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Trodelvy® (sacituzumab govitecan-hziy) Use in Older Patients With mBC

This document is in response to your request for information regarding the use of Trodelvy® (sacituzumab govitecan-hziy [SG]) in older patients (defined as ≥65 years of age) with metastatic breast cancer (mBC).

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]

Geriatric use as a single agent:

- Of the 641 patients with TNBC who were treated with SG in clinical studies, 20% of patients were ≥65 years and 5% were ≥75 years. No overall differences in effectiveness were observed between patients ≥65 years of age and younger adult patients. Patients ≥65 had an increased incidence of neutropenia with fatal outcomes.
- Of the 322 patients with HR+/HER2- breast cancer who were treated with SG, 26% of patients were ≥65 years and 6% were ≥75 years. No overall differences in effectiveness were observed between patients ≥65 years of age and younger patients. There was a higher discontinuation rate due to adverse reactions in patients aged ≥65 years (14%) compared with younger patients (3%).

Geriatric use in combination with pembro:

- Of the 221 patients with TNBC who were treated with SG in combination with pembro in ASCENT-04, 26% of patients were ≥65 years and 5% were ≥75 years. No overall differences in effectiveness were observed between patients ≥65 years of age and younger adult patients. There was a higher rate of serious adverse reactions in patients aged ≥65 years (31%) compared with younger adult patients (26%).

SG Clinical Data in Older Patients With mBC

Post hoc subgroup analyses of patients <65 y and ≥65 y, treated with SG 10 mg/kg IV on Days 1 and 8 of a 21-day cycle (unless noted otherwise), as monotherapy and in combination with pembro, are summarized.

Clinical Data of SG Monotherapy

Results from ASCENT, a study in 2L+ mTNBC,[2] showed that regardless of age, mPFS and mOS numerically favored SG vs TPC.[3]

- mPFS (HR [95% CI]) for SG and TPC, respectively, was 7.1 vs 2.4 mo (0.246 [0.141–0.428]) in patients ≥65 y (n=101), 4.2 vs 1.6 mo (0.45 [0.353–0.573]) in patients <65 y (n=428), and 4.8 vs 1.7 mo (0.414 [0.333–0.516]) in the ITT population (N=529). mOS (HR [95% CI]) for SG and TPC, respectively was 14.7 vs 8.9 mo (0.467 [0.292–0.749]) in patients ≥65 y, 10.8 vs 6.7 mo (0.535 [0.433–0.622]) in patients <65 y, and 11.8 vs 6.9 mo (0.526 [0.433–0.637]) in the ITT population.[2,3]
- Older patients in the SG arm had a slightly higher rate of Grade ≥3 TEAEs vs TPC (69 vs 63%). Patients ≥65 y experienced higher rates of TEAEs that led to dose reduction vs patients <65 y (37 vs 19%). The incidence of TEAEs leading to SG treatment discontinuation was 2% in older patients and 5% in the OSP and patients <65 y.[3] In older patients treated with SG vs TPC, the most common Grade ≥3 TEAEs were neutropenia (47 vs 40%) and anemia (14 vs 6%). Grade ≥3 diarrhea was reported by 12% of patients receiving SG, there were no reported cases with TPC.[3,4]

Results of a predefined subgroup analysis from ASCENT-03, an ongoing study in 1L PD-(L)1 inhibitor ineligible mTNBC, showed that mPFS numerically favored SG vs TPC; mPFS (HR [95% CI]) for SG vs TPC, respectively, was 11.1 vs 9 mo (0.91 [0.58–1.44]) in patients ≥65 y (n=143), 9.6 vs 5.7 mo (0.58 [0.45–0.74]) in patients <65 y (n=415), and 9.7 vs 6.9 mo (0.66 [0.53–0.82]) in the ITT population (N=558). Results for OS were immature at the time of the analysis. Safety has not been presented for subgroups.[5]

Results from TROPiCS-02, a study in pretreated HR+/HER2- mBC,[6] showed that regardless of age, mPFS and mOS numerically favored SG vs TPC.[7,8]

- mPFS (HR [95% CI]) for SG vs TPC, respectively, was 6.7 vs 3.5 mo (0.59 [0.38–0.93]) in patients ≥65 y (n=140), 5.5 vs 4.1 mo (0.69 [0.53–0.89]) in patients <65 y (n=403), and 5.5 vs 4 mo (0.66 [0.53–0.82]) in the ITT population (N=543). mPFS (HR [95% CI]) in patients ≥65 y with an SG RDI >90% was 6.7 vs 5.5 mo for SG RDIs ≤74 and >74 to ≤90%. mOS (HR [95% CI]) in the SG and TPC arms, respectively was 14.9 vs 10.1 mo (0.8 [0.54–1.19]) in patients ≥65 y, 14.1 vs 11.5 mo (0.81 [0.64–1.02]) in patients <65 y, and 14.4 vs 11.2 mo (0.79 [0.65–0.96]) in the ITT population.[6,8,9]
- Older patients in the SG arm had more TEAEs that led to dose reduction and treatment discontinuation vs TPC; 38 vs 28% and 17 vs 5%, respectively. TEAEs within the older SG subgroup led to dose reduction and treatment discontinuation more commonly vs the <65 y subgroup; 38 vs 32% and 17 vs 3%, respectively. Rates of Grade ≥3 TEAEs were similar across age subgroups but occurred at higher rates in patients treated with SG vs TPC; 73 vs 60% and 75 vs 61% in patients <65 and ≥65 y, respectively. In older patients treated with SG vs TPC, the most common Grade ≥3 TEAEs were neutropenia (44 vs 36%) and diarrhea (17 vs 2%).[8]

