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Trodelvy® (sacituzumab govitecan-hziy) Second-Line and Later Use in Patients With mNSCLC

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and its use in the second-line and later (2L+) setting in patients with metastatic non-small cell lung cancer (mNSCLC).

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Trodelvy is not indicated for use in patients with mNSCLC. 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

EVOKE-01 Study: 2L+ Treatment[1]

EVOKE-01 is a phase 3 study evaluating the efficacy and safety of SG vs docetaxel in 603 patients with advanced or mNSCLC, who have progressed on or after PLT-based chemotherapy, anti-PD-(L)1, and targeted treatment for AGAs.

- In the ITT population (SG, n=299; docetaxel, n=304), median OS with SG was 11.1 months vs 9.8 with docetaxel (HR 0.84; 95% CI 0.68–1.04; *P*=0.0534) and the median PFS was 4.1 months vs 3.9 with docetaxel (HR 0.92; 95% CI 0.77–1.11).
- In the ITT population, the ORR with SG was 13.7% vs 18.1% with docetaxel.
- The most common Grade ≥3 TEAEs in the SG group vs docetaxel included neutropenia (24.7% vs 36.8%), leukopenia (5.1% vs 17.4%), and fatigue (12.5% vs 9.7), respectively.
- TEAEs leading to treatment discontinuations were seen in 9.8% in the SG group and 16.7% in the docetaxel group.
- Multiple subgroup analyses have been performed and results are described below.

IMMU-132-01 Study: 2L+ Treatment

IMMU-132-01, a phase 1/2 study investigated the efficacy and safety of SG in patients with metastatic epithelial cancers, including mNSCLC, who had progressed on ≥1 prior therapy for metastatic disease.[2,3]

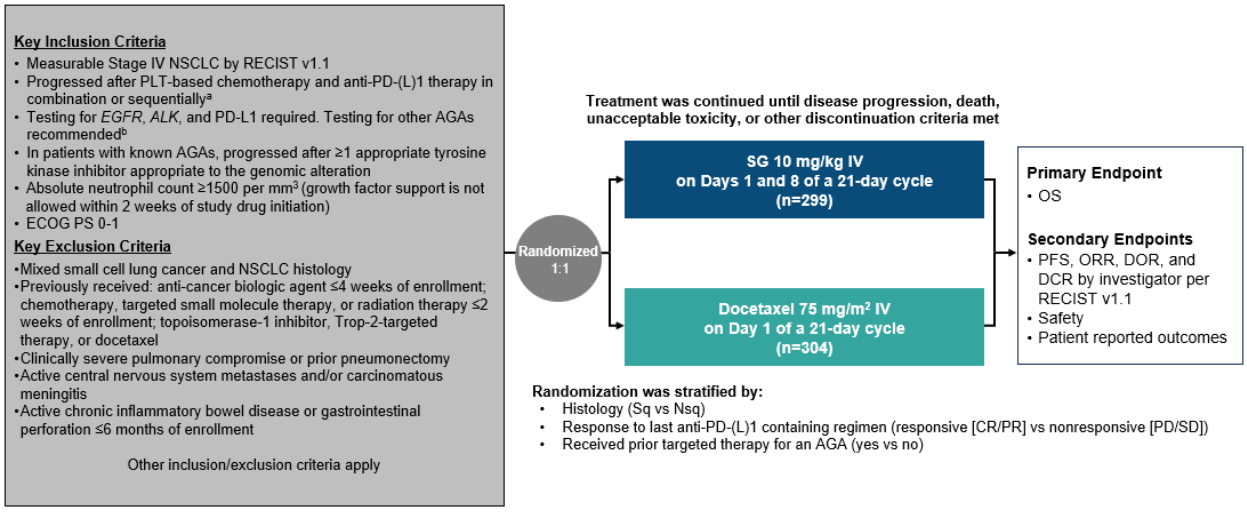
- The ORR was 19% in the response-assessable mNSCLC population (n=47) and 17% in the mNSCLC ITT population (n=54).[3]
- In the mNSCLC ITT population, the median PFS and median OS were 5.2 months and 9.5 months, respectively.[3]
- Grade ≥3 AEs that occurred in ≥5% patients included neutropenia, leukopenia, pneumonia, diarrhea, nausea, and fatigue.[3]

