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Trodelvy® (sacituzumab govitecan-hziy) HR+/HER2- mBC and HRQoL

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and health-related quality of life (HRQoL) outcomes in the treatment of hormone receptor-positive/human epidermal growth factor receptor 2-negative metastatic breast cancer (HR+/HER2- mBC).

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Summary

Relevant Product Labeling[1]

SG is indicated for the treatment of adult patients with unresectable locally advanced or metastatic HR+/HER2- (IHC 0, IHC 1+, or IHC 2+/ISH-) BC who have received endocrine-based therapy and ≥2 additional systemic therapies in the metastatic setting.

HRQoL Assessments in HR+/HER2- mBC Studies

The phase 3 TROPiCS-02 study compared the safety and efficacy of SG with that of chemotherapy TPC in 543 patients with HR+/HER2- mBC who were previously treated with ≥1 taxane, ≥1 ET, and ≥1 CDK4/6i in any setting and who have received 2 to 4 prior chemotherapy regimens for metastatic disease.[2] PRO/HRQoL assessment results were compared between the SG and TPC arms.[2-4]

- The TTD for the primary EORTC QLQ-C30 domains of GHS/QoL, physical functioning, and fatigue was significantly longer in the SG arm than the TPC arm; the TTD for the role functioning and pain domains was not significantly different between treatment arms.[2,3] Overall, EORTC QLQ-C30 domains generally improved from baseline in the SG arm compared with the TPC arm, and a greater proportion of patients in the TPC arm had clinically meaningful worsening of scores than those in the SG arm.[4]
- The TTD of the EQ-VAS was significantly longer for the SG arm than for the TPC arm; however, the TTD of the EQ-5D-5L health utility index was not significantly different between arms.[3]
- The proportions of patients who had meaningful worsening on the PRO-CTCAE were similar between arms for most items; exceptions were diarrhea and amount of hair loss, which were reported as worsening by a higher proportion of patients in the SG arm than in the TPC arm.[3]

A meta-analysis of the two phase 3 studies, TROPiCS-02 and EVER-132-002, compared the HRQoL outcomes for SG vs TPC in patients with HR+/HER2- mBC who progressed after ET, taxane, CDK4/6i, and ≥2 systemic therapies in the advanced setting.[5]

The EVER-132-002 study evaluated SG vs TPC (ie, gemcitabine, eribulin, capecitabine, or vinorelbine) in Asian patients with HR+/HER2- locally recurrent inoperable BC or mBC who progressed after 2 to 4 systemic therapies in the advanced setting including ≥1 ET, ≥1 taxane, or CDK4/6i (not mandatory).[6]

- The TTDs for the EORTC QLQ-C30 domains of GHS/QoL, physical functioning, emotional functioning, fatigue, pain, and dyspnea (death=censored) were significantly longer with SG than with TPC in the overall population and the prior CDK4/6i-treated population. The TTDs for nausea and vomiting and for diarrhea significantly favored TPC vs SG in those two populations.[5]
- The TTD for the fast-progressor population significantly favored SG vs TPC for the six previously mentioned domains and for the financial difficulties domain.[5]
- The TTD was significantly longer with SG than with TPC for the EQ-5D-5L VAS in the overall, prior CDK4/6i-treated, and fast-progressor populations.[5]