- ASCENT-07, an ongoing study in 1L post-ET HR+/HER2- mBC, did not meet its primary endpoint of PFS. Results of a predefined subgroup analysis showed that mPFS numerically favored SG vs TPC regardless of age. mPFS (HR [95% CI]) for SG vs TPC, respectively, was 9.7 vs 9.4 mo (0.88 [0.59–1.30]) in patients ≥65 y (n=180), 8.3 vs 8.2 mo (0.87 [0.68–1.1]) in patients <65 y (n=510), and 8.3 vs 8.3 mo (0.88 [0.72–1.08]) in the ITT population (N=690). OS results were immature at the time of the analysis. Safety has not been presented for subgroups.[10]

Clinical Data of SG in Combination With Pembro

- Results of a predefined subgroup analysis from ASCENT-04, an ongoing study in 1L PD-L1+ mTNBC, showed that mPFS numerically favored SG vs TPC. mPFS (HR [95% CI]) for SG vs TPC, respectively, was 11.1 vs 9.3 mo (0.85 [0.52–1.39]) in patients ≥65 y (n=115), 11.3 vs 7.5 mo (0.61 [0.45–0.82]) in patients <65 y (n=328), and 11.2 vs 7.8 mo

(0.66 [0.51–0.85]) in the ITT population (N=443). OS results were immature at the time of the analysis. Safety has not been presented for subgroups.[11,12]

Real World Data of SG in Older Patients With mBC

A retrospective mTNBC study (N=303), across 18 oncology centers in Poland, the Czech Republic and Slovakia reported outcomes for SG as monotherapy. mPFS (HR [95% CI]) for patients >65 vs ≤65 y, respectively, was 5.42 vs 4.07 mo (0.716 [0.534–0.960], *P*=0.026); mOS (HR [95% CI]) was 12.81 vs 10.91 mo (0.691 [0.485–0.985], *P*=0.041) respectively. AE-related dose reductions occurred in 46.1% of patients >65 y and 34.8% of patients ≤65 y (*P* =0.106).[13,14]

In a retrospective cohort study in patients with mBC treated with SG (N=97), no significant differences in survival outcomes were observed between patients aged <70 y (n=74) vs ≥70 y (n=23), with mPFS of 2.7 vs 2.8 (*P*=0.072) mo and mOS of 8.3 vs 7.8 mo (*P*=0.579). In addition, no significant difference in Grade 3 or 4 toxicity was observed according to age (<70 y: 14.9% vs ≥70 y: 26.1%; *P*=0.216). However, significantly more patients aged ≥70 y had SG dose reductions compared with those aged <70 y (52.2% vs 23%; *P*=0.008).[15]

In a multicenter, retrospective study in patients aged ≥70 y (n=84) treated with SG, mPFS (95% CI) was 4.1 (2.7–7.2) mo in patients with HR+/HER2- aBC (n=35) and 3.7 (2.1–4.7) mo in patients with TNBC (n=49); OS (95% CI) was 11.2 (7.7–NA) mo and 12.4 (8.5–13.9) mo, respectively. No new safety signals were identified. Dose reductions occurred in 40.5% of patients, whereas dose delays and discontinuation of SG occurred in 33% and 8.3% of patients, respectively.[16]

In an observational study of patients aged ≥65 years with aTNBC (N=69) treated with SG, rwPFS (95% CI) was 7.1 (5.7–8.8) mo, rwOS (95% CI) was 16.3 (13.1–NR) mo, with an ORR of 39.1%. No significant differences in rwPFS or rwOS were observed between participants stratified by age (65–69 y vs ≥70 y). In the overall population, any-grade and Grade 3 TRAEs occurred in 97.1% and 27.5% of patients, respectively. Grade 4 treatment-related neutropenia was reported in 4.3% of patients. When stratified by age, the most commonly reported TRAEs were similar in patients aged 65–69 y vs those aged ≥70 y and included neutropenia (42.9% vs 47.1%), anemia (42.9% vs 47.1%), diarrhea (37.1% vs 52.9%), and nausea (54.3% vs 35.3%). Two patients aged ≥70 years discontinued SG due to TRAEs.[17]

SG Clinical Data in Older Patients With mBC

Post hoc subgroup analyses of patients <65 y and ≥65 y, treated with SG 10 mg/kg IV on Days 1 and 8 of a 21-day cycle (unless noted otherwise) as monotherapy and combination therapy are summarized. The primary endpoint across all SG clinical studies in mBC was mPFS by BICR per RECIST v1.1.

Clinical Data of SG Monotherapy

ASCENT study in 2L+ mTNBC

An open-label, randomized, phase 3 study, compared the efficacy and safety of SG (n=267) vs TPC (n=262; eribulin, vinorelbine, capecitabine, or gemcitabine) in patients with refractory or relapsed mTNBC who had received ≥2 prior chemotherapies for unresectable, locally advanced, or metastatic disease. The primary endpoint was mPFS in patients without brain metastasis. In the ITT population, mPFS was 4.8 vs 1.7 mo (HR 0.43; 95% CI 0.35–

0.54), and mOS was 11.8 vs 6.9 mo (HR 0.51; 95% CI 0.41–0.62) with SG and TPC, respectively.[2]

Post Hoc Subgroup Analysis in Patients <65 and ≥65 Years

Approximately 19% of patients were ≥65 y, of these, 8 and 13 patients in the SG and TPC arms respectively, were ≥75 y. Most older patients vs patients <65 y were female (99 vs >99%) and White (85 vs 78%).[3,18] See Table 1 for select baseline demographics and characteristics.

Table 1. ASCENT: Select Baseline Demographics and Characteristics[3]

Select Demographics and Characteristics		ITT (N=529)	<65 y (n=428)	≥65 y (n=101)
Age, median (range), y		54 (27–82)	51 (27–64)	70 (65–82)
ECOG PS, n (%)	0/ 1	229 (43)/ 300 (57)	187 (44)/ 241 (56)	42 (42)/ 59 (58)
Prior anticancer regimen[a], median (range)		4 (2–17)	3 (1–16)	3 (1–10)
Prior chemotherapies, n (%)	2-3/ >3	365 (69)/ 164 (31)	300 (70)/ 128 (30)	65 (64)/ 36 (36)

[a]Refers to any prior metastatic/neoadjuvant/locally advanced regimens used to treat an eligible breast cancer patient. Prior therapy in the adjuvant setting is excluded from this count.

