Original Abstract

Phase II confirmatory study of cemiplimab (350mg IV Q3W) in patients with locally advanced or metastatic cutaneous squamous cell carcinoma (CSCC): Study 1540 Group 6

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Background

While most patients (pts) diagnosed with CSCC are cured with local therapies, for the small percentage developing advanced CSCC the disease is life threatening with dismal prognosis. In a phase 1 (NCT02383212) and a pivotal phase 2 (NCT02760498) clinical trials, cemiplimab, an anti–programmed cell death receptor-1 [anti–PD-1], was the first systemic therapy to demonstrate significant antitumor activity in pts with advanced CSCC. Here, we report results from group 6 of the pivotal phase 2 trial, providing additional efficacy and safety data for cemiplimab monotherapy, 350 mg every 3 weeks (Q3W) up to 104 weeks, in patients with advanced CSCC.

Methods

Patients with advanced CSCC (metastatic [nodal or distant] or locally advanced) were treated with cemiplimab 350 mg intravenous (IV) Q3W for up to 108 weeks. The primary endpoint was objective response rate (ORR; complete response + partial response) per independent central review (ICR). Secondary endpoints included duration of response (DOR), progression-free survival (PFS), and overall survival (OS) by central and investigator review as well as safety and tolerability of cemiplimab.

Results

At data cut-off date of Oct 25 2021, 167 pts were enrolled, of which 165 pts received at least one dose of cemiplimab and were followed-up for a median of 8.71 months (range: 0.0 - 19.5). 5 of 167 pts received prior systemic therapies. Per ICR, ORR was 45.1 % (74/164, 95 % CI: 37.4-53.1 %) with complete response in 5.5 % (9/164), partial response in 39.6 % (65/164), and DOR was not reached (95 % CI: 13.0 months, not evaluable [NE]). Among treated patients, median PFS was 14.7 months (95 % CI: 10.4, NE) and median OS was not reached (95 % CI: 17.6 months, NE). The most common treatment-emergent adverse events (TEAEs) by any grade were fatigue (26.1 %), diarrhoea and pruritus (each 21.2 %), and nausea (17.0 %). The most common grade ≥3 TEAEs were hypertension and pneumonia (each 3.6 %), and general physical health deterioration (3.0 %).

Conclusion

The group 6 primary analysis demonstrates a safety and efficacy profile that is consistent with that of the earlier groups of the study.

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Zusammenfassung

Konfirmatorische Phase-II-Studie mit Cemiplimab (350 mg i.v. Q3W) bei Patient*innen mit lokal fortgeschrittenem oder metastasiertem kutanen Plattenepithelkarzinom (CSCC): Studie 1540 Gruppe 6

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Hintergrund

In einer Phase-I-Studie (NCT02383212) und einer zulassungsrelevanten Phase-II-Studie (NCT02760498) war Cemiplimab die erste systemische Therapie, die bei Patient*innen mit fortgeschrittenem CSCC eine Antitumoraktivität zeigte. Hier präsentieren wir die Ergebnisse der Gruppe 6 der zulassungsrelevanten Phase-II-Studie, die zusätzliche Wirksamkeits- und Sicherheitsdaten für die Cemiplimab-Monotherapie, 350 mg alle 3 Wochen (Q3W) bis zu 108 Wochen, bei Patient*innen mit fortgeschrittenem CSCC liefern.

Methoden

167 Patient*innen mit fortgeschrittenem CSCC (metastasiert [nodale oder Fernmetastasen] oder lokal fortgeschritten) wurden mit Cemiplimab 350 mg intravenös (i.v.) Q3W für bis zu 108 Wochen behandelt.