HRQoL Assessments in HR+/HER2- mBC Studies

TROPiCS-02 Study

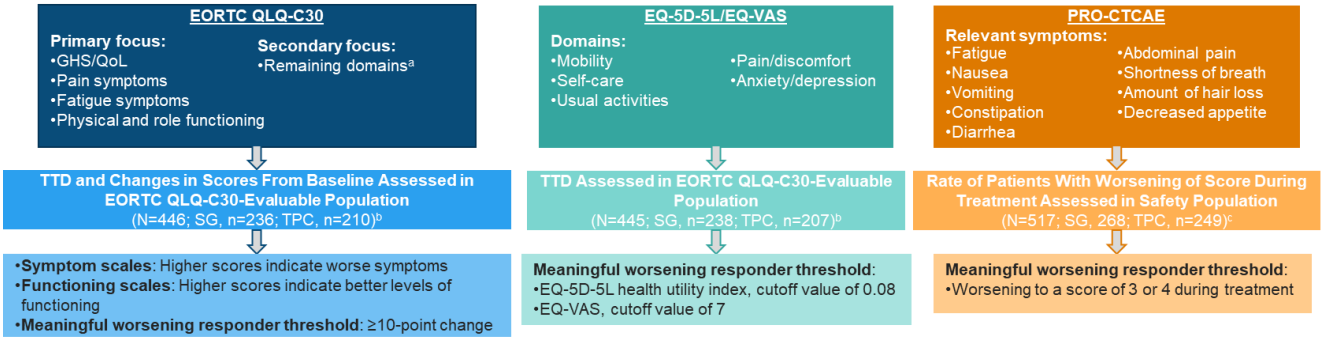
Study design

TROPiCS-02, an open-label, randomized, multicenter phase 3 study, compared the safety and efficacy of SG 10 mg/kg IV on Days 1 and 8 of a 21-day cycle with TPC (ie, eribulin, vinorelbine, capecitabine or gemcitabine) in 543 patients with HR+/HER2- locally recurrent, inoperable or mBC who were previously treated with ≥1 taxane, ≥1 ET, and ≥1 CDK4/6i in any setting and who had received 2 to 4 prior chemotherapy regimens for metastatic disease. Treatment was continued until disease progression, unacceptable adverse events, or investigator's decision.[2]

In the statistical testing hierarchy, once progression-free survival (primary endpoint) was statistically significant, then overall survival was formally tested for significance, followed by testing of other key secondary endpoints (once the prior endpoint in the hierarchy was significant) including objective response rate and TTD of EORTC QLQ-C30 GHS/QoL, fatigue, and pain.[2,7,8] The time to first meaningful HRQoL worsening was defined as the time between study randomization and the time a patient experienced a meaningful worsening (defined as changes from baseline that were equal to or greater than the responder definition threshold for worsening; Figure 1) or death.[7,8]

Results of HRQoL analyses using the EORTC QLQ-C30 (secondary endpoint), EQ-5D-5L/EQ-VAS (exploratory endpoint), and PRO-CTCAE scales (exploratory endpoint) were reported at data cutoff dates of January 3, 2022, and July 1, 2022 (EORTC QLQ-C30 only). HRQoL assessments (Figure 1) were performed at baseline, Day 1 of each treatment cycle from Cycle 2 onwards (SG, 3 weeks; TPC, 3 or 4 weeks), and an end-of-treatment visit (≥30 days after the last study drug dose and prior to the start of other treatment, or at the time of premature study drug discontinuation).[2,3,7]

Figure 1. TROPiCS-02: PRO Assessments: Domains and Symptoms, Analysis Populations, and Meaningful Worsening Responder Thresholds[2-4,7,8]



[a]Remaining domains included the following: emotional, cognitive, and social functioning; nausea and vomiting; dyspnea; insomnia; appetite loss; constipation; diarrhea; and financial difficulties.
[b]Included all patients in the ITT population with evaluable assessments at baseline and ≥1 assessment after baseline.
[c]Included all patients in the ITT population who received ≥1 dose of study drug.

Patient demographics and completion rates

Baseline demographics and disease characteristics were comparable between arms for the EORTC QLQ-C30-evaluable population (Table 1). Completion rates for each of the HRQoL assessments were generally similar between arms.[3,4]

Table 1. TROPiCS-02: EORTC QLQ-C30-Evaluable Population: Baseline Demographics and Disease Characteristics[4]

Key Demographics and Characteristics		SG (n=236)	TPC (n=210)
Age, mean (SD), years		57 (12)	56 (11)
ECOG PS, 0/1, n (%)		102 (43)/134 (57)	101 (48)/109 (52)
Number of prior chemotherapy regimens in the metastatic setting, n (%)	2 lines	95 (40)	93 (43)
	3–4 lines	141 (60)	117 (56)
Visceral metastasis, n (%)		224 (95)	198 (94)
Prior ET use in the metastatic setting, n (%)		208 (88)	185 (88)
Baseline scores of primary domains of EORTC QLQ-C30, mean (SD)	GHS/QoL	63.6 (21.2)	63.7 (20)
	Physical functioning	78.2 (19.9)	78.4 (19.7)
	Role functioning	76.3 (26.4)	75.8 (25.9)
	Fatigue	35 (23.6)	35.6 (23.9)
	Pain	28.4 (27.8)	31.4 (27.2)

Abbreviation: ECOG PS=Eastern Cooperative Oncology Group performance status.

