).

Safety

AEs included lymphopenia (40%), neutropenia (40%), hypokalemia (35%), elevated alkaline phosphatase (30%), and anemia (30%). Grade ≥3 neutropenia deemed related to SG was reported in 4 patients.

Phase 0 Study in rGBM

Study design and demographics[2]

A prospective, single-center, non-randomized, window-of-opportunity, phase 0 study evaluated the intratumoral concentrations and intracranial activity of SG in 25 adult patients undergoing craniotomy for BCBM or rGBM. The secondary endpoints of efficacy specific to the rGBM cohort and safety for both patient groups are presented below.

Patients received a single IV dose of SG 10 mg/kg administered 1 d before surgical resection and resumed treatment with SG on Days 1 and 8 of a 21-d treatment cycle following recovery from surgery. MRI and CT imaging assessments were conducted at screening, during the postsurgical visit, and every third cycle (from Cycle 4 onward).

Intracranial disease response in the rGBM cohort was assessed by RANO 1.0. ORR, PFS, and OS were calculated from Cycle 1, Day 1.

In the rGBM cohort (n=12), patients had a mean (range) age of 55.2 (38–77) y and were predominantly male (75%). Nine patients (75%) had GBMs that were IDH wild type, and 9 patients (75%) had GBMs that were O^6-methylguanine-DNA methyltransferase promoter unmethylated.

Efficacy[2,3]

In the 12 patients with rGBM, median (range) OS was 38 (3.7–112.1) wk, and median (range) PFS was 8 (2–53) wk. In an unplanned exploratory analysis (n=7), intracranial ORR was 28% (SD, 28%; PR, 28%; and CR, 0%).

Safety[2]

Across the rGBM and BCBM population (N=25), most AEs were Grade 1 or 2. The most common AEs included fatigue (60%), diarrhea (52%), alopecia (44%), headache (40%), neutropenia (40%), and nausea (36%). Grade ≥3 AEs included neutropenia (28%) and hypokalemia, seizure, thromboembolic event, UTI, and lower limb muscle weakness (8% each). There was one instance of Grade 4 neutropenia. One patient in the rGBM cohort had Grade 5 pneumonia, which was assessed to be unrelated to SG.

IMMU-132-01 Study in Metastatic Epithelial Cancer[4]

Study design

IMMU-132-01, a phase 1/2, single-arm, multicenter, open-label basket study, evaluated the efficacy and safety of SG in patients with metastatic epithelial cancers, including 3 patients with GBM, who had relapsed after or were refractory to ≥1 prior standard therapy.

In the GBM cohort, SG 10 mg/kg IV was administered on Days 1 and 8 of a 21-d treatment cycle.

Efficacy

No patient had a CR or PR (ORR=0%), and SD was observed in 1 patient (33.3%) in the GBM cohort. Other efficacy outcomes were not reported due to the small sample size.

Safety

To date, safety data specific to patients with GBM have not been published.

References

1. Kelly W, Cordova C, Vaillant B, et al. CTNI-26. A phase II study of sacituzumab govitecan in recurrent glioblastoma [Abstract NOAE165.0393]. *Neuro-Oncology.* 2024;26(Suppl 8):viii101.
2. Balinda HU, Kelly WJ, Kaklamani VG, et al. Sacituzumab govitecan in patients with breast cancer brain metastases and recurrent glioblastoma: a phase 0 window-of-opportunity trial. *Nat Commun.* 2024;15(6707):1-11.
3. Balinda HU, Kelly WJ, Kaklamani VG, et al. Sacituzumab govitecan in patients with breast cancer brain metastases and recurrent glioblastoma: a phase 0 window-of-opportunity trial [Supplementary Information]. *Nat Commun.* 2024;15(6707):1-11.
4. 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.

Abbreviations

AE=adverse event
BCBM=breast cancer brain metastases
CR=complete response
CTCAE=Common Terminology Criteria for Adverse Events
GBM=glioblastoma
H-score=histochemical score
IDH=isocitrate dehydrogenase
ORR=objective response rate
OS=overall survival
PD=progressive disease
PFS=progression-free survival
PR=partial response
RANO=Response Assessment in Neuro-Oncology
rGBM=recurrent glioblastoma
SD=stable disease
SG=sacituzumab govitecan-hziy
Trop-2=trophoblast cell surface antigen-2
UTI=urinary tract infection

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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