Primäre Endpunkte:

- Objektive Ansprechrate (ORR; komplettes Ansprechen + partielles Ansprechen) bewertet durch ein unabhängiges zentrales Review (ICR)

Wichtigste sekundäre Endpunkte:

- Dauer des Ansprechens (DOR)
- Progressionsfreies Überleben (PFS)
- Gesamtüberleben (OS)
- Sicherheit und Verträglichkeit

Wirksamkeit

- Die ORR bewertet durch ICR betrug 45,1 % (74/167, 95 % Konfidenzintervall [KI]: 37.4–53.1) mit 9 Patient*innen mit vollständigem Ansprechen (5,5 %) und 65 Patient*innen mit partiellem Ansprechen (39.6 %).
- Die DOR war zum Zeitpunkt des Datenschnitts am 25. Oktober 2021 nicht erreicht (95 % KI: 13,0 Monate–nicht auswertbar [NA]).
- Das mediane PFS betrug 14,7 Monate (95 % KI: 10,4–NA).
- Das mediane OS wurde nicht erreicht (95 % KI: 17,6 Monate–NA).

Sicherheit und Verträglichkeit

- Die häufigsten Behandlungs-assoziierten unerwünschten Ereignisse (UE) jeglichen Grades waren Fatigue (26,1 %), Diarrhö (21,2 %), Pruritus (21,2 %) sowie Nausea (17,0 %).
- Insgesamt trat bei 16 Patient*innen (9,7 %) mindestens ein immunvermitteltes UE Grad ≥ 3 auf. Das häufigste immunvermittelte UE war eine Nebenniereninsuffizienz (1,2 %).

Fazit

Die primäre Analyse der Gruppe 6 zeigte ein Sicherheits- und Wirksamkeitsprofil, das mit den zuvor berichteten klinischen Studienerfahrungen der Gruppen 1, 2 und 3 der Studie übereinstimmte. Cemiplimab bleibt eine Standardtherapieoption für Patient*innen mit fortgeschrittenem CSCC, bei denen eine kurative Operation oder kurative Strahlentherapie nicht in Betracht kommt.

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WISSENSCHAFTLICHE INFORMATION

CSCC
kutanes Platten-epithelkarzinom

CEMIPLIMAB
beim **CSCC**

ESMO 2022

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Phase 2 confirmatory study of cemiplimab (350 mg IV Q3W) in patients with locally advanced or metastatic cutaneous squamous cell carcinoma (CSCC): Study 1540 Group 6

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Introduction

- CSCC is the second most common malignancy in the US, accounts for 20 % of skin cancer cases, and results in 1 million cases per year, with the incidence continuing to rise 50–200 % annually within the last three decades.[1]
- Surgical excision is most commonly used and provides most patients a favourable prognosis; unfortunately the recurrence rate of CSCC is higher than with other cancers and the development of locally advanced (laCSCC) or metastatic disease (mCSCC) occurs in a number of these cases.[2,3]
- The discovery of the programmed cell death-1 (PD-1) receptor and its associated ligands programmed cell death-ligand 1 (PD-L1) and programmed cell death-ligand 2 (PD-L2) in tumours has offered a new direction for clinical cancer immunotherapies in targeting anti–PD-1/PD-L1.[4]
- Cemiplimab is a high-affinity, fully human, hinge-stabilised immunoglobulin G4 anti–PD-1 antibody that blocks the interaction of PD-1 receptor with its ligands, PD-L1 and PD-L2.[5]
- In the Phase 1 (NCT02383212) and the pivotal Phase 2 (NCT02760498) clinical trials, cemiplimab was the first systemic therapy to demonstrate significant antitumour activity in patients with advanced CSCC.[6-9]
- Here, we report additional efficacy and safety data from the pivotal Phase 2 trial that examined the Group 6 patients with advanced CSCC undergoing cemiplimab monotherapy, 350 mg every 3 weeks (Q3W) for up to 108 weeks.

Objective

- The primary objective was to assess the clinical benefits of cemiplimab by measuring the objective response rate (ORR; complete response [CR] + partial response [PR]) per independent central review (ICR).
- The secondary objectives were to report the duration of response (DOR), progression-free survival (PFS), and overall survival (OS) by central and investigator review, and safety and tolerability of cemiplimab.

Methods

- EMPOWER-CSCC 1 is an open-label, non-randomised, multicentre, international Phase 2 study of patients with advanced CSCC (NCT02760498).
- At data cutoff date of 25 October 2021, 167 patients ≥18 years old with histologically confirmed metastatic or unresectable laCSCC were enrolled in the study.
- The patients enrolled were treated with cemiplimab 350 mg intravenous or with the option to switch to subcutaneous dosing, for up to 108 weeks.