HRQoL results

EORTC QLQ C-30 results (secondary endpoint)

As of the July 1, 2022, data cutoff, the median (IQR) treatment duration was 4.1 (1.2–8) months and 2.3 (1–5.1) months in the SG and TPC arms (safety population), respectively. The TTD for EORTC QLQ-C30 GHS/QoL and fatigue symptom assessments was significantly longer in the SG treatment arm than in the TPC arm (Table 2); however, the TTD for pain was similar between arms.[2,8] In a post hoc subgroup analysis that compared TTD between treatment arms in patients aged <65 or ≥65 years, SG had a significantly longer TTD for fatigue than TPC in patients <65 years (Table 2).[9]

Table 2. TROPiCS-02: TTD of EORTC QLQ-C30 GHS/QoL, Fatigue, and Pain Scales Overall (Secondary Endpoint) and in Patients <65 and ≥65 Years (Post Hoc Analysis)[2,8,9]

Domain	Overall		<65 Years		≥65 Years	
	SG	TPC	SG	TPC	SG	TPC
GHS/QoL	n=234	n=207	Not reported	Not reported	Not reported	Not reported
Median (95% CI), months	4.3 (3.1–5.7)	3 (2.2–3.9)	4.4 (3.2–6.4)	3 (2.2–4.4)	3.4 (2.1–5.7)	2.9 (1.4–4.9)
HR (95% CI)	0.75 (0.61–0.92); *P*=0.0059		0.81 (0.64–1.02); *P*=0.066		0.71 (0.47–1.06); *P*=0.094	
Fatigue	n=234	n=205	Not reported	Not reported	Not reported	Not reported
Median (95% CI), months	2.2 (1.6–2.8)	1.4 (1.1–1.9)	2 (1.5–2.8)	1.1 (1–1.8)	2.2 (1.2–4.4)	2.3 (1.3–3.7)
HR (95% CI)	0.73 (0.6–0.89); *P*=0.0021		0.76 (0.61–0.96); *P*=0.021		0.82 (0.55–1.22); *P*=0.32	
Pain	n=229	n=202	Not reported	Not reported	Not reported	Not reported
Median (95% CI), months	3.8 (2.8–5)	3.5 (2.8–5)	3.7 (2.8–5.2)	4.6 (3.1–6.3)	4.4 (1.5–5.3)	2.6 (1.7–3.6)
HR (95% CI)	0.92 (0.75–1.13); *P*=0.415		1 (0.79–1.27); *P*=0.97		0.73 (0.49–1.09); *P*=0.12	

As shown in Table 3, in general, a higher proportion of patients in the TPC arm than in the SG arm had clinically meaningful worsening in the primary domains of EORTC QLQ-C30 assessments at Cycles 2, 6, and 11.[4]

Table 3. TROPiCS-02: Patients With Clinically Meaningful Worsening in Primary EORTC QLQ-C30 Domains at Cycles 2, 6, and 11[4]

Patients With Clinically Meaningful Worsening, %	Cycle 2			Cycle 6			Cycle 11		
	SG	TPC	OR (95% CI)	SG	TPC	OR (95% CI)	SG	TPC	OR (95% CI)
GHS/QoL	23	28	0.74 (0.46–1.19)	19	21	0.78 (0.37–1.62)	11	27	0.24 (0.05–1.05)
Physical functioning	22	25	0.82 (0.51–1.32)	13	26	0.44 (0.21–0.9)[a]	16	31	0.49 (0.16–1.43)
Role functioning	32	34	0.89 (0.58–1.36)	27	42	0.5 (0.27–0.92)[a]	36	39	0.88 (0.33–2.36)
Fatigue	39	51	0.58 (0.38–0.88)[a]	26	37	0.52 (0.27–0.99)[a]	27	35	0.46 (0.15–1.43)
Pain	26	26	0.92 (0.57–1.48)	18	22	0.71 (0.34–1.47)	31	31	1 (0.36–2.77)

[a]*P*<0.05.