In general, disease characteristics were similar between patients <65 y and ≥65 y with some exceptions. Patients <65 y with known *BRCA* 1/2 status had a higher rate (61%) of negative germline BRCA mutations vs patients ≥65 y (35%). Generally, the most common prior regimens were used at higher frequencies in patients <65 vs ≥65 y, including anthracyclines (86 vs 67%, respectively) and cyclophosphamide (85 vs 73%), prior checkpoint inhibitors (30 vs 23%), and neoadjuvant systemic therapies (53 vs 24%).[3]

Efficacy results[3]

SG improved outcomes vs TPC in older patients. See Table 2 for outcomes by age.

Table 2. ASCENT: Efficacy in Patients <65 and ≥65 Years[3]

Outcomes	<65 y		≥65 y	
	SG (n=218)	TPC (n=210)	SG (n=49)	TPC (n=52)
mPFS by BICR (95% CI), mo	4.2 (3.2–5.5)	1.6 (1.5–2.5)	7.1 (4.9–8.4)	2.4 (1.5–2.9)
HR (95% CI)	0.45 (0.35–0.57)		0.25 (0.14–0.43)	
mOS (95% CI), mo	10.8 (9.5–13)	6.7 (5.4–7.5)	14.7 (12.2–22.5)	8.9 (6.2–10.2)
HR (95% CI)	0.54 (0.43–0.66)		0.47 (0.29–0.75)	
ORR, n (%)	61 (28)	11 (5)	22 (45)	0

Safety results

Within the OSP, patients who received ≥1 dose of study drug (n=482), older patients in the SG arm had a slightly higher rate of Grade ≥3 TEAEs vs TPC. Patients ≥65 y were more likely to undergo dose reduction due to TEAEs vs patients <65 y. The incidence of TEAEs leading to SG treatment discontinuation was 2% in older patients and 5% in the OSP. See Table 3 for further TEAEs in the OSP and in patients <65 and ≥65 y.[3]

Table 3. ASCENT: Safety Summary of the OSP and Patients <65 and ≥65 Years[3]

TEAE, n (%)	OSP		<65 y		≥65 y	
	SG (n=258)	TPC (n=224)	SG (n=209)	TPC (n=176)	SG (n=49)	TPC (n=48)
Any TEAE	257 (100)	219 (98)	208 (100)	171 (97)	49 (100)	48 (100)
Grade ≥3	188 (73)	145 (65)	154 (74)	115 (65)	34 (69)	30 (63)
Led to dose reduction	57 (22)	59 (26)	39 (19)	43 (24)	18 (37)	16 (33)

TEAE, n (%)	OSP		<65 y		≥65 y	
	SG (n=258)	TPC (n=224)	SG (n=209)	TPC (n=176)	SG (n=49)	TPC (n=48)
Led to dose interruption	162 (63)	87 (39)	137 (66)	66 (38)	25 (51)	21 (44)
Led to study drug discontinuation	12 (5)	12 (5)	11 (5)	11 (6)	1 (2)	1 (2)
Led to death	1 (0)	3 (1)	0	3 (2)	1 (2)	0
Any serious AE	69 (27)	64 (29)	57 (27)	47 (27)	12 (24)	17 (35)

In the OSP, the most common any grade TEAEs, in both treatment arms, included diarrhea (65%), neutropenia (64%), nausea (62%), and fatigue (52%). These were the most common any grade TEAEs in older patients; all occurred at a higher frequency with SG than TPC. The most common Grade ≥3 TEAEs for SG in the OSP were neutropenia (52%) and diarrhea (11%); these were the most common Grade ≥3 TEAEs in patients ≥65 y and occurred at a higher frequency than with TPC (Table 4).[3]

Table 4. ASCENT: TEAEs in Patients <65 and ≥65 Years[4]

TEAEs, n (%)[a]	<65 y				≥65 y			
	SG (n=209)		TPC (n=176)		SG (n=49)		TPC (n=48)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Neutropenia	136 (65)	112 (54)	77 (44)	57 (32)	29 (59)	23 (47)	21 (44)	19 (40)
Anemia	75 (36)	17 (8)	47 (27)	10 (6)	28 (57)	7 (14)	15 (31)	3 (6)
Diarrhea	132 (63)	24 (11)	29 (16)	2 (1)	36 (74)	6 (12)	9 (19)	0
Nausea	136 (65)	NR[b]	54 (31)	NR[b]	25 (51)	NR[b]	14 (29)	NR[b]
Constipation	78 (37)		43 (24)		18 (37)		9 (19)	
Fatigue	107 (51)		65 (37)		26 (53)		24 (50)	
Alopecia	103 (49)		28 (16)		18 (37)		8 (17)	

[a]Any grade and Grade ≥3 TEAEs occurring in ≥36% and ≥8% of patients treated with SG in either subgroup.
[b]Grade ≥3 AE not reported in ≥5% of patients in the SG arm or TPC arm.

ASCENT-03 study in 1L PD-(L)1 inhibitor ineligible mTNBC[5]

An ongoing, global, open-label, randomized, phase 3 study, compares the efficacy and safety of SG vs TPC (gemcitabine + carboplatin, paclitaxel, or nab-paclitaxel), as 1L treatment in patients with previously untreated, locally advanced, inoperable or mTNBC who are not candidates for PD-(L)1 inhibitor therapy. See Table 5 for select baseline demographics and characteristics.