EVOKE-01 Study: 2L+ Treatment

Study Design and Demographics

EVOKE-01 is an open-label, global, multicenter, randomized, phase 3 study evaluating the efficacy and safety of SG vs docetaxel in 603 patients with advanced or mNSCLC, who progressed on or after PLT-based chemotherapy, anti-PD-(L)1, and targeted treatment for AGAs.[1]

Figure 1. EVOKE-01 Study Design[1,4]



Abbreviations: NSCLC=non-small cell lung cancer; RECIST=Response Evaluation Criteria in Solid Tumours
[a](Neo)adjuvant therapy counted if progression within 6 months of PLT treatment and while on maintenance with CPI agent; [b]To be performed as per local standard of care and availability of targeted treatment.

The demographics and baseline characteristics are shown in Table 1.[1]

Table 1. EVOKE-01: Demographics and Baseline Characteristics[1]

Characteristic		SG (n=299)	Docetaxel (n=304)
Age, median (range), years		66 (31–84)	64 (32–83)
<65 years, n (%)		136 (45.5)	161 (53)
Male, n (%)		194 (64.9)	216 (71.1)
Race or ethnic group, n (%)	White	229 (76.6)	216 (71.1)
	Black	6 (2)	7 (2.3)
	Asian	17 (5.7)	26 (8.6)
	Other[a]/not specified	47 (15.7)	55 (18.1)
ECOG PS,[b] n (%)	0	101 (33.8)	89 (29.3)
	1	198 (66.2)	212 (69.7)
Histology, n (%)	Nsq[c]	215 (71.9)	224 (73.7)
	Sq	84 (28.1)	80 (26.3)
Stage at diagnosis,[d] n (%)	I-III	76 (25.4)	102 (33.6)
	IV	219 (73.2)	202 (66.4)
Patients with brain metastasis, n (%)		35 (11.7)	39 (12.8)
Previous lines of therapy, n (%)	1	167 (55.9)	167 (54.9)
	2	103 (34.4)	101 (33.2)
	≥3	29 (9.7)	36 (11.8)
Best response to last anti–PD-(L)1–containing regimen,[e] n (%)	Responder (CR/PR)	106 (35.5)	113 (37.2)
	Nonresponder (SD/PD)	192 (64.2)	191 (62.8)
Previous therapy for AGA,[f] n (%)	Yes	19 (6.4)	25 (8.2)
	EGFR alteration	6 (2)	13 (4.3)
	ALK alteration	1 (0.3)	1 (0.3)

[a]Other races included American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, and other.
[b]In docetaxel group scores were missing for 2 patients and score was 2 for 1 patient on cycle 1, day 1.
[c]Histologies not otherwise specified were included in the nsq subgroup.
[d]Missing for 4 patients.
[e]Response was investigator assessed and unavailable for 1 patient in SG group.
[f]Patients with multiple types of AGA were counted once for each type.

In the statistical testing hierarchy, OS (primary endpoint) was formally tested for significance first. If the significance boundary (1 sided $P \leq 0.0223$) was reached for the primary endpoint, the secondary endpoints would be tested in this order: PFS, ORR, and TTD in the shortness of breath domain and total score in NSCLC-SAQ.

