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Trodelvy® (sacituzumab govitecan-hziy) Incidence of Alopecia in Patients with mBC

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

This document summarizes 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, with a focus on patients with mBC.

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.

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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: Pooled Safety Analyses

A total of 1063 patients from four studies (ASCENT,[3] TROPiCS-02,[4] TROPHY-U-01,[5] and IMMU-132-01[2]) were included in this analysis.[6] These studies included patients with mTNBC treated in the 2L+ setting, and pre-treated HR+/HER2-.[6] The median (range) treatment duration of SG was 4.1 (0–63) mo.[1]

- Alopecia was among the most common (≥15%) any-grade treatment-emergent adverse events (TEAEs), and was reported in 45% of patients.[6,1]

A total of 969 patients, with either mTNBC treated in the 2L+ setting or pre-treated HR+/HER2- mBC, were included in a pooled analysis of clinical studies in the NA/EU

(ASCENT,[3] TROPiCS-02,[4] IMMU-132-01[2]) and Asia (EVER-132-001,[7] EVER-132-002,[8] and ASCENT-J02[9]) regions.[10]

- Across NA/EU (n=688) and Asia (n=281), treatment-emergent any-grade alopecia was reported in 314 (46%) and 146 (52%) patients, respectively.[10]

Incidence of Alopecia in SG mBC Clinical Studies

In ASCENT, a study in 2L+ mTNBC, treatment-related alopecia of any grade was reported in 46% and 16% of patients in the SG and chemotherapy treatment of physician's choice (TPC) arms, respectively.[11] The effectiveness of scalp cooling to prevent alopecia induced by SG in this patient group is unknown.[12]

In ASCENT-03, a study in 1L mTNBC, incidence of any-grade treatment-emergent alopecia was 55% (SG) and 27% (TPC).[13]

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

In ASCENT-07, a study in 1L post-ET HR+/HER2- mBC, any-grade treatment-emergent alopecia occurred in 61% and 36% of patients treated with SG and TPC, respectively.[14]

In IMMU-132-01, a study in metastatic epithelial cancer,[2,15,16] the incidence of alopecia in the mTNBC cohort was 36%.[15] Incidence of alopecia in the HR+/HER2- mBC cohort was 44.4%.[16]

Pooled SG Safety Analyses

Safety Analysis in Patients With Multiple Epithelial Tumors

A pooled analysis examined exposure to SG in 1063 patients from four studies.[2-6] These studies included patients with mTNBC treated in the 2L+ setting, and pre-treated HR+/HER2- mBC (Figure 1).[6] The median treatment duration of SG in this population was 4.1 (range: 0–63) mo.[1]

Figure 1. Pooled Clinical Studies[6]

ASCENT, Phase 3 (n=258) An open label, randomized, confirmatory study, in patients with refractory or relapsed mTNBC who had received ≥2 prior chemotherapies for unresectable, locally advanced, or metastatic disease.	**TROPiCS-02, Phase 3 (n=268)** An open-label, randomized, multicenter study, in patients with HR+/HER2- mBC who had received ≥1 taxane, ≥1 endocrine therapy, and ≥1 CDK4/6i in any setting and 2–4 prior chemotherapy regimens for metastatic disease.
SG 10 mg/kg IV on Days 1 and 8 of a 21-day cycle Continue treatment until loss of clinical benefit or unacceptable toxicity	
TROPHY-U-01, Phase 2 (n=135) A multi-cohort, open-label study in patients with unresectable locally advanced, or mUC whose disease progressed: 1. After prior PLT-based and CPI-based therapies 2. After CPI-based therapies and who were ineligible for PLT-based therapy.	**IMMU-132-01, Phase 1/2 (n=402)** A single-arm, open-label basket study in patients with metastatic epithelial cancers (including cervical, colorectal, endometrial, esophageal, gastric adenocarcinoma, glioblastoma multiforme, hepatocellular, non-small cell lung, non-TNBC, ovarian, pancreatic, prostate, renal cell, small-cell lung, squamous cell head and neck, TNBC, and urothelial) who had relapsed after or were refractory to ≥1 prior therapy for metastatic disease.

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

Table 1. Pooled Safety in Multiple Epithelial Tumors: Baseline Demographics and Disease Characteristics[6]

Key Demographics and Characteristics		All Patients (N=1063)
Age, median (range), y		59 (27–90)
Sex, n (%)	Female	840 (79)
Race, n (%)	White/Black/Asian	826 (78)/55 (5)/38 (4)
	Other or unknown	144 (14)
ECOG PS, %	0/1	36/64
Time since metastatic disease diagnosis, median (range), mo		28.7 (-0.1 to 412.6)
Number of prior lines of systemic therapy, median (range), n		5 (1–17)
Presence of visceral metastasis, n (%)		882 (83)
UGT1A1 status, n (%)	**1/*1*	416 (39)
	**1/*28*	420 (40)
	**28/*28*	112 (11)
	Other/unknown	13 (1)/102 (10)

Abbreviation: ECOG PS=Eastern Cooperative Oncology Group Performance Status.