Results

Patients

- A total of 167 patients were enrolled with a median age of 76.0 years (range, 40–94). Most patients had a primary cancer site of the head and neck (n=113, 67.7 %) **(Table 1)**.
- 165 of 167 patients received at least one dose of cemiplimab and were followed up for a median of 8.71 months (range, 0.0–19.5). The median duration of exposure was 35.7 weeks (range, 0.9–86.9).
- ORR, CR and PR analysis were performed with the total number of 164 patients, excluding patients who did not receive cemiplimab (n=2) or had no baseline tumour assessment due to COVID-19 (n=1).
- Five of 167 patients received prior systemic therapies (0.03 %).

Table 1. Patient demographics and baseline characteristics

Characteristic	Advanced CSCC (n=167)
Age, median (range), years	76.0 (40–94)
Male, n (%)	130 (77.8)
ECOG performance status, n (%)	
0	67 (40.1)
1	98 (58.7)
Missing	2 (1.2)
Primary CSCC site: head and neck, n (%)	113 (67.7)
Metastatic CSCC, n (%)	100 (59.9)
Locally advanced CSCC, n (%)	47 (40.1)
Duration of exposure to cemiplimab, median (range), weeks	35.7 (0.9–86.9)
Number of cemiplimab doses administered, median (range)	11.0 (1–29)

CSCC, cutaneous squamous cell carcinoma; ECOG, Eastern Cooperative Oncology Group.

Response

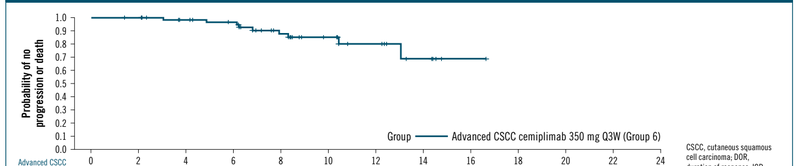
- Tumour response per ICR, median PFS and OS remained generally consistent with the previous update (data cutoff, 11 October 2020) **(Table 2)**.
- The median ORR was 45.1 % (74/164; 95 % confidence interval [CI], 37.4 %, 53.1 %) with CR in 5.5 % (9/164) and PR in 39.6 % (65/164) **(Table 2)**.
- As of the data cutoff date of 25 October 2021, the median DOR was not reached (95 % CI, 13.0 months, not evaluable [NE]) **(Table 2, Figure 1)**.
- Among treated patients, the median PFS was 14.7 months (95 % CI, 10.4, NE) and the median OS was not reached (95 % CI, 17.6 months, NE) **(Table 2, Figure 2)**.

Table 2. Tumour response per ICR

Characteristic	Patients, n	Advanced CSCC cemiplimab: 350 mg Q3W (Group 6)
Duration of follow-up, median (range), months	165[§]	8.71 (0.0–19.5)
ORR, % (95 % CI)	164[†]	45.1 (37.4–53.1)
CR, n (%)		9 (5.5)
PR, n (%)		65 (39.6)
DOR, median (95% CI), months	74[‡]	NR (13.0–NE)
PFS, median (95% CI), months	165[§]	14.7 (10.4–NE)
OS, median (95% CI), months	165[§]	NR (17.6–NE)

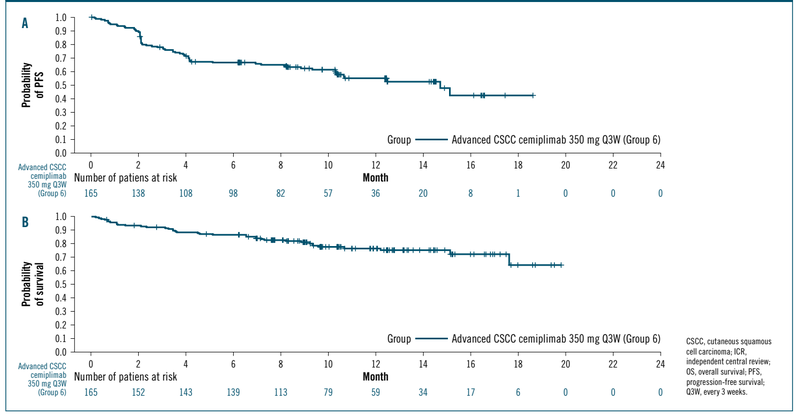
[†] The total number of patients in the tumour response analysis was 164, excluding patients who did not receive cemiplimab (n=2) or had no baseline tumour assessment due to COVID-19 (n=1). [‡] Full analysis set: patients with confirmed CR or PR (n=74). [§] Full analysis set: Group 6 patients who received at least one dose of cemiplimab (n=165). CI, confidence interval; CR, complete response; DOR, duration of response; NE, not evaluable; NR, not reached; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PR, partial response; Q3W, every 3 weeks.