Efficacy

The median (range) follow-up was 12.7 (6–24) months and the median (range) duration of exposure for SG was 3.45 (0.03–18.69) months and 2.33 (0.03–19.75) months for docetaxel.[1]

Table 2. EVOKE-01: Efficacy Results (ITT population)[1]

Endpoints	SG (n=299)	Docetaxel (n=304)
OS, median (95% CI), mo	11.1 (9.4–12.3)	9.8 (8.1–10.6)
HR (95% CI); one-sided *P*-value	0.84 (0.68–1.04); 0.0534	
12-month OS rate, % (95% CI)	46.59 (40.45–52.5)	36.72 (30.88–42.57)
PFS, median (95% CI), mo	4.1 (3–4.4)	3.9 (3.1–4.2)
HR[a] (95% CI)	0.92 (0.77–1.11)	
6-month PFS, % (95% CI)	33.71 (28.21–39.28)	31.39 (25.75–37.17)
ORR (BOR of confirmed CR + PR),[b] n (%) [95% CI]	41 (13.7) [10–18.1]	55 (18.1) [13.9–22.9]
CR, n (%)	0	3 (1)

Endpoints	SG (n=299)	Docetaxel (n=304)
PR, n (%)	41 (13.7)	52 (17.1)
SD, n (%)	161 (53.8)	149 (49)
PD, n (%)	66 (22.1)	64 (21.1)
Not evaluable, n (%)	31 (10.4)	36 (11.8)
DOR,[c] median (95% CI), mo	6.7 (4.4–9.8)	5.8 (4.1–8.3)
6-month DOR, % (95% CI)	52.5 (35.6–66.9)	46.5 (31.9–59.8)
DCR (confirmed CR + PR + SD),[c,d] n (%) [95% CI]	202 (67.6) [61.9–72.8]	204 (67.1) [61.5–72.4]

[a]Investigator-assessed.
[b]Patients without tumor assessment (SG, n=28; docetaxel, n=35).
[c]Evaluated in patients with confirmed CR and PR.
[d]Based on Kaplan-Meier estimates.

In the ITT population, 37.8% of patients in the SG group received subsequent anticancer therapy (most commonly docetaxel) and 31.3% of patients in the docetaxel group received subsequent anticancer therapy (most commonly single-agent gemcitabine or vinorelbine).[1]

OS and PFS across prespecified subgroups were consistent with the ITT population and select subgroup results are shown in Table 3. In the subgroups of patients by best response to last anti-PD-(L)1 containing regimens, baseline characteristics, demographics, and use of subsequent therapy were similar between groups.[1,5]

Table 3. EVOKE-01: OS and PFS by Select Subgroups[1,5]

Endpoints		SG	Docetaxel	HR (95% CI)
Histology				
OS, median (95% CI), mo	Sq (n=164)	10.2 (8.1–12.7)	9.2 (6.9–11)	0.83 (0.56–1.22)
	Nsq (n=439)	11.3 (9.4–12.6)	9.9 (7.8–10.8)	0.87 (0.68–1.11)
PFS, median (95% CI), mo	Sq (n=164)	3.8 (2.8–5.4)	3.9 (2.7–5.4)	0.94 (0.67–1.32)
	Nsq (n=439)	4.1 (2.9–5.3)	4 (3.1–4.2)	0.93 (0.75–1.15)
Best response to last anti-PD-(L)1 containing regimen				
OS, median (95% CI), mo	Nonresponder (PD/SD)	n=192 11.8 (9.6–12.5)	n=191 8.3 (7–10.6)	0.75 (0.58–0.97)
	Responder (CR/PR)	n=106 9.6 (8.1–14.4)	n=113 10.6 (8.9–12.8)	1.09 (0.76–1.56)
PFS, median (95% CI), mo	Nonresponder (PD/SD)	n=192 4.2 (3–5.3)	n=191 3.7 (2.9–4.2)	0.88 (0.7–1.1)
	Responder (CR/PR)	n=106 3.9 (2.8–5.4)	n=113 4.2 (2.9–5.5)	1 (0.74–1.36)
Race				
OS, median (95% CI), mo	White (n=445)	10.7 (8.9–12.2)	8.9 (7.3–10.6)	0.87 (0.68–1.1)
	Non-White (n=65)	12 (12.9–NR)	11.2 (9.3–15.3)	0.41 (0.15–1.13)
PFS, median (95% CI), mo	White (n=445)	4.1 (2.9–4.4)	3.8 (2.9–4.2)	0.89 (0.72–1.11)
	Non-White (n=65)	5.7 (4–8.1)	5.4 (3.3–9.3)	1.08 (0.59–1.97)
Baseline ECOG status				
OS, median (95% CI), mo	0 (n=190)	12.9 (10–NR)	13.6 (10.4–NR)	1.06 (0.7–1.6)
	1 (n=410)	9.6 (8.1–11.9)	7.6 (6.8–9.8)	0.81 (0.64–1.04)
PFS, median (95% CI), mo	0 (n=190)	5.4 (3.1–6.1)	5.7 (4.2–7)	1.23 (0.88–1.72)
	1 (n=410)	3.5 (2.8–4.2)	2.9 (2.8–4)	0.83 (0.67–1.03)
Received previous therapy for AGA				
OS, median (95% CI), mo	No (n=559)	11 (9.2–12.3)	9.9 (8.1–10.7)	0.89 (0.72–1.11)
	Yes (n=44)	NR (7.2–NR)	7 (5.2–11.6)	0.52 (0.22–1.23)
PFS, median (95% CI), mo	No (n=559)	4.2 (3-5)	4 (3.1–4.7)	0.92 (0.76–1.11)
	Yes (n=44)	2.8 (1.4–4.3)	3.3 (2.8–4)	1.06 (0.54–2.1)