Table 5. ASCENT-03: Select Baseline Demographics and Disease Characteristics[5]

Select Demographics and Characteristics		SG (n=279)	TPC (n=279)
Age, median (range), y		56 (28–84)	54 (23–86)
Age ≥65, n (%)		65 (23)	78 (28)
ECOG PS, n (%)	0/1	183 (66)/96 (34)	187 (67)/92 (33)
Prior (neo)adjuvant therapies, n (%)	Taxane	162 (58)	162 (58)
	Capecitabine	50 (18)	57 (20)
	Platinum agents	51 (18)	49 (18)
	PD-(L)1 inhibitors	13 (5)	11 (4)

In the ITT population, mPFS (95% CI) was 9.7 (8.1–11.1) vs 6.9 (5.6–8.2) mo (stratified HR 0.62 [95% CI 0.5–0.77] *P*<0.001) with SG and TPC, respectively; see Table 6 for results of a predefined subgroup analysis for PFS in older and younger patients. OS results were immature at the time of the primary analysis.

Table 6. ASCENT-03: Subgroup Analysis of PFS in Patients <65 and ≥65 Years[5]

Outcome	ITT		<65 y		≥65 y	
	SG (n=279)	TPC (n=279)	SG (n=214)	TPC (n=201)	SG (n=65)	TPC (n=78)
mPFS by BICR (95% CI), mo	9.7 (8.1–11.1)	6.9 (5.6–8.2)	9.6 (7.6–10.3)	5.7 (4.4–7)	11.1 (7.3–13.9)	9 (8.3–10)
Unstratified HR (95% CI)	0.66 (0.53–0.82)		0.58 (0.45–0.74)		0.91 (0.58–1.44)	

TROPiCS-02 study in pretreated HR+/HER2- mBC

An open-label, randomized, multicenter, phase 3 study, compared the efficacy and safety of SG (n=272) vs TPC (n=271; eribulin, vinorelbine, gemcitabine, capecitabine) in patients with HR+/HER2- mBC who were previously treated with ≥1 taxane, ≥1 endocrine therapy, and ≥1 CDK4/6i in any setting, and who had received ≥2 and ≤4 prior chemotherapy regimens for metastatic disease.[6]

In the ITT population, mPFS was 5.5 (4.2–7) vs 4 (3.1–4.4) mo (HR, 0.66; 95% CI 0.53–0.83; *P*=0.0003)[6] and mOS was 14.4 (13–15.7) vs 11.2 (10.1–12.7) mo (HR, 0.79; 95% CI 0.65–0.96; *P*=0.02) for SG and TPC, respectively.[9]

Post Hoc Subgroup analysis

Safety and efficacy was assessed in patients <65 vs ≥65 y[8] and <75 vs ≥75 y[7]; ≈26% (n=140) were ≥65 y, of those, 24 were ≥75 y. Most older patients were female (SG, 100%; TPC, 99%) and White (SG, 68%; TPC, 64% [race was not reported in 41 older patients]). Baseline characteristics were generally similar across treatments. A higher proportion of patients had an ECOG PS of 1 vs 0 in the ≥65 vs <65 y (Table 7) and the ≥75 vs <75 y subgroups, respectively.[7,8]

Table 7. TROPiCS-02: Select Demographics and Baseline Characteristics in Patients <65 and ≥65 Years[8]

Select Demographics and Characteristics		<65 y		≥65 y	
		SG (n=199)	TPC (n=204)	SG (n=73)	TPC (=67)
Age, median (range), y		53 (29–64)	52 (27–63)	71 (65–86)	69 (65–78)
ECOG PS 1, n (%)		107 (54)	100 (49)	50 (68)	45 (67)
Prior CDK4/6i use,[a] n (%)	≤12 mo	121 (61)	129 (63)	40 (55)	37 (55)
	>12 mo	74 (37)	72 (35)	32 (44)	30 (45)
Pre-existing comorbidities, n (%)	0	4 (2)	7 (3)	0	1 (1)
	1–3	48 (24)	44 (22)	8 (11)	12 (18)
	≥4	147 (74)	153 (75)	65 (89)	54 (81)

[a]Use was unknown in 7 patients <65 y and in 1 patient ≥65 y.

Efficacy results

Regardless of age, mPFS and mOS numerically favored SG vs TPC (Table 8).[7,8]

Table 8. TROPiCS-02: Efficacy According to Age Subgroup[7,8]

Outcome	<65 y		≥65 y		<75 y		≥75 y	
	SG (n=199)	TPC (n=204)	SG (n=73)	TPC (n=67)	SG (n=256)	TPC (n=263)	SG (n=16)	TPC (n=8)
mPFS by BICR (95% CI), mo	5.5 (4.1–6.9)	4.1 (3–4.4)	6.7 (4.2–9)	3.5 (1.7–5.6)	5.5 (4.1–6.9)	4 (3.1–4.4)	9 (3.8–NE)	5.5 (0.3–NE)
HR (95% CI)	0.69 (0.53–0.89)		0.59 (0.38–0.93)		0.7 (0.56–0.87)		0.3 (0.08–1.12)	

Outcome	<65 y		≥65 y		<75 y		≥75 y	
	SG (n=199)	TPC (n=204)	SG (n=73)	TPC (n=67)	SG (n=256)	TPC (n=263)	SG (n=16)	TPC (n=8)
mOS (95% CI), mo	14.1 (12.7–16.4)	11.5 (10.3–13.3)	14.9 (12–17.5)	10.1 (7.6–14.2)	14.6 (13–16)	11.2 (10.1–12.9)	12.3 (6.4–NE)	11.6 (5.6–NE)
HR (95% CI)	0.81 (0.64–1.02)		0.8 (0.54–1.19)		0.82 (0.67–1.01)		0.56 (0.2–1.56)	
ORR,[a] n (%)[b] or % (95% CI)[c]	42 (21)	28 (14)	15 (21)	10 (15)	21 (16–27)	14 (10–18)	19 (4–4.6)	25 (3–65)
Odds ratio (95% CI)	1.68 (1–2.84)		1.47 (0.61–3.55)		NR			

