GILEAD | Medical Information

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.

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 described in the Warnings and Precautions section of the US FDA-approved Prescribing Information reflect exposure to SG as a single agent in 1354 patients. The median (range) duration of treatment among these patients was 4.9 (0–63) mo. Alopecia was among the most common (≥25%) adverse reactions and occurred in 47% of patients.

Incidence of Alopecia: Pooled Safety Analyses

A total of 1354 patients from four studies with SG as a single agent (ASCENT-03,[2] ASCENT,[3] TROPiCS-02,[4] and IMMU-132-01[5]) were included in a pooled safety analysis. These studies included 641 patients with metastatic triple-negative breast cancer (mTNBC; in a 1L or 2L+ setting) and 322 patients with pretreated hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) mBC; 391 patients had other tumor types. The median treatment duration of SG was 4.9 (range: 0–63) mo.[1]

- Alopecia was among the most common (≥25%) adverse reactions and was reported in 47% of patients.[1]

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

(ASCENT,[6] TROPiCS-02,[4] IMMU-132-01[5]) 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.[3] The effectiveness of scalp cooling to prevent alopecia induced by SG in this patient group is unknown.[11]

In ASCENT-03, a study in 1L mTNBC, incidence of any-grade treatment-emergent alopecia was 55% (SG) and 27% (TPC).[2]

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.[12]

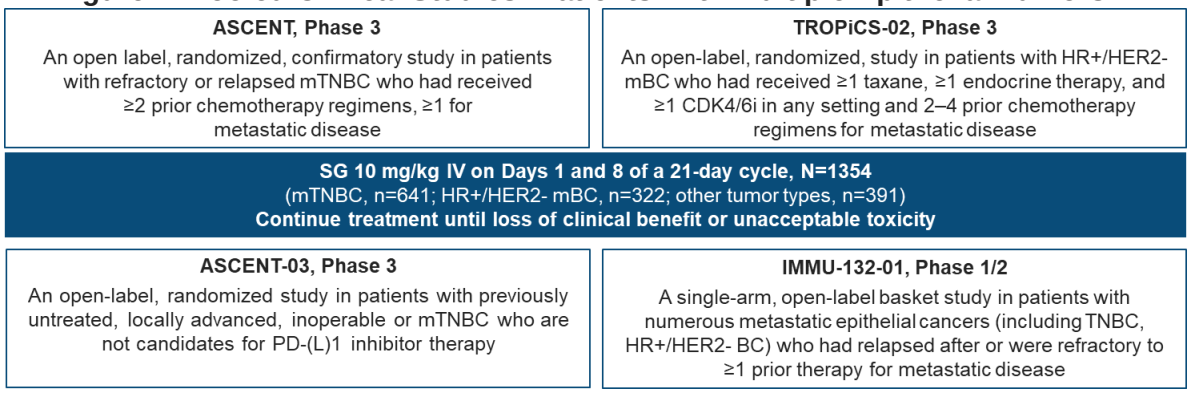
In IMMU-132-01, a study in metastatic epithelial cancer,[5,13,14] the incidence of alopecia in the mTNBC cohort was 36%.[13] Incidence of alopecia in the HR+/HER2- mBC cohort was 44.4%.[14]

Pooled SG Safety Analyses

Safety Analysis in Patients With Multiple Epithelial Tumors

A total of 1354 patients from four studies (ASCENT-03,[2] ASCENT,[3] TROPiCS-02,[4] and IMMU-132-01[5]) were included in a pooled safety analysis. These studies included 641 patients with mTNBC (in a 1L or 2L+ setting) and 322 patients with pretreated HR+/HER2- mBC; 391 patients had other tumor types (Figure 1). The median treatment duration of SG was 4.9 (range: 0–63) mo.[1]

Figure 1. Pooled Clinical Studies: Patients With Multiple Epithelial Tumors[1-5]



Abbreviations: CKD4/6i=cyclin-dependent 4/6 inhibitor; CPI=checkpoint inhibitor therapies; PD-(L)1=programmed death (ligand)-1; PLT=platinum; TNBC=triple-negative breast cancer.

Alopecia was among the most common (≥25%) adverse reactions and was reported in 47% of patients.[1]

Safety Analysis in Patients With mBC

A pooled analysis of clinical studies in the NA/EU (ASCENT,[6] TROPiCS-02,[4] IMMU-132-01[5]) 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; treatment-emergent adverse events (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 Eastern Cooperative Oncology Group Performance Status 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 1. 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.[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.[15]

The effectiveness of scalp cooling to prevent alopecia induced by SG is unknown.[11]

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.[2] The median (range) duration of SG treatment at the final PFS analysis was 8.3 (<0.1–28.7) mo.[2,16] The incidence of any-grade treatment-emergent alopecia was 55% (SG) and 27% (TPC).[2]

TROPiCS-02 Study in Pretreated HR+/HER2- mBC

TROPiCS-02 (N=543) investigated the safety and efficacy of SG vs TPC (eribulin, vinorelbine, capecitabine, or gemcitabine) in patients with pretreated 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).[17]

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 2).[17]

Table 2. EAIR for Alopecia of Any Grade (≥10% of Patients) Per PYE[17]

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[12]

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 (0–22.1) mo. 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[5], including mTNBC (n=108)[13] and HR+/HER2- mBC (n=54).[14]

The mTNBC cohort received a mean (range) of 9.6 (1–51) SG cycles, with a median (range) duration of exposure of 5.1 (0.03–36.1) mo; the incidence of any-grade alopecia was 36%.[13]

The median (range) duration of SG treatment was 4.6 (0–29.4) mo for the HR+/HER2- mBC cohort; incidence of treatment-related all grade alopecia was 44.4%.[14]

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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

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or https://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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