Supplementary Table 1. Tumor response per investigator assessment

	Group 3 Cemiplimab 350 mg IV Q3W (n=56)	Group 1 Cemiplimab 3 mg/kg IV Q2W (n=59)	Total (Groups 1 + 3) (n=115)
ORR, % (95% CI)	51.8 (38.0–65.3)	49.2 (35.9–62.5)	50.4 (41.0–59.9)
Best overall response, n (%)			
Complete response	3 (5.4)	4 (6.8)	7 (6.1)
Partial response	26 (46.4)	25 (42.4)	51 (44.3)
Stable disease	11 (19.6)	14 (23.7)	25 (21.7)
Progressive disease	12 (21.4)	11 (18.6)	23 (20.0)
Not evaluable	4 (7.1)	5 (8.5)	9 (7.8)
Disease control rate (95% CI)	71.4 (57.8–82.7)	72.9 (59.7–83.6)	72.2 (63.0–80.1)
Durable disease control rate*, % (95% CI)	60.7 (46.8–73.5)	64.4 (50.9–76.4)	62.6 (53.1–71.5).
Median time to response, months (range)	2.1 (1.4–10.3)	1.9 (1.7–9.2)	2.1 (1.4–10.3)
Kaplan–Meier 8-month estimate of DOR (95% CI)†	100 (Not evaluable)	92.9 (74.3–98.2)	95.4 (82.5–98.8)
Kaplan–Meier 12-month estimate of DOR (95% CI)†	Not evaluable	89.0 (69.6–96.3)	86.0 (69.0–94.0)

CI, confidence interval; DOR, duration of response; IV, intravenous; ORR, objective response rate; Q2W, every 2 weeks; Q3W, every 3 weeks.

*Stable disease or response lasting ≥16 weeks.

†Percentages are based on number of patients with confirmed complete or partial response.

6 **Supplementary Table 2. Treatment-related adverse events reported in ≥5% of patients in either treatment group**

	Group 3 Cemiplimab 350 mg IV Q3W (n=56)		Group 1 Cemiplimab 3 mg/kg IV Q2W (n=59)		Total (Groups 1 + 3) (n=115)	
Adverse event	**Any Grade**	**Grade ≥3**	**Any Grade**	**Grade ≥3**	**Any Grade**	**Grade ≥3**
Any	36 (64.3)	7 (12.5)	46 (78.0)	9 (15.3)	82 (71.3)	16 (13.9)
Fatigue	6 (10.7)	1 (1.8)	9 (15.3)	0 (0.0)	15 (13.0)	1 (0.9)
Maculopapular rash	5 (8.9)	1 (1.8)	8 (13.6)	0 (0.0)	13 (11.3)	1 (0.9)
Rash	7 (12.5)	0 (0.0)	6 (10.2)	0 (0.0)	13 (11.3)	0 (0.0)
Hypothyroidism	6 (10.7)	0 (0.0)	6 (10.2)	0 (0.0)	12 (10.4)	0 (0.0)
Diarrhea	4 (7.1)	0 (0.0)	7 (11.9)	1 (1.7)	11 (9.6)	1 (0.9)
Nausea	4 (7.1)	0 (0.0)	6 (10.2)	0 (0.0)	10 (8.7)	0 (0.0)
Pneumonitis	2 (3.6)	0 (0.0)	6 (10.2)	3 (5.1)	8 (7.0)	3 (2.6)
Pruritus	2 (3.6)	0 (0.0)	6 (10.2)	0 (0.0)	8 (7.0)	0 (0.0)
Cough	1 (1.8)	0 (0.0)	5 (8.5)	0 (0.0)	6 (5.2)	0 (0.0)