[a]Per BICR. [b]Refers to patients <65 and ≥65 y. [c]Refers to patients <75 and ≥75 y.

mPFS was numerically higher in older patients with an RDI (cumulative SG dose divided by total planned SG dose) of >90 vs ≤74% and >74 to ≤90% (Table 9).[8]

Table 9. TROPiCS-02: Efficacy by RDI in Patients <65 and ≥65 Years[8]

Outcome (95% CI), mo	<65 y			≥65 y		
	≤74% (n=60)	>74 to ≤90% (n=73)	>90% (n=61)	≤74% (n=28)	>74 to ≤90% (n=16)	>90% (n=27)
mPFS per BICR	2.9 (1.6–5.6)	4.7 (3.3–6.9)	8.5 (4.4–9.4)	5.5 (2.1–21)	5.5 (3.8–NE)	6.7 (2.4–9)
mOS	13 (11.4–15.3)	13.6 (11.7–18.4)	18.1 (12.8–19.8)	13.9 (8.1–20.6)	25.6 (5.3–NE)	15.4 (8.5–21.9)

SG had a longer TTD for fatigue in patients <65 y (Table 10) vs TPC. SG was also numerically favored vs TPC for median TTD for global health status/QoL in patients <65 and ≥65 y, and for median TTD for pain in patients ≥65 y.[8]

Table 10. TROPiCS-02: TTD of QoL in Patients <65 and ≥65 Years[8]

	<65 y		≥65 y	
	SG	TPC	SG	TPC
Global health status/QoL, median (95% CI), mo	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); *P*-value	0.81 (0.64–1.02); 0.066		0.71 (0.47–1.06); 0.094	
Fatigue, median (95% CI), mo	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); *P*-value	0.76 (0.61–0.96); 0.021		0.82 (0.55–1.22); 0.32	
Pain, median (95% CI), mo	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); *P*-value	1 (0.79–1.27); 0.97		0.73 (0.49–1.09); 0.12	

Safety results

Patients ≥65 y treated with SG, experienced more TEAEs that led to dose reduction and treatment discontinuation vs patients ≥65 y treated with TPC. TEAEs in the SG arm that led to dose reduction and treatment discontinuation were more common in patients ≥65 vs those <65 y. Grade ≥3 TEAEs and TEAEs that led to treatment interruptions occurred at higher rates in patients treated with SG vs TPC, and the rates of these TEAEs were similar across age subgroups (Table 11and Table 12).[8] In the ≥75 y subgroup, Grade ≥3 TEAEs were more common vs other subgroups, as were TEAEs that led to dose reductions, however, the small sample size for this subgroup limits interpretation.[7]

Table 11. TROPiCS-02: TEAEs According to Age Subgroup[7,8]

TEAEs, n, (%)	<65 y		≥65 y		<75 y		≥75 y	
	SG (n=196)	TPC (n=188)	SG (n=72)	TPC (n=61)	SG (n=252)	TPC (n=242)	SG (n=16)	TPC (n=7)
All	196 (100)	178 (95)	72 (100)	61 (100)	252 (100)	232 (96)	16 (100)	7 (100)
Grade ≥3	144 (73)	113 (60)	54 (75)	37 (61)	179 (71)	145 (60)	13 (81)	5 (71)
Led to dose reduction	63 (32)	65 (35)	27 (38)	17 (28)	82 (33)	80 (33)	8 (50)	2 (29)
Led to treatment interruption	129 (66)	82 (44)	49 (68)	27 (44)	NR			
Led to treatment discontinuation	5 (3)	8 (4)	12 (17)	3 (5)	15 (6)	10 (4)	2 (13)	1 (14)

Table 12. TROPiCS-02: Most Common TEAEs in Patients <65 and ≥65 Years[8]

TEAEs, n, (%)	<65 y				≥65 y			
	SG (n=196)		TPC (n=188)		SG (n=72)		TPC (n=61)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Neutropenia	142 (72)	106 (54)	106 (56)	75 (40)	47 (65)	32 (44)	30 (49)	22 (36)
Nausea	117 (60)	2 (1)	69 (37)	6 (3)	40 (56)	1 (1)	18 (30)	1 (2)
Diarrhea	112 (57)	15 (8)	40 (21)	2 (1)	54 (75)	12 (17)	17 (28)	1 (2)
Alopecia	98 (50)	0	31 (16)	0	30 (42)	0	15 (25)	0
Fatigue	78 (40)	8 (4)	59 (31)	7 (4)	27 (38)	8 (11)	23 (38)	2 (3)
Constipation	72 (37)	1 (1)	45 (24)	0	21 (29)	0	16 (26)	0
Anemia	70 (36)	12 (6)	51 (27)	8 (4)	28 (39)	8 (11)	18 (30)	1 (2)

TEAEs occurring in ≥30% of patients in either treatment arm within either age subgroup.

ASCENT-07 study in 1L post-ET in HR+/HER2- mBC[10]

An ongoing, global, randomized, open-label, phase 3 study, compares the efficacy and safety of SG vs TPC (capecitabine, paclitaxel, or nab-paclitaxel) in patients with HR+/HER2- (IHC 0, IHC 1+, IHC 2+/ISH-) locally advanced, inoperable, or mBC who have received prior ET and are candidates for first chemotherapy. See Table 13 for select demographics and characteristics, including prior therapies.