Alopecia was among the most common (≥15%) treatment-emergent any-grade adverse events (TEAEs), and was reported in 45% of patients.[6,1]

Safety Analysis in Patients With mBC

A pooled analysis of clinical studies in the NA/EU (ASCENT,[3] TROPiCS-02,[4] IMMU-132-01[2]) and Asia (EVER-132-001,[7] EVER-132-002,[8] and ASCENT-J02[9]) regions, evaluated SG in 969 patients with either mTNBC or HR+/HER2- mBC; TEAEs were analyzed by region, NA/EU and Asia.[10]

Baseline age, sex, and BMI were similar in both groups; race data are in Table 2. Asian patients had a higher rate of ECOG PS 1 (67% vs 59%) and shorter time from metastatic diagnosis to randomization vs NA/EU patients (25.2 vs 35.7 mo). UGT1A1 genotypes differed: NA/EU had more *1/*28 and *28/*28, while Asia had more *1/*1 and *1/*6.[10]

Table 2. Pooled Safety in mBC: Baseline Race by Region[10]

Race, n (%)	White	Black	Asian	Other/Unknown
NA/EU (n=688)	517 (75)	41 (6)	26 (4)	104 (15)
Asia (n=281)	0	0	281 (100)	0

Across NA/EU and Asia, any-grade treatment-emergent alopecia was reported in 314 (46%) and 146 (52%) patients, respectively.[10]

Incidence of Alopecia in SG mBC Clinical Studies

ASCENT Study in 2L+ mTNBC

ASCENT (N=529) investigated the safety and efficacy of SG vs TPC (eribulin, vinorelbine, gemcitabine, or capecitabine) in patients with refractory or relapsed 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) mo. [20]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.[11]

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.[17]

The effectiveness of scalp cooling to prevent alopecia induced by SG is unknown.[12]

ASCENT-03 Study in 1L mTNBC

ASCENT-03, an ongoing, global, open-label, randomized, phase 3 study, compares the efficacy and safety of SG vs TPC (gem + carbo, paclitaxel, or nab-paclitaxel), as 1L treatment in patients (N=558) with previously untreated, locally advanced, inoperable or mTNBC who are not candidates for PD-(L)1 inhibitor therapy.[13] The median (range) duration of SG treatment at the final PFS analysis was 8.3 mo (<0.1–28.7).[13,18] The incidence of any-grade treatment-emergent alopecia was 55% (SG) and 27% (TPC).[13]

TROPiCS-02 Study in Pre-Treated HR+/HER2- mBC

TROPiCS-02 (N=543) investigated the safety and efficacy of SG vs TPC (eribulin, vinorelbine, capecitabine, or gemcitabine) in patients with pre-treated HR+/HER2- mBC. Patients in the SG arm received a mean (range) of 8.2 (1–35) treatment cycles, over a median (range) duration of treatment of 4.1 (03–24.2) mo. 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).[19]

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 3).[19]

Table 3. EAIR for Alopecia of Any Grade (≥10% of Patients) Per PYE[19]

Alopecia	SG (n=268)	TPC (n=249)
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)	

ASCENT-07 Study in 1L Post-ET in HR+/HER2- mBC[14]

ASCENT-07, an on-going, global, open-label, randomized, phase 3 study (N=690), compares the efficacy and safety of SG vs TPC (capecitabine, paclitaxel, or nab-paclitaxel) in patients with HR+/HER2- (IHC 0, IHC 1+, IHC2+/ISH-) locally advanced, inoperable, or mBC who have received prior ET. The median (range) duration of SG treatment at the PFS analysis was 8.3 mo (0–22.1). Any-grade treatment-emergent alopecia occurred in 61% and 36% of patients treated with SG and TPC, respectively.

IMMU-132-01 Study in Metastatic Epithelial Cancer

IMMU-132-01 investigated the safety and efficacy of SG in patients with metastatic epithelial cancers[2], including mTNBC (n=108)[15] and HR+/HER2- mBC (n=54).[16]

The mTNBC cohort received a mean (range) of 9.6 (1–51) SG cycles, with a median (range) duration of exposure of 5.1 mo (0.03–36.1); the incidence of any-grade alopecia was 36%.[15]

The median (range) duration of SG treatment was 4.6 mo (0–29.4) for the HR+/HER2- mBC cohort; incidence of treatment-related all grade alopecia was 44.4%.[16]

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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

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