In the subgroup of patients that did not respond to their last anti-PD-(L)1-containing regimen, OS results across nonsquamous (median OS 11.8 months for SG vs 8.4 months for docetaxel; HR, 0.79 [95% CI, 0.59-1.07]) and squamous (median OS 10.7 months for SG vs 7.9 months for docetaxel; HR, 0.62 [95% CI, 0.38-1.02]) histologies were consistent.[1]

Patient-reported outcomes

Patient-reported symptoms were secondary and exploratory endpoints.[1,6]

The NSCLC-SAQ total score, which represents the sum of all five symptom-domain scores at each visit, ranges from 0 to 20, and each symptom is rated verbally on a 5-point scale. TTD was defined as the time from randomization to a 1-point (shortness-of-breath domain) or 2-point (total score) worsening from baseline.[1,5] Additional secondary and exploratory PRO endpoints included time to confirmed deterioration. This was defined as a meaningful deterioration, from baseline, confirmed at the following scheduled visit or by a death within 21 days after onset of deterioration. For each EORTC QLQ-C30 domain, the meaningfulness of within-patient changes was interpreted based on published thresholds.[6]

Patients completed questionnaires on day 1 of each cycle before dosing and at the end of treatment. Baseline PRO scores were comparable between arms but worse compared with the general population for EORTC QLQ-C30 domains. PRO completion rates were high (>85%) for most visits and comparable in both arms.[6]

Median TTD for the NSCLC-SAQ shortness of breath domain was 2.8 months in the SG group vs 2.1 months in the docetaxel group (HR 0.75; 95% CI 0.61–0.91). Median TTD for the NSCLC-SAQ total score was 3.1 months in the SG group vs 2.7 months in the docetaxel group (HR 0.8; 95% CI 0.66–0.97).[1,6]

Compared with docetaxel, treatment with SG delayed time to first meaningful deterioration or death for NSCLC-SAQ fatigue (HR 0.7; 95% CI 0.57–0.86), and EORTC QLQ-C30 fatigue (HR 0.8; 95% CI, 0.66–0.96) and dyspnea (HR 0.74; 95% CI 0.6–0.9). Compared with SG, docetaxel numerically delayed time to first meaningful deterioration or death for NSCLC-SAQ appetite (HR 1.03; 95% CI 0.85–1.26) and EORTC QLQ-C30 nausea/vomiting (HR 1.12; 95% CI 0.91–1.37), constipation (HR 1.07; 95% CI 0.86–1.31) and diarrhea (HR 1.2; 95% CI 0.99–1.45).[6]