Table 13. ASCENT-07: Select Baseline Demographics and Disease Characteristics[10]

Select Demographics and Characteristics		SG (n=456)	TPC (n=234)
Age, median (range), y		57 (29–88)	58 (27–80)
Age ≥65 y, n (%)		106 (23)	74 (32)
ECOG PS, n (%)	0/1	269 (59)/ 187 (41)	145 (62)/ 89 (38)
Prior therapies in the metastatic setting			
Number of lines, median (range)		2 (0–8)	2 (0–4)
Lines of ET, n (%)	None	8 (2)	1 (<1)
	1	122 (27)	63 (27)
	2	263 (58)	139 (59)
	≥3	63 (14)	31 (13)
Previous endocrine-based therapies,[a] n (%)	ET with CDK4/6i	416 (91)	216 (92)
	1L ET with CDK4/6i ≤6 mo	74 (16)	35 (15)
	ET monotherapy	182 (40)	95 (41)
	ET with other targeted therapy[b]	160 (35)	74 (32)
Prior therapies in the (neo)adjuvant setting[a,c], n (%)			
ET (monotherapy and combination therapy)		295 (65)	158 (68)

Select Demographics and Characteristics	SG (n=456)	TPC (n=234)
ET with CDK4/6i	17 (4)	8 (3)
Chemotherapy	260 (57)	140 (60)
Taxane	211 (46)	115 (49)
Anthracycline	217 (48)	118 (50)
Prior CDK4/6i use in metastatic setting, n (%)		
None	32 (7)	19 (8)
≤12 mo	197 (43)	98 (42)
>12 mo	227 (50)	117 (50)

[a]Therapies reported are not mutually exclusive.
[b]Other targeted therapies in the SG and TPC groups included everolimus (25 and 22%), alpelisib (5 and 3%), and olaparib (2 and 3%).
[c]Some patients had unknown adjuvant therapy history.

The study did not meet its primary endpoint; mPFS (95% CI) in the ITT population was 8.3 mo (8.1–10.3) for SG vs 8.3 mo (6.9–10) for TPC; HR 0.85 (95% CI 0.69–1.05), *P*=0.13. See Table 14 for results of a predefined subgroup analysis of PFS in older and younger patients. OS results were immature at the time of the primary analysis.

Table 14. ASCENT-07: Subgroup Analysis of PFS in Patients <65 and ≥65 Years[10]

Outcome	ITT		<65 y		≥65 y	
	SG (n=456)	TPC (n=234)	SG (n=350)	TPC (n=160)	SG (n=106)	TPC (n=74)
mPFS by BICR (95% CI), mo	8.3	8.3	8.3	8.2	9.7	9.4
Unstratified HR (95% CI)	0.88 (0.72–1.08)		0.87 (0.68–1.10)		0.88 (0.59–1.30)	

Clinical Data of SG in Combination With Pembro

ASCENT-04 Study in 1L PD-L1+ mTNBC

An ongoing, global, open-label, randomized, phase 3 study, is comparing the efficacy and safety of SG + pembro vs TPC (gemcitabine + carboplatin, paclitaxel, or nab-paclitaxel) + pembro, as 1L treatment in patients with PD-L1+ (combined positive score ≥10), inoperable, locally advanced or mTNBC. See Table 15 for select demographics and characteristics.

Table 15. ASCENT-04: Select Baseline Demographics and Disease Characteristics[12]

Select Demographics and Characteristics		SG + Pembro (n=221)	TPC + Pembro (n=222)
Age, median (range), y		54 (23–88)	55 (27–82)
≥65 y, n (%)		58 (26)	57 (26)
ECOG PS, n (%)	0/1	156 (71)/65 (29)	154 (69)/67 (30)
Chemotherapy received during study, n (%)	Taxane	-	113 (51)
	Gem + carbo	-	107 (49)
Prior anti-PD-(L)1 therapy,[a] n (%)		9 (4)	11 (5)

[a]While 20 patients were included in the stratified subgroup of prior exposure to anti-PD-(L)1 therapy (yes) per the interactive response technology system, only 6 patients received prior treatment with anti-PD-(L)1 agents per the clinical database (3 in each treatment group).

In the ITT population, SG + pembro prolonged mPFS (95% CI) vs TPC + pembro (11.2 vs 7.8 mo; stratified HR, 0.65; 95% CI: 0.51–0.84; *P*<0.001). See Table 16 for results of a predefined subgroup analysis for PFS in older vs younger patients. OS results were immature at the time of the primary analysis.

Table 16. ASCENT-04: Subgroup Analysis of PFS in Patients <65 and ≥65 Years[12]

Outcome	ITT		<65 y		≥65 y	
	SG (n=221)	TPC (n=222)	SG (n=163)	TPC (n=165)	SG (n=58)	TPC (n=57)
mPFS by BICR (95% CI), mo	11.2 (9.3–16.7)	7.8 (7.3–9.3)	11.3 (9.3–16.8)	7.5 (7–9.2)	11.1 (7.5–NR)	9.3 (7.3–13.2)
Unstratified HR (95% CI)	0.66 (0.51–0.85)		0.61 (0.45–0.82)		0.85 (0.52–1.39)	

Abbreviation: NR=not reached.

Real-World Data of SG in Older Patients

A retrospective, real-world study (N=303), across 18 oncology centers in Poland, the Czech Republic and Slovakia reviewed outcomes for SG as monotherapy in older vs younger women with mTNBC. A total of 25.1% were older patients; see Table 17 for select demographics and characteristics.[13,14]

Table 17. Select Baseline Demographics and Disease Characteristics[13,14]

Select Demographics and Characteristics	≤65 y	>65 y	*P*-Value
	SG (n=227)	SG (n=76)	
Age, median (range), y	52 (27–64)	70 (65–84)	-
ECOG PS			0.026
0/1/2-3, n (%)	103 (45.4)/116 (51.1)/7 (3.1)	22 (28.9)/50 (65.8)/4 (5.3)	
Number of prior palliative systemic therapies			0.039
Mean (SD)	1.7 (±1.1)	1.9 (±1.2)	
Median (range)	1 (1–2)	2 (1–2)	

Abbreviation: SD=standard deviation

A reduced starting dose of SG ≤8 mg/kg at cycle 1 day 1 was administered in 13.2 and 7.5% of older and younger patients, respectively (*P*=0.204).[14] The median number of full SG cycles was similar across age groups (*P*=0.240).[13] See Table 18 for results of efficacy outcomes.

