

SUPPLEMENTARY MATERIAL

Health-Related Quality of Life With Pembrolizumab in Patients With Locally Advanced or Recurrent or Metastatic Cutaneous Squamous Cell Carcinoma: KEYNOTE-629

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Supplementary Material Table 1: List of independent ethics committees (*IECs*) and independent review boards (*IRBs*)

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^a If the original investigator has been replaced, that investigator's name is followed by a slash (/) and the replacement investigator's name.

Supplementary Material Table 2: Baseline characteristics of patients with LA cSCC in the HRQoL population

	EORTC QLQ-C30 and EQ-5D-5L
	<i>n</i> = 47
Age, median (range), y	75.0 (35–95)
≥65	36 (77)
Sex	
Male	35 (74)
Female	12 (26)
Region	
European Union	24 (51)
North America	12 (26)
Rest of world	11 (23)
ECOG PS	
0	18 (38)
1	29 (62)
PD-L1 CPS	
≥1	40 (85)
<1	4 (9)
Missing	3 (6)
Overall cancer staging	
II	7 (15)
III	23 (49)
IV	17 (36)
Primary tumor staging	
T1	2 (4)
T2	12 (26)
T3	24 (51)
T4	8 (17)
TX	1 (2)

Nodal involvement staging	
N0	34 (72)
N1	3 (6)
N2a	1 (2)
N2b	3 (6)
N2c	1 (2)
N3	5 (11)
Metastasis staging	
M0	47 (100)
M1	0
Disease status	
Locally advanced	47 (100)
Presence of ulceration	
Yes	21 (45)
No	26 (55)
Presence of synchronous primary lesion	
Yes	9 (19)
No	36 (77)
Unknown	2 (4)
Prior radiation therapy	33 (70)
Prior systemic therapy for curative intent	12 (26)

Data are *n* (%) unless otherwise specified.

CPS, combined positive score; *cSCC*, cutaneous squamous cell carcinoma; *ECOG PS*, Eastern Cooperative Oncology Group Performance Status; *EORTC QLQ-C30*, EORTC Quality of Life Questionnaire Core 30; *HRQoL*, health-related quality of life; *LA*, locally advanced; *PD-L1*, programmed death ligand 1.

Supplementary Material Table 3: Proportion of patients in total HRQoL population, including LA and R/M cohorts, with improved, stable, or deteriorated^a EORTC QLQ-C30 GHS/QoL and physical functioning scores relative to baseline

	Overall		Responders (CR or PR) ^{c,d}		Non-responders (SD or PD) ^c	
	<i>n</i>	% (95% CI) ^b	<i>n</i>	% (95% CI) ^b	<i>n</i>	% (95% CI) ^b
Total HRQoL Population	146		64		84	
GHS/QoL						
Not deteriorated ^e	107	73.3 (65.3–80.3)	57	89.1 (78.8–95.5)	50	59.5 (48.3–70.1)
Improved	49	33.6 (26.0–41.8)	35	54.7 (41.7–67.2)	14	16.7 (9.4–26.4)
Stable	58	39.7 (31.7–48.1)	22	34.4 (22.9–47.3)	36	42.9 (32.1–54.1)
Deteriorated	39	26.7 (19.7–34.7)	5	7.8 (2.6–17.3)	34	40.5 (29.9–51.7)
Physical functioning						
Not deteriorated ^e	99	67.8 (59.6–75.3)	54	84.4 (73.1–92.2)	45	53.6 (42.4–64.5)
Improved	25	17.1 (11.4–24.2)	18	28.1 (17.6–40.8)	7	8.3 3.4–16.4)
Stable	74	50.7 (42.3–59.0)	36	56.3 (43.3–68.6)	38	45.2 (34.3–56.5)
Deteriorated	47	32.3 (24.7–40.4)	8	12.5 (5.6–23.2)	39	46.4 (35.5–57.6)

^aOverall improvement was defined as a ≥ 10 -point increase in score from baseline at any time during the trial with confirmation at the next visit[19]. For patients who did not achieve improved HRQoL scores, stable scores were defined as any of the following: improvement (a ≥ 10 -point increase in score) confirmed by a < 10 -point change in score at the next visit, < 10 -point change in score confirmed by a < 10 -point change at the next visit, or a < 10 -point change in score confirmed by an improvement at the next visit.

Deterioration was defined as a ≥ 10 -point decrease in score from baseline at any time during the trial for patients without improved or stable scores.

^bBased on the exact method for binomial data.

^cResponse per Response Evaluation Criteria in Solid Tumors, version 1.1, by blinded independent central review.

^dResponse was not evaluable in 2 patients.

^eIncludes improved + stable scores.

CI, confidence interval; *CR*, complete response; *ECOG PS*, Eastern Cooperative Oncology Group Performance Status; *EORTC QLQ-C30*, EORTC Quality of Life Questionnaire Core 30; *GHS/QoL*, global health status/quality of life; *HRQoL*, health-related quality of life; *LA*, locally advanced; *PD*, progressive disease; *PD-L1*, programmed death ligand 1; *PR*, partial response; *R/M*, recurrent/metastatic; *SD*, stable disease.