Integrated analysis of a phase 2 study of cemiplimab in advanced cutaneous squamous cell carcinoma: extended follow-up of outcomes and quality of life analysis

Objective: To provide pooled longer-term data from three groups of a phase 2 study of cemiplimab 3 mg/kg intravenously (IV) every 2 weeks (Q2W) or 350 mg IV every 3 weeks (Q3W) in patients with locally advanced (la) or metastatic (m) cutaneous squamous cell carcinoma (CSCC), and to determine duration of response (DOR) and impact on quality of life (QoL).

Cemiplimab
3 mg/kg Q2W IV
for up to 96 weeks
(Group 1; Group 2)

mCSCC n=59 **laCSCC** n=78

Cemiplimab
350 mg Q3W IV
for up to 54 weeks
(Group 3)

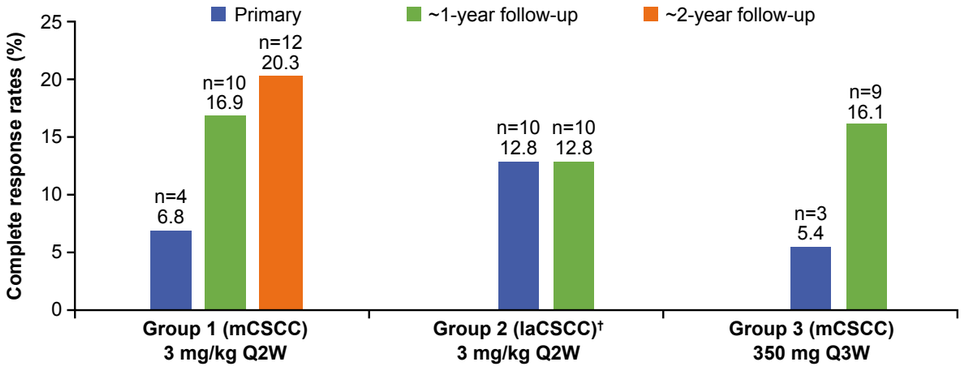
mCSCC n=56

Clinicaltrials.gov: NCT02760498

46.1%

Objective response rate
per independent central review
Median duration of follow-up: 15.7 months

Complete response rates per independent central review

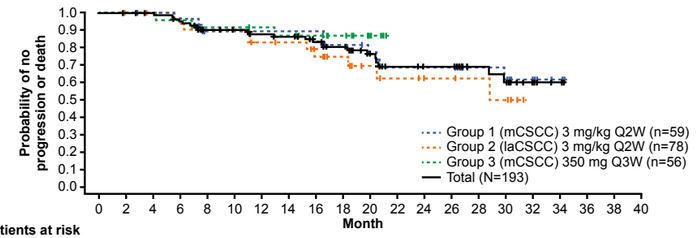


†At the time of the Group 1 primary analysis, a pre-specified Group 2 interim analysis was performed. Among the 23 laCSCC patients included in this pre-specified interim analysis, there were no complete responses.

Median DOR not reached; estimated percentage of patients who remained in response at 12 months was **87.8%**

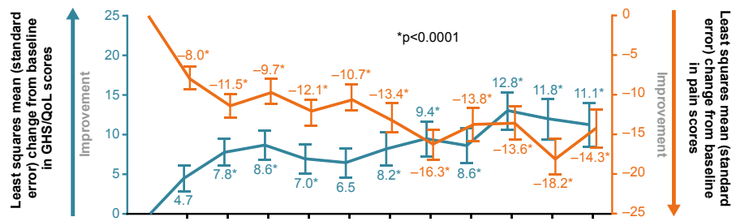
87.8%

Kaplan–Meier curves for DOR per independent central review



Number of patients at risk																				
Group 1 (n=59)	30	30	29	28	23	23	23	23	23	20	18	16	16	16	10	9	6	2	0	0	0
Group 2 (n=78)	35	33	32	30	27	25	22	21	17	14	10	8	6	6	5	4	0	0	0	0	0
Group 3 (n=56)	24	24	24	23	21	21	20	19	17	11	5	0	0	0	0	0	0	0	0	0	0
Total (N=193)	89	87	85	81	71	69	65	63	57	45	33	24	22	22	15	13	6	2	0	0	0

Change from baseline in Global Health Status/ health-related QoL (GHS/HRQoL) and pain scores



Cycle	Baseline	2	3	4	5	6	7	8	9	10	11	12
Approximate months	0	4	6	8	10	12	14	16	18	20	22	24
n (GHS/HRQoL)	150	136	122	104	104	101	84	73	65	59	52	43
n (pain)	152	137	125	105	105	101	84	73	65	59	52	43

Summary: In patients with advanced CSCC, cemiplimab 3 mg/kg Q2W or 350 mg IV Q3W was associated with sustained substantial clinical activity, including improved complete response rates over time, durable pain control, and QoL improvement.

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