Median time to confirmed deterioration in NSCLC-SAQ shortness of breath domain was 8.9 months in the SG group vs 3.52 months in the docetaxel group (HR 0.59; 95% CI 0.44–0.77). Median time to confirmed deterioration in the NSCLC-SAQ total score was 8.87 months in the SG group vs 5.88 months in the docetaxel group (HR 0.8; 95% CI 0.6–1.05). Compared with docetaxel, treatment with SG delayed time to confirmed deterioration from baseline in NSCLC-SAQ fatigue (HR 0.7; 95% CI 0.52–0.95), and EORTC QLQ-C30 fatigue (HR 0.75; 95% CI 0.59–0.95). Numerical improvements with docetaxel versus SG were observed for EORTC QLQ-C30 cognitive functioning (HR 1.11; 95% CI 0.84-1.46), nausea/vomiting (HR 1.02; 95% CI 0.76-1.38), constipation (HR 1.08; 95% CI 0.79-1.48), and diarrhea (HR 1.14; 95% CI 0.87-1.5).[6]

LS mean changes from baseline at week 25 were compared between arms. Select results, where differences exceeded the between-group MID thresholds or nominal *P*-values were presented, can be found in Table 4. All *P*-values presented for between group differences are nominal.[6]

Table 4. EVOKE-01: Select LS Mean Changes in PRO Scores From Baseline at Week 25[6]

PRO Domain	LS Mean Change From Baseline (95% CI)		Difference in LS Mean Change (95% CI)	MID
	SG	Docetaxel		
NSCLC-SAQ				
Total score	-0.61 (-1.15 to -0.07)	0.78 (0.14 to 1.42)	-1.39[c,d] (-2.21 to -0.57)	±1.2[a]
Shortness of breath	-0.05 (-0.21 to 0.12)	0.39 (0.20 to 0.59)	-0.44[c,d] (-0.69 to -0.19)	±0.4[a]
Fatigue	-0.12 (-0.27 to 0.04)	0.28 (0.10 to 0.45)	-0.39[c,d] (-0.62 to -0.16)	±0.3[a]
EORTC QLQ-C30				
Summary score	-0.09 (-2.46 to 2.27)	-4.93 (-7.57 to -2.29)	4.84[c] (1.38 to 8.29)	±5[a]
Role functioning	-2.3 (-6.94 to 2.33)	-14.43 (-19.69 to -9.17)	12.13[c,d] (5.28 to 18.98)	±6[b]
Fatigue	-0.18 (-3.94 to 3.57)	9.01 (4.72 to 13.31)	-9.2[c,d] (-14.78 to -3.61)	±5[b]
Dyspnea	-2.29 (-6.87 to 2.29)	10.44 (5.18 to 15.69)	-12.72[c,d] (-19.55 to -5.9)	±4[b]
Appetite loss	-4.87 (-10.11 to 0.37)	0.23 (-5.69 to 6.15)	-5.1[d] (-12.86 to 2.67)	±5[b]
Financial difficulties	3.94 (0.23 to 7.65)	7.03 (2.9 to 11.16)	-3.09[d] (-8.48 to 2.29)	±3[b]

[a]Based on 0.3 times standard deviation of the baseline score for each domain.
[b]Based on published thresholds.
[c]Nominal *P*<0.01 for between-group differences.
[d]Differences exceeding the between-group MID thresholds.

Safety[1]

In the safety analysis set (all treated patients; SG, n=296; docetaxel, n=288), any-grade TEAEs occurred in 99.7% of the SG group and 97.9% of docetaxel group and Grade ≥3 TEAEs occurred in 66.6% of the SG group and 75.7% of docetaxel group. The most common Grade ≥3 TEAEs in the SG group vs docetaxel included neutropenia (24.7% vs 36.8%), leukopenia (5.1% vs 17.4%), and fatigue (12.5% vs 9.7%), respectively (Table 5).

