Original Abstract

Phase II study of cemiplimab in patients with advanced cutaneous squamous cell carcinoma (CSCC): Final analysis from EMPOWER-CSCC 1 groups 1, 2 and 3

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Background

Previous analyses from EMPOWER-CSCC 1 phase 2 study (NCT02760498) demonstrated substantial clinical benefit and an acceptable safety profile with cemiplimab in patients with