Overall, EORTC QLQ-C30 secondary domains generally improved from baseline in the SG arm compared with the TPC arm; however, the least-squares mean score for diarrhea was significantly worse with SG than with TPC.[4]

At the earlier data cutoff (January 3, 2022), the TTD for the primary EORTC QLQ-C30 domains of GHS/QoL, fatigue, and pain was similar to the later data cutoff results; the TTD for the role functioning was not significantly different between arms (Table 4). The TTD for the secondary EORTC QLQ-C30 domains is shown in Table 4. There was a significantly shorter TTD for diarrhea within the SG arm than within the TPC arm.[3]

Table 4. TROPiCS-02: TTD of EORTC QLQ-C30 Scores From Earlier Data Cutoff (January 3, 2022)[3]

EORTC QLQ-C30 (n=446)		TTD, Median, Months		HR (95% CI)
		SG (n=236)	TPC (n=210)	
Primary domains	GHS/QoL	4	2.9	0.74 (0.59–0.91); *P*<0.01
	Physical functioning	5	3.7	0.77 (0.62–0.96); *P*<0.05
	Role functioning	2.6	2.8	0.92 (0.75–1.14)
	Fatigue	2.1	1.4	0.76 (0.62–0.93); *P*<0.01
	Pain	3.7	3.4	0.92 (0.74–1.14)

EORTC QLQ-C30 (n=446)		TTD, Median, Months		HR (95% CI)
		SG (n=236)	TPC (n=210)	
Secondary domains	Emotional functioning	7.4	5	0.67 (0.54–0.84); *P*<0.01
	Cognitive functioning	4.6	4.6	0.89 (0.72–1.1)
	Social functioning	2.9	3.6	0.89 (0.72–1.1)
	Nausea and vomiting	2.2	4.6	1.13 (0.91–1.39)
	Dyspnea	5.7	4.4	0.75 (0.61–0.94); *P*<0.05
	Insomnia	6.2	4.4	0.77 (0.62–0.97); *P*<0.05
	Appetite loss	3.6	4.5	0.98 (0.78–1.22)
	Constipation	3.8	4.9	1.07 (0.86–1.33)
	Diarrhea	2.2	5.8	1.54 (1.24–1.91); *P*<0.01
	Financial difficulties	9.2	6.8	0.79 (0.62–0.99); *P*<0.05
	Summary score	5	5.3	0.92 (0.74–1.15)

EQ-5D-5L and PRO-CTCAE results (exploratory endpoints; January 3, 2022)[3]

The TTD for the EQ-5D-5L health utility index (n=445) was similar between arms (SG vs TPC: 5.3 vs 5.1 months; HR: 0.94 [95%CI: 0.75–1.17]); however, the TTD for the EQ-5D-5L EQ-VAS was significantly longer in the SG arm than the TPC arm (4.4 vs 3.5 months; HR: 0.79; 95% CI: 0.64–0.98; *P*<0.05). PRO-CTCAE results are shown in Table 5.

Table 5. TROPiCS-02: PRO-CTCAE: Worsening of Scores from Baseline to 3 or 4 During Treatment From Earlier Data Cutoff (January 3, 2022)[3]

PRO-CTCAE Items, %	SG (n=268)	TPC (n=249)
Decreased appetite, severity/interference	16/13	13/11
Nausea, frequency/severity	12/12	11/7
Vomiting, frequency/severity	7/8	4/4
Constipation, severity	16	10
Diarrhea, frequency	35	11
Abdominal pain, frequency/severity/interference	19/16/11	15/8/8
Shortness of breath, severity/interference	10/13	12/10
Hair loss, amount	71	24
Fatigue, severity/interference	27/27	25/21

Note: The denominators for these rates are the number of patients in the safety population who did not have missing scores at baseline and had ≥1 post-baseline visit (including the end-of-treatment visit).