Table 5. EVOKE-01: TEAEs in ≥20% of Patients in Either Group[1]

TEAEs, n (%)	SG (n=296)		Docetaxel (n=288)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Fatigue	168 (56.8)	37 (12.5)	161 (55.9)	28 (9.7)
Diarrhea	156 (52.7)	31 (10.5)	97 (33.7)	11 (3.8)
Alopecia	128 (43.2)	2 (0.7)	86 (29.9)	2 (0.7)
Nausea	123 (41.6)	5 (1.7)	75 (26)	3 (1)
Anemia	119 (40.2)	19 (6.4)	89 (30.9)	17 (5.9)
Neutropenia	111 (37.5)	73 (24.7)	123 (42.7)	106 (36.8)
Constipation	86 (29.1)	0	49 (17)	1 (0.3)
Decreased appetite	78 (26.4)	7 (2.4)	69 (24)	6 (2.1)
Vomiting	62 (20.9)	7 (2.4)	43 (14.9)	6 (2.1)
Stomatitis	39 (13.2)	3 (1)	58 (20.1)	7 (2.4)
Leukopenia	38 (12.8)	15 (5.1)	63 (21.9)	50 (17.4)

AEs leading to treatment discontinuations, interruptions, and dose reductions are summarized in Table 6. Seven deaths from TEAEs were considered treatment-related and

included 4 in the SG group (febrile neutropenia, neutropenic colitis, sepsis, and septic shock [1 each]) and 3 in the docetaxel group (unknown, pneumonia, and pneumonitis [1 each]).

Table 6. EVOKE-01: TEAEs Summary[1]

TEAEs, n (%)	SG (n=296)	Docetaxel (n=288)
TEAEs that led to treatment discontinuations	29 (9.8)	48 (16.7)
Treatment-related[a]	20 (6.8)	41 (14.2)
TEAEs that led to dose reductions	87 (29.4)	112 (38.9)
TEAEs leading to treatment interruption	171 (57.8)	81 (28.1)
TEAEs that led to death	10 (3.4)	13 (4.5)

[a]Determined by investigator.

Subgroup Analysis in Patients Non-Responsive to Last Anti-PD-(L)1 Containing Regimen[7]

Efficacy and safety were evaluated in a prespecified subgroup analysis of 383 patients that did not respond (SD/PD) to their last anti-PD-(L)1 containing regimen. Baseline characteristics and prior therapies (Table 7) were well balanced between treatment groups and consistent with those of the ITT population.

Table 7. EVOKE-01 Subgroup Analysis: Prior Anti-PD-(L)1 Therapy and Response[7]

Characteristic	ITT (N=603)		Non-responsive (SD/PD) (n=383)	
	SG (n=299)[a]	Docetaxel (n=304)	SG (n=192)	Docetaxel (n=191)
Received anti-PD-(L)1 as most recent prior therapy, n (%)	247 (82.6)	261 (85.9)	161 (83.9)	165 (86.4)
Monotherapy Combined with chemotherapy Combined with another type of therapy	44 (14.7) 201 (67.2) 2 (0.7)	54 (17.8) 201 (66.1) 6 (2)	38 (19.8) 121 (63) 2 (1)	36 (18.8) 126 (66) 3 (1.6)
Did not receive anti-PD-(L)1 as most recent prior therapy, n (%)	51 (17.1)	43 (14.1)	31 (16.1)	26 (13.6)
Treatment duration of the last anti-PD-(L)1-containing regimen, median, mo	6.2	7	5.6	5.8

[a]One patient did not have data available on their response to a prior anti-PD-(L)1 containing regimen.

Efficacy

Median OS was 11.8 (95% CI 9.6–12.5) months in the SG group and 8.3 (95% CI 7–10.6) months in the docetaxel group (HR 0.75; 95% CI 0.58–0.97). Median PFS was 4.2 (95% CI 3–5.3) months in the SG group and 3.7 (95% CI 2.9–4.2) months in the docetaxel group (HR 0.88; 95% CI 0.70–1.10).

OS was reported by best response (SD or PD) to last anti-PD-(L)1-containing regimen, histology, and duration of response to last anti-PD-(L)1 containing regimen (Table 8).