Figure 1. Kaplan-Meier curve of DOR per ICR



CSCC, cutaneous squamous cell carcinoma; DOR, duration of response; ICR, independent central review; Q3W, every 3 weeks.

Figure 2. Kaplan-Meier curves of PFS and OS per ICR



CSCC, cutaneous squamous cell carcinoma; ICR, independent central review; OS, overall survival; PFS, progression-free survival; Q3W, every 3 weeks.

Safety

- 163 (98.8 %) of 165 patients that received at least one dose of cemiplimab experienced at least one treatment-emergent adverse event (TEAE) of any grade regardless of attribution **(Table 3)**.
- The most common TEAE of any grade was fatigue (n=43, 26.1 %), followed by diarrhoea (n=35, 21.2 %), pruritus (n=35, 21.2 %) and nausea (n=28, 17.0 %).
- Grade ≥3 TEAEs were reported in 75 patients (45.5 %), the most common being hypertension (n=6, 3.6 %) and pneumonia (n=6, 3.6 %), followed by general physical health deterioration (n=5, 3.0 %).
- In total, 16 patients (9.7 %) experienced at least one Grade ≥3 immune-related adverse event based on investigator assessment, with the most common being adrenal insufficiency (n=2, 1.2 %).
- 23 patients (13.9 %) discontinued treatment due to possibly treatment-related TEAEs of any grade, with those resulting in death reported in 14 cases (8.5 %) in Group 6.
  - None of the deaths were considered to be related to cemiplimab. The fatal AEs were due to: COVID-19–related events (n=2), other infection (n=4), sudden death not otherwise specified without autopsy (n=2), myocardial infarction, gastrointestinal bleed, pulmonary embolism, acute myelogenous leukemia, and declining mental status in setting of morphine patient-controlled analgesia and pulmonary oedema, and meningitis that was likely infectious (n=1 each).

Table 3. TEAEs[†]

	Advanced CSCC (n=165)	
TEAEs, n (%)	**Any grade**	**Grade ≥3**
Any	163 (98.8)	75 (45.5)
Serious	72 (43.6)	57 (34.5)
Leading to discontinuation	23 (13.9)	12 (7.3)
Leading to death	14 (8.5)	14 (8.5)
Any-grade TEAEs occurring in ≥10 % of patients, n (%)		
Fatigue	43 (26.1)	
Diarrhoea	35 (21.2)	
Pruritus	35 (21.2)	
Nausea	28 (17.0)	
Asthenia	23 (13.9)	
Arthralgia	22 (13.3)	
Constipation	19 (11.5)	
Decreased appetite	19 (11.5)	
Rash maculo-papular	17 (10.3)	
Most common Grade ≥3 TEAEs, n (%)		
Constipation	6 (3.6)	
Decreased appetite	6 (3.6)	
Rash maculo-papular	5 (3.0)	

Adverse events were coded according to the Preferred Terms of the Medical Dictionary for Regulatory Activities, version 22.1. The severity of adverse events was graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03.
[†]TEAE, treatment emergent adverse event.

Conclusions

- Group 6 in the EMPOWER-CSCC 1 study demonstrated a safety and efficacy profile that was consistent with the previously reported clinical trial experience for groups 1, 2, and 3 of the study.
- Cemiplimab remains a standard-of-care option in patients with advanced CSCC who are not candidates for curative surgery or radiation.

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Disclosure

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