TROPiCS-02 and EVER-132-002 Studies

Study design

A meta-analysis of the TROPiCS-02 (study design described above) and EVER-132-002 studies was performed to compare the HRQoL outcomes with SG vs TPC.[5]
The EVER-132-002 study evaluated SG vs TPC (ie, gemcitabine, eribulin, capecitabine, or vinorelbine) in Asian patients with HR+/HER2- locally recurrent inoperable BC or mBC who progressed after 2 to 4 systemic therapies in the advanced setting including ≥1 ET, ≥1 taxane, or CDK4/6i (not required).[6] TTD in EORTC QLQ-C30 domains (≥10-point change) and EQ-5D-5L VAS (≥15-point change) was assessed in evaluable patients (ie, those who completed ≥1 domain/dimension at baseline and ≥1 post-baseline assessment), in the overall ITT population, and two subgroups: patients who had prior CDK4/6i treatment and patients who were fast progressors (defined as a prior CDK4/6i treatment duration of ≤12 months). Death was excluded from the base-case analysis but was included as an event in a sensitivity analysis.[5]

Results[5]

In the base-case analysis (death=censored), SG vs TPC was associated with an increase in TTD in six of the 15 EORTC QLQ C-30 domains, including GHS/QoL, physical functioning, emotional functioning, fatigue, pain, and dyspnea. These observations were noted in the overall population and in the prior CDK4/6i-treated population; the TTDs for nausea and vomiting and for diarrhea were significantly worsened with SG vs TPC in the overall and in the prior CDK4/6i-treated population. In the fast-progressor population, the TTD was also significantly improved with SG vs TPC for the previously mentioned six domains and for the financial difficulties domain (Table 6).

Table 6. TROPiCS-02 and EVER-132-002: TTD in EORTC QLQ C-30 in Base-Case Analysis (Death=Censored)[5]

EORTC QLQ-C30	Overall Population		Prior CDK4/6i Treated		Fast Progressors	
	n	HR (95% CI)	n	HR (95% CI)	n	HR (95% CI)
GHS/QoL	**756**	**0.76 (0.63–0.92); *P*=0.005**	**592**	**0.69 (0.56–0.86); *P*=0.001**	**366**	**0.62 (0.47–0.82); *P*=0.001**
Physical functioning	**762**	**0.72 (0.59–0.88); *P*=0.001**	**597**	**0.74 (0.59–0.93); *P*=0.009**	**371**	**0.69 (0.51–0.92); *P*=0.01**
Role functioning	749	0.84 (0.7–1.01); *P*=0.06	586	0.88 (0.71–1.08); *P*=0.404	361	0.83 (0.64–1.08); *P*=0.169
Emotional functioning	**752**	**0.73 (0.58–0.91); *P*=0.006**	**588**	**0.64 (0.49–0.83); *P*=0.001**	**365**	**0.53 (0.38–0.74); *P*=0**
Cognitive functioning	760	0.83 (0.68–1.02); *P*=0.071	596	0.87 (0.69–1.1); *P*=0.23	370	0.77 (0.57–1.03); *P*=0.079
Social functioning	742	0.88 (0.72–1.06); *P*=0.181	578	0.88 (0.71–1.1); *P*=0.262	362	0.76 (0.58–1.01); *P*=0.059
Fatigue	**755**	**0.8 (0.67–0.95); *P*=0.011**	**591**	**0.77 (0.63–0.94); *P*=0.009**	**366**	**0.71 (0.55–0.91); *P*=0.007**
Nausea and vomiting	**762**	**1.48 (1.21–1.79); *P*<0.001**	**597**	**1.33 (1.07–1.65); *P*=0.011**	372	1.22 (0.93–1.6); *P*=0.154
Pain	**744**	**0.82 (0.67–0.99); *P*=0.042**	**580**	**0.77 (0.62–0.96); *P*=0.021**	**357**	**0.72 (0.55–0.96); *P*=0.024**
Dyspnea	**748**	**0.71 (0.57–0.88); *P*=0.002**	**584**	**0.69 (0.54–0.88); *P*=0.003**	**361**	**0.62 (0.45–0.85); *P*=0.003**
Insomnia	718	0.87 (0.69–1.08); *P*=0.208	559	0.81 (0.63–1.05); *P*=0.119	343	0.78 (0.56–1.07); *P*=0.12
Appetite loss	739	1.13 (0.93–1.39); *P*=0.216	575	1 (0.8–1.26); *P*=0.978	359	0.86 (0.65–1.16); *P*=0.325
Constipation	747	1.11 (0.89–1.38); *P*=0.366	585	1.13 (0.89–1.44); *P*=0.325	363	1.08 (0.79–1.47); 0.641
Diarrhea	**757**	**2.21 (1.77–2.76); *P*<0.001**	**593**	**2.25 (1.76–2.88); *P*<0.001**	**367**	**2.14 (1.57–2.91); *P*<0.001**
Financial difficulties	715	1.09 (0.83–1.44); *P*=0.53	570	1.02 (0.73–1.44); *P*=0.889	**352**	**0.6 (0.39–0.93); *P*=0.022**
Summary score	764	0.89 (0.72–1.09); *P*=0.259	599	0.87 (0.69–1.11); *P*=0.265	372	0.84 (0.63–1.14); *P*=0.264

