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Trodelvy® (sacituzumab govitecan-hziy) Incidence of Alopecia

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and incidence of alopecia.

Gilead continually assesses safety data from all sources for unidentified drug reactions and updates the product label information accordingly to reflect the safety profile of SG. Because case reports of potential adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish causal relationship to drug exposure. For this reason, Gilead does not provide information from post-marketing spontaneous reports.

Information summarized in this document includes data for SG monotherapy (10 mg/kg IV on Days 1 and 8 of a 21-day treatment cycle) from Phase 2 and 3 clinical studies that constitute the largest pooled safety population of SG.

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

Summary

Relevant Product Labeling[1]

The pooled safety population reflect exposure to SG in 1063 patients, which included 366 patients with metastatic triple negative breast cancer (mTNBC) and 322 patients with hormone receptor positive/human epidermal growth factor receptor 2-negative breast cancer (HR+/HER2-) from IMMU-132-01,[2] ASCENT,[3] and TROPiCS-02[4]; and 375 patients with other tumor types. Among the 1063 patients treated with SG, the median duration of treatment was 4.1 months (range: 0–63 months). Within the pooled safety population, alopecia occurred in 45% of patients.[1]

Incidence of Alopecia in SG Clinical Studies

A pooled safety analysis examined exposure to SG 10 mg/kg IV as monotherapy in 1063 patients from four studies of multiple epithelial tumors (IMMU-132-01,[2] ASCENT,[3] TROPiCS-02,[4] and TROPHY-U-01[5-7]).

These studies included patients with metastatic triple negative breast cancer (mTNBC), hormone receptor-positive/human epidermal growth factor receptor 2-negative metastatic breast cancer (HR+/HER2- mBC), and metastatic urothelial cancer (mUC).[8]

The median (range) treatment duration of SG in this population was 4.1 (0–63) months[1]; alopecia was among the most common (≥15%) any-grade treatment-emergent adverse events (TEAEs), and was reported in 45% of patients.[8,1]

In ASCENT, in patients with mTNBC, treatment-related alopecia of any grade was reported in 46% and 16% of patients in the SG and treatment of physician's choice (TPC) arms, respectively.[3] The effectiveness of scalp cooling to prevent alopecia induced by SG is unknown.[9]

In TROPiCS-02, in patients with HR+/HER2- mBC, treatment-related alopecia occurred in 46% and 16% of patients in the SG and TPC arms, respectively.[4]

In TROPHY-U-01, in patients with locally advanced or mUC, treatment-related alopecia of any grade occurred in 47% of patients in Cohort 1,[5,7] and 50% of patients in Cohort 2.[10]

In IMMU-132-01, in patients with metastatic epithelial cancer, treatment-related alopecia occurred in 40.4% of patients.[2]

Incidence of Alopecia in SG Clinical Studies

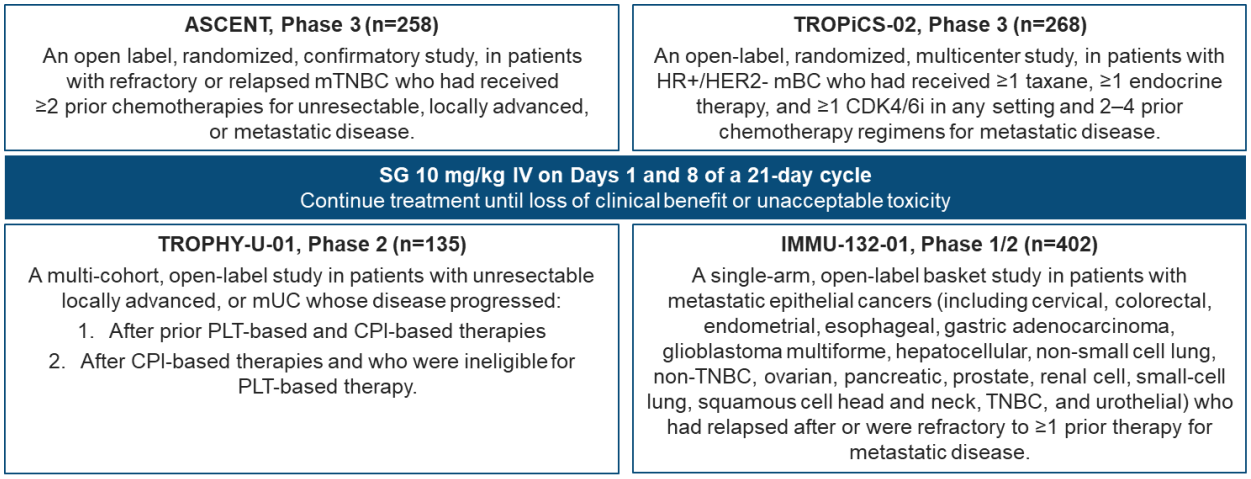
Pooled Safety Analysis

A pooled safety analysis (Figure 1) examined exposure to SG 10 mg/kg IV as monotherapy in 1063 patients from four studies of multiple epithelial tumors (IMMU-132-01,[2] ASCENT,[3] TROPiCS-02,[4] and TROPHY-U-01[5-7]).