Table 8. EVOKE-01 Subgroup Analysis: OS by Subgroups[7]

Endpoints		SG	Docetaxel	HR (95% CI)
Histology				
OS, median (95% CI), mo	Nsq	n=142 11.8 (9.4–12.6)	n=145 8.4 (7–11.2)	0.79 (0.59–1.07)

Endpoints		SG	Docetaxel	HR (95% CI)
	Sq	n=50 10.7 (6.9–16)	n=46 7.9 (5.3–10.2)	0.62 (0.38–1.02)
Best response to last anti-PD-(L)1 containing regimen				
OS, median (95% CI), mo	Nonresponder (SD)	n=98 12.5 (7.9–NR)	n=115 9.9 (7.4–11.7)	0.79 (0.55–1.13)
	Nonresponder (PD)	n=94 10.8 (9.4–12.2)	n=76 7 (5.3–10)	0.67 (0.46–0.98)
Duration of response to last anti-PD-(L)1 containing regimen[a]				
OS, median (95% CI), mo	Primary resistance[b]	n=141 10.3 (7.9–11.8)	n=125 7.6 (5.9–9.8)	0.79 (0.59–1.07)
	Secondary resistance[c]	n=51 NR (11.9–NR)	n=66 10.7 (7.4–13.6)	0.55 (0.32–0.96)

[a]Resistance per Society of Immunotherapy of Cancer (SITC)-based criteria for immune-checkpoint inhibitor combinations.
[b]Patients with PD or SD (<6 months on treatment).
[c]Patients with SD (≥6 months on treatment).

Safety

Rates of Grade ≥3 TEAEs and TEAEs leading to dose reductions or discontinuations were lower with SG than with docetaxel, consistent with the ITT population (Table 9).

Table 9. EVOKE-01 Subgroup Analysis: Overall Safety Summary[7]

TEAEs[a]	SG (n=189)	Docetaxel (n=182)
Any grade	189 (100)	177 (97.3)
Grade ≥3	128 (67.7)	132 (72.5)
Serious	92 (48.7)	78 (42.9)
Leading to dose reduction	58 (30.7)	60 (33)
Leading to discontinuation	16 (8.5)	24 (13.2)
Leading to death[b]	5 (2.6)	7 (3.8)

[a]Safety-evaluable patients
[b]As determined by the investigator and included cerebrovascular accident, febrile neutropenia, hematemesis, neutropenic colitis, and sepsis (1 each) in the SG arm; and death (n=4), pneumonia (n=2), and pneumonitis (n=1) in the docetaxel arm.

IMMU-132-01 Study: 2L+ Treatment

Study Design and Demographics

IMMU-132-01, a phase 1/2, single-arm, multicenter, open-label basket study in adult patients (N=495) with metastatic epithelial cancer, included 54 patients (10.9%) with mNSCLC who had progressed after ≥1 previous treatment.[2,3] In the mNSCLC cohort, patients received SG 8 mg/kg (n=8), or 10 mg/kg (n=46) IV on Days 1 and 8 of a 21-day treatment cycle, and continued until disease progression or unacceptable toxicity. Patients received a median of 5 SG cycles, over a median (range) duration of 3.3 (0.5–27.3) months. Median (range) age was 64 (40–86) years, 56% of patients were male, and 45 (83%) and 9 (17%) patients had Nsq and Sq histology, respectively. Patients received a median (range) of 3 (2–7) prior lines of therapy for metastatic disease.[3]

Efficacy[3]

ORR in the protocol-specified response-assessable population, and additional efficacy outcomes are shown in Table 10. In the ITT population, the ORR was 17% (9/54); in these 9 patients, median (range) time to tumor response was 3.8 (1.8–11.6) months, and median (95% CI) DOR was 6 (4.8–8.3) months, with 2 responses ongoing at time of publication.