Alanine aminotransferase increased	1 (1.8)	0 (0.0)	4 (6.8)	0 (0.0)	5 (4.3)	0 (0.0)
Aspartate aminotransferase increased	3 (5.4%)	0 (0.0)	2 (3.4%)	0 (0.0)	5 (4.3)	0 (0.0)
Decreased appetite	0	0 (0.0)	5 (8.5)	0 (0.0)	5 (4.3)	0 (0.0)
Dry mouth	1 (1.8)	0 (0.0)	4 (6.8)	0 (0.0)	5 (4.3)	0 (0.0)
Dysgeusia	1 (1.8)	0 (0.0)	4 (6.8)	0 (0.0)	5 (4.3)	0 (0.0)
Arthralgia	1 (1.8)	0 (0.0)	3 (5.1)	0 (0.0)	4 (3.5)	0 (0.0)
Dry skin	0 (0.0)	0 (0.0)	4 (6.8)	0 (0.0)	4 (3.5)	0 (0.0)
Dizziness	0 (0.0)	0 (0.0)	3 (5.1)	0 (0.0)	3 (2.6)	0 (0.0)
Vomiting	3 (5.4)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.6)	0 (0.0)

7 IV, intravenous; Q2W, every 2 weeks; Q3W, every 3 weeks.

8 Data are number of patients (%).

Supplementary Table 3. Immune-related adverse events reported in ≥5% of patients in either treatment group (per investigator assessment)

	Group 3 Cemiplimab 350 mg IV Q3W (n=56)		Group 1 Cemiplimab 3 mg/kg IV Q2W (n=59)		Total (Groups 1 + 3) (n=115)	
	Any Grade	**Grade ≥3**	**Any Grade**	**Grade ≥3**	**Any Grade**	**Grade ≥3**
Overall immune-related adverse events	32 (57.1)	7 (12.5)	40 (67.8)	8 (13.6)	72 (62.6)	15 (13.0)
Maculopapular rash	5 (8.9)	1 (1.8)	8 (13.6)	0 (0.0)	13 (11.3)	1 (0.9)
Rash	7 (12.5)	0 (0.0)	6 (10.2)	0 (0.0)	13 (11.3)	0 (0.0)
Hypothyroidism	6 (10.7)	0 (0.0)	6 (10.2)	0 (0.0)	12 (10.4)	0 (0.0)
Diarrhea	3 (5.4)	0 (0.0)	6 (10.2)	1 (1.7)	9 (7.8)	1 (0.9)
Pneumonitis	2 (3.6)	0 (0.0)	6 (10.2)	3 (5.1)	8 (7.0)	3 (2.6)
Fatigue	2 (3.6%)	1 (1.8%)	5 (8.5%)	0 (0.0)	7 (6.1)	1 (0.9)
Nausea	3 (5.4)	0 (0.0)	3 (5.1)	0 (0.0)	6 (5.2)	0 (0.0)

Pruritus	0 (0.0)	0 (0.0)	6 (10.2)	0 (0.0)	6 (5.2)	0 (0.0)
Arthralgia	1 (1.8)	0 (0.0)	3 (5.1)	0 (0.0)	4 (3.5)	0 (0.0)
Blood creatinine increased	3 (5.4)	0 (0.0)	1 (1.7)	0 (0.0)	4 (3.5)	0 (0.0)
Cough	1 (1.8)	0 (0.0)	3 (5.1)	0 (0.0)	4 (3.5)	0 (0.0)
Alanine aminotransferase increased	0 (0.0)	0 (0.0)	3 (5.1)	0 (0.0)	3 (2.6)	0 (0.0)
Dry skin	0 (0.0)	0 (0.0)	3 (5.1)	0 (0.0)	3 (2.6)	0 (0.0)
Dysgeusia	0 (0.0)	0 (0.0)	3 (5.1)	0 (0.0)	3 (2.6)	0 (0.0)

IV, intravenous; Q2W, every 2 weeks; Q3W, every 3 weeks.

Data are number of patients (%).

Supplementary Table 4. Efficacy for CSCC patients treated at 350 mg IV Q3W (Group 3 study 1540) with high body weight (>120 kg)

Weight on Cycle 1/Day 1 (kg)	Number of doses of cemiplimab received	Best overall response	DOR (months)
125.0	17	PR	4.17
145.0	3	PD	
150.4	2*	PD	
171.6	15	PR	6.24†

CSCC, cutaneous squamous cell carcinoma; DOR, duration of response; IV, intravenous; PD, progressive disease; PR, partial response; Q3W, every 3 weeks.

*Reason for treatment discontinuation was worsening of psoriasis.

†Response ongoing at the time of data cut-off.