Note: Blue text indicates a significant improvement with SG vs TPC. Teal text indicates a significant improvement with TPC vs SG.

Results of the sensitivity analysis (death=event) in the overall and prior CDK4/6i-treated populations were generally similar to the results for those populations in the base-case analysis; however, the TTD favoring of SG vs TPC was no longer significant for the pain subscale (overall, *P*=0.199; prior CDK4/6i-treated, *P*=0.103) and became significant for the

financial difficulties subscale (overall, *P*=0.035; prior CDK4/6i-treated, *P*=0.008). For the fast-progressor population, results were also generally similar to those in the base-case analysis, with the addition of a significantly longer TTD for insomnia with SG vs TPC.

In the base-case and sensitivity analyses, SG vs TPC had significantly longer TTD in the EQ-5D-5L VAS for the overall, prior CDK4/5i-treated, and fast-progressor populations (Table 7).

Table 7. TROPiCS-02 and EVER-132-002: TTD in EQ-5D-5L VAS in Base-Case (Death=Censored) and Sensitivity (Death=Event) Analyses[5]

EQ-5D-5L VAS	Overall Population		Prior CDK4/6i Treated		Fast Progressors	
	n	HR (95% CI)	n	HR (95% CI)	n	HR (95% CI)
Death=censored	**754**	**0.68 (0.53–0.87); *P*=0.002**	**589**	**0.63 (0.48–0.83); *P*=0.001**	**365**	**0.69 (0.48–0.97); *P*=0.034**
Death=event	**754**	**0.76 (0.64–0.9); *P*<0.001**	**589**	**0.73 (0.61–0.87); *P*<0.001**	**365**	**0.74 (0.59–0.94); *P*=0.012**

Note: Blue text indicates a significant improvement with SG vs TPC.

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Abbreviations

BC=breast cancer
CDK4/6i=cyclin-dependent kinase 4/6 inhibitor
CTCAE=Common Terminology Criteria for Adverse Events
EORTC QLQ-C30= European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire
EQ-VAS=EuroQol Visual Analog Scale
ET=endocrine therapy
GHS=global health status
HER2-=human epidermal growth factor receptor 2-negative
HR=hazard ratio
HR+=hormone receptor-positive
HRQoL=health-related quality of life
IHC=immunohistochemistry
ISH=in situ hybridization
mBC=metastatic breast cancer
PRO=patient-reported outcomes
QoL=quality of life
SG=sacituzumab govitecan-hziy
TTD=time to deterioration
TPC=treatment of physicians' choice

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:

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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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