Table 18. Efficacy Outcomes in Patients ≤65 and >65 Years[13,14]

Outcomes	≤65 y	>65 y	HR (95% CI)	*P*-value
	SG (n=227)	SG (n=76)		
mPFS, mo	4.07	5.42	0.716 (0.534–0.96)	0.026
mOS, mo	10.91	12.81	0.691 (0.485–0.985)	0.041
ORR, %	30.8	30.3	-	1
DCR, %	61.7	72.4	-	0.122
CBR ≥ 6 mo, %	22.3	32.4	-	0.13
mDOR, %, mo	4.8	3.7	-	0.101

Abbreviations: CBR=clinical benefit rate; DCR=disease control rate; mDOR=median duration of response.

AE-related dose reductions occurred in 46.1% of patients >65 y and 34.8% of patients ≤65 y (*P*=0.106).[14]

Retrospective cohort study in mBC[15]

A retrospective, cohort study in France (N=97) evaluated the effectiveness and safety of SG in patients with mBC (TNBC: n=63 [65%] and HR+ mBC: n=34 [35%]) and sought to identify significant predictors of treatment outcomes, including age <70 y vs ≥70 y. In the overall population, the median age was 60 y; 74 patients (76%) were aged <70 y and 23 (24%) were aged ≥70 y. Overall, 74% of patients had an ECOG PS of 0 or 1, and 26% had an

ECOG PS ≥2. The median (range) number of previous lines of therapy for metastatic disease was 3 (0–12), and the median (range) number of SG cycles administered was 3 (1–28).

No significant differences in survival outcomes were observed between patients aged <70 y vs ≥70 y, with mPFS of 2.7 vs 2.8 mo (*P*=0.072) and mOS of 8.3 vs 7.8 mo (*P*=0.579). Similarly, no significant differences in survival outcomes were observed between patients aged <70 y vs ≥70 y on multivariate analysis for PFS (HR, 0.98; 95% CI: 0.57–1.68; *P*=0.939) or OS (HR, 0.83; 95% CI: 0.39–1.76; *P*=0.622).

No significant difference in Grade 3 or 4 toxicity was observed according to age (<70 y: 14.9% vs ≥70 y: 26.1%; *P*=0.216). However, SG dose reductions were significantly more frequent in patients aged ≥70 y (52.2%) than in those aged <70 y (23%; *P*=0.008).

S-GOLD: multicenter, retrospective study in aBC[16]

A multicenter, retrospective study in France evaluated the effectiveness and safety of SG in patients ≥70 y (n=84) with aBC (HR+/HER2- or TNBC). See Table 19 for select demographics and characteristics.

Table 19. Select Baseline Demographics and Disease Characteristics[16]

Select Demographics and Characteristics		SG (N=84)	
		HR+/HER2- (n=35)	TNBC (n=49)
Age, median (Q1, Q3), y		75 (73–76)	74 (72–76)
ECOG PS, 0/1/≥2, n (%)		1 (3)/23 (79)/5 (17)	7 (15)/31 (67)/8 (17)
HER2 status, 0/low, n (%)		27 (79)/7 (20.9)	33 (67)/16 (32)
Metastatic sites, n (%)	Visceral metastases	25 (71)	37 (76)
	CNS metastases	4 (11)	6 (13)
	Bone-only disease	4 (11)	2 (4)
Most frequent comorbidities, n (%)	Hypertension	10 (29)	16 (33)
	Hypothyroidism	6 (17)	7 (14)
	Dyslipidemia	6 (17)	6 (12)
	Chronic renal disease	3 (9)	7 (14)
Number of prior lines of therapy, median (range)[a]		5 (1–10)	2 (1–8)
Total SG cycles, mean (Q1–Q3), n		5.5 (3–10)	6 (3–9)
G-CSF prophylaxis, n (%)		32 (100)	34 (89)

Abbreviations: G-CSF=granulocyte colony-stimulating factor; Q=quartile.
[a]*P*<0.001 for significance between groups.

Effectiveness results

The median follow-up was 12.4 mo. Overall, 52 patients (61.9%) received a starting dose of SG 10 mg/kg, whereas 28 patients (33.3%) and 4 patients (4.8%) received starting doses of 7.5 mg/kg and 5 mg/kg, respectively. See Table 20 for results of effectiveness outcomes.

Table 20. Effectiveness Outcomes[16]

Outcomes	SG (N=84)	
	HR+/HER2- (n=35)	TNBC (n=49)
mPFS, (95% CI), mo	4.1 (2.7–7.2)	3.7 (2.1–4.7)
OS, (95% CI), mo	11.2 (7.7–NA)	12.4 (8.5–13.9)

Outcomes		SG (N=84)	
		HR+/HER2- (n=35)	TNBC (n=49)
Best overall response, n (%)	PD	14 (41)	18 (41)
	SD	11 (32)	11 (25)
	PR	9 (26)	13 (30)
	CR	-	2 (5)

Abbreviations: CR=complete response; PR=partial response; NA=not available.

Safety results

No new safety signals were identified. Dose reductions occurred in 40.5% of patients, whereas dose delays and SG discontinuations occurred in 33.3% and 8.3% of patients, respectively. Safety outcomes for the overall population are presented in Table 21.

Table 21. Safety Outcomes[16]

AEs, %	SG (N=84)				
	Any Grade	Grade 1	Grade 2	Grade 3	Grade ≥4
Asthenia	92	51	34	6	-
Anemia	68	31	32	5	-
Diarrhea	43	26	13	4	-
Neutropenia	43	6	7	19	11
Nausea	39	29	11	-	-
Anorexia	38	29	10	-	-
Constipation	32	27	5	-	-
Alopecia	27	27	-	-	-
Thrombocytopenia	17	7	8	-	1
Febrile neutropenia	10	-	-	8	1
Vomiting	7	7	-	-	-
Colitis	6	-	5	1	-

Observational study in aTNBC[17]

An observational study in Italy evaluated the effectiveness and safety of SG in patients aged ≥65 y with aTNBC (N=69). Efficacy and safety outcomes were assessed according to RECIST v1.1 and the National Cancer Institute Common Terminology Criteria for Adverse Events v5.0, respectively. A descriptive subgroup analysis comparing patients aged 65–69 y (n=35; 50.7%) and ≥70 y (n=34; 49.3%) was also performed. See Table 22 for select demographics and characteristics.

Table 22. Select Baseline Demographics and Disease Characteristics[17]

Select Demographics and Characteristics	SG (N=69)
Age, median (range), y	70 (65–85)
ECOG PS, 0/1/2/unknown (%)	34 (49.3)/33 (47.8)/1 (1.4)/1 (1.4)
TNBC at initial diagnosis, yes/no/unknown, n (%)	34 (49.3)/33 (47.8)/2 (2.9)
HER2-low at initial diagnosis, yes/no/unknown, n (%)	20 (29)/48 (69.6)/1 (1.4)
Number of metastatic sites, 1/2/≥3, n (%)	10 (14.5)/27 (39.1)/32 (46.4)
Number of prior regimens for metastatic disease, median (range)	2 (1–10)
Lines of therapy with SG, 2/≥3, n (%)	16 (23.2)/ 53 (76.8)
Previous use of PD-(L)1 inhibitors, yes/no, n (%)	38 (55.1)/ 31 (44.9)

Effectiveness results

Eighteen patients initiated SG at a reduced dose, including 8.7% of patients aged 65 to 69 y and 17.4% of those aged ≥70 y. RDI at treatment initiation was 95% in patients aged 65 to 69 y and 85% in those aged ≥70 y, which decreased to 77% and 63%, respectively, during treatment. Median follow-up was 19.6 mo. See Table 23 for effectiveness outcomes in the overall population.

Table 23. Effectiveness Outcomes[17a]

Outcomes	SG (N=69)
rwPFS, (95% CI), mo	7.1 (5.7–8.8)
rwOS, (95% CI), mo	16.3 (13.1–NR)
ORR, %	39.1
SD, %	31.9
PD, %	26.1

Abbreviation: NR=not reached.
[a]Response outcomes were not evaluable in 2.9% of patients.

No significant differences were observed in subgroups of evaluable patients aged 65–69 y (n=28) vs those aged ≥70 y (n=27) for rwPFS (HR, 1.18; 95% CI: 0.59–2.34; *P*=0.6) or rwOS (HR, 0.82; 95% CI: 0.34–1.94; *P*=0.644).

Safety results

TRAEs in the overall population are summarized in Table 24. When stratified by age, the most commonly reported TRAEs were similar in patients aged 65–69 y vs those aged ≥70 y and included neutropenia (42.9% vs 47.1%), anemia (42.9% vs 47.1%), diarrhea (37.1% vs 52.9%), and nausea (54.3% vs 35.3%). In the overall population, Grade 4 treatment-related neutropenia was reported in 3 patients (4.3%), no other Grade 4 AEs were reported. Two patients aged ≥70 y discontinued SG due to TRAEs.

Table 24. Summary of TRAEs[17]

TRAEs, n (%)		SG (N=69)	
		Any Grade	Grade 3
Any TRAEs		67 (97.1)	19 (27.5)
Hematologic events	Neutropenia	31 (44.9)	12 (17.4)
	Anemia	31 (44.9)	0
	Thrombocytopenia	4 (5.8)	0
Gastrointestinal events	Diarrhea	31 (44.9)	4 (5.8)
	Nausea	31 (44.9)	0
	Mucositis	6 (8.7)	0
	Vomiting	3 (4.3)	0
	Constipation	2 (2.9)	0
	Epigastric pain	2 (2.9)	0
Investigations	ALT/AST increased	4 (5.8)	2 (2.9)
	Bilirubin increased	2 (2.9)	0
General disorders and administration site conditions	Alopecia	41 (59.4)	1 (1.4)
	Asthenia	16 (23.2)	1 (1.4)
	Fatigue	2 (2.9)	0
	Dizziness	1 (1.4)	0
Neuropathy		1 (1.4)	0

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Abbreviations

aBC=advanced breast cancer
AE=adverse event
aTNBC=advanced triple-negative breast cancer
BICR=blinded independent central review
BRCA=breast cancer gene
CDK4/6i=cyclin-dependent kinase 4/6 inhibitor
ECOG PS=Eastern Cooperative Oncology Group performance status
ET=endocrine therapy
HR=hazard ratio
HR+=hormone receptor-positive
HER2-=human epidermal growth factor receptor 2-negative
IHC=immunohistochemical
ISH=in situ
mBC=metastatic breast cancer
mTNBC=metastatic triple-negative breast cancer
NE=not estimable
NR=not reported
ORR=objective response rate
OSP=overall safety population
PD=progressive disease
PD-(L)1=programmed death (ligand) 1
pembro=pembrolizumab
QoL=quality of life
RECIST=Response Evaluation Criteria in Solid Tumors
RDI=relative dose intensity
rwPFS=real-world progression-free survival
rwOS=real-world overall survival
SD=stable disease
SG=sacituzumab govitecan-hziy
TEAE=treatment-emergent adverse event
TNBC=triple-negative breast cancer
TRAE=treatment-related adverse event
TPC=treatment of physician's choice
TTD=time to deterioration

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