These studies included patients with mTNBC, HR+/HER2- mBC, and mUC.[8]

The median treatment duration of SG in this population was 4.1 (range: 0–63) months[1]; alopecia was among the most common (≥15%) any-grade treatment-emergent adverse events (TEAEs), and was reported in 45% of patients.[8,1]

Figure 1. Pooled Clinical Studies[8]



Abbreviations: CKD4/6i, cyclin-dependent 4/6 inhibitor; CPI, checkpoint inhibitor therapies; PLT=platinum; TNBC, triple-negative breast cancer.

ASCENT Study in mTNBC

Patients in the SG treatment arm received a median (range) of 7 treatment cycles (1–33), over a median (range) duration of treatment of 4.4 (0.03–22.9) months.[11]

Treatment-related alopecia of any grade was reported in 46% (n=119) and 16% (n=35) of patients in the SG and TPC arms, respectively.[3]

Safety outcomes were also assessed according to age group in both the SG (<65, n=209; ≥65, n=49) and TPC (<65, n=176; ≥65, n=48) arms in ASCENT. Treatment-related alopecia of any grade was reported in 48% (n=101) and 37% (n=18) of patients who were <65 vs ≥65 years respectively, in the SG arm, and in 15% (n=27) and 17% (n=8) of patients who were <65 vs ≥65 years respectively, in the TPC arm.[12]

The effectiveness of scalp cooling to prevent alopecia induced by SG is unknown.[13]

TROPiCS-02 Study in HR+/HER2- mBC

Patients in the SG arm received a mean (range) of 8.2 treatment cycles (1–35), over a median (range) duration of treatment of 4.1 (03–24.2) months. Treatment-related alopecia occurred in 46% and 16% of patients in the SG and TPC arms, respectively.[4]

Exposure-Adjusted Incidence Rates

EAIRs are measured by time-at-risk analysis, defined as the number of patients with ≥1 specific AE divided by the total exposure time (patient-year of exposure [PYE]) in each group. For patients who experienced specific AEs, exposure time was calculated from the date of first dose up to the first AE onset, and for patients who did not experience a specific AE, from the date of first dose up to data cut-off (if still on study treatment) or up to last dose (if discontinued study treatment).[14]

The exposure-adjusted incidence rate (EAIR) for alopecia of any grade (≥ 10% of patients) per patient years of exposure (PYE) was higher for SG, compared with TPC (Table 1).[14]

Table 1. EAIR for Alopecia of Any Grade (≥ 10% of Patients) Per PYE[14]

Alopecia	SG (n=268) Per PYE	TPC (n=249) Per PYE
PYE	62.3	56.1
EAIR (95% CI)	2.06 (1.71 to 2.44)	0.82 (0.6 to 1.09)
EAIR difference vs TPC (95% CI)	1.23 (0.8 to 1.68)	

TROPHY-U-01 Study in mUC

In the Cohort 1 primary analysis, 113 patients received a median of 6 treatment cycles, with a median (range) treatment duration of 3.7 (0–20) months.[5] Treatment-related all grade alopecia occurred in 47% of patients.[5,7]

Uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1) testing was conducted and results from evaluable patients (n=106) are as follows. The incidence of alopecia (all grades) was 57% among patients who were homozygous for the *UGT1A1*28* allele (n=14), 47% in patients who were heterozygous (n=47), and 44% in patients with the wild-type allele (n=45).[7]

In the Cohort 2 primary analysis, 38 patients treated with SG had median (range) follow-up duration of 9.3 (0.5–30.6) months. Treatment-related alopecia (all grades) was reported by 19 (50%) patients.[10]

IMMU-132-01 Study in Metastatic Epithelial Cancer[2]

Patients received a median (range) of six SG treatment cycles (1–73), over a median (range) treatment duration of 3.7 (0–55.2) months. *UGT1A1* testing was conducted in all patients.

Treatment-related all grade alopecia occurred in 40.4% (n=200) of patients.

The incidence of alopecia (all grades) was 33% among patients who were homozygous for the *UGT1A1*28* allele (n=46), 41% in patients who were heterozygous (n=180), and 42% in patients with the wild-type allele (n=177).

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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

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Gilead Pharmacovigilance and Epidemiology ☎ 1-800-445-3235, option 3 or 🖱 www.gilead.com/utility/contact/report-an-adverse-event

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