Table 10. IMMU-132-01 (mNSCLC Cohort): Efficacy Results[3]

Responses		All Evaluable Patients (n=47)	Patients Previously Treated With CPIs (n=14)
BOR, n (%)	PR	9 (19)	2 (14)
	SD	23 (49)	7 (50)
	PD	15 (32)[a]	5 (36)
DOR, median (95% CI), months		6 (4.8–8.3)	N/A
CBR (PR + SD for ≥4 months), n (%)		20 (43)	5 (36)
PFS,[b,c] median (95% CI), months		5.2 (3.2–7.1)[e]	5.2 (2–5.5)
OS,[b,d] median (95% CI), months		9.5 (5.9–16.7)[e]	14.6 (5.9–14.6)

Abbreviations: CBR=clinical benefit rate; CPI=checkpoint inhibitor; PD=progressive disease.
[a]PD was noted at the first CT assessment for 13 patients and without CT assessment for 2 patients.
[b]Kaplan-Meier estimates of PFS and OS were assessed in the ITT population.
[c]Five patients were undergoing follow-up (PFS was >7.3 months for each).
[d]Twenty patients were surviving at the time of publication.
[e]Results were available for 54 patients.

Safety[3]

All-grade and Grade ≥3 AEs are shown in Table 11. Febrile neutropenia occurred in 2 patients (4%). Eight patients received cytokine support for Grade ≥3 neutropenia. Dose reductions, due to neutropenia, were required by 23 patients (43%); 3 of these patients required additional dose reductions. Although an antidiarrheal protocol was not used in this study, premedication was permitted if clinically indicated; 4 patients received atropine for diarrhea prevention. SG discontinuations due to AEs occurred in 1 patient due to Grade 3 pneumonia and in a second patient due to Grade 3 recurrent pruritus.

Table 11. IMMU-132-01 (mNSCLC Cohort): All-Grade (≥25%) and Grade ≥3 AEs (≥5%)[3]

AEs, n (%)	All Grades			Grade ≥3		
	Overall (N=54)	8 mg/kg (n=8)	10 mg/kg (n=46)	Overall (N=54)	8 mg/kg (n=8)	10 mg/kg (n=46)
Nausea	43 (80)	7 (88)	36 (78)	4 (7)	0	4 (9)
Diarrhea	33 (61)	5 (63)	28 (61)	4 (7)	1 (13)	3 (7)
Fatigue	25 (46)	3 (38)	22 (48)	3 (6)	0	3 (7)
Alopecia	21 (39)	3 (38)	18 (39)	N/A	N/A	N/A
Neutropenia	20 (37)	2 (25)	18 (39)	15 (28)	1 (13)	14 (30)
Vomiting	19 (35)	4 (50)	15 (33)	2 (4)	1 (13)	1 (2)
Anemia	17 (31)	1 (13)	16 (35)	2 (4)	0	2 (4)
Constipation	17 (31)	3 (38)	14 (30)	0	0	0
Anorexia	13 (28)	0	13 (28)	1 (2)	0	1 (2)
Leukopenia	10 (19)	2 (25)	8 (17)	5 (9)	1 (13)	4 (9)
Dyspnea	8 (15)	2 (25)	6 (13)	2 (4)	1 (13)	1 (2)

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Abbreviations

2L+=second-line and later
AE=adverse event
AGA=actionable genomic alteration
ALK= anaplastic lymphoma kinase
BOR=best overall response
CR=complete response
DCR=disease control rate
DOR=duration of response
ECOG PS=Eastern Cooperative Oncology Group performance status
EGFR=epidermal growth factor receptor
EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30
LS=least squares
MID=minimal important difference
mNSCLC=metastatic non-small cell lung cancer
NR=not reached
NSCLC-SAQ=Non-Small Cell Lung Cancer Symptom Assessment Questionnaire
Nsq=nonsquamous
ORR=objective response rate
OS=overall survival
PD=progressive disease
PD-(L)1=programmed cell death-(ligand)1
PFS=progression-free survival
PLT=platinum
PR=partial response
PRO=patient reported outcome
SD=stable disease
SG=sacituzumab govitecan
Sq=squamous
TEAE=treatment-related adverse event
TTD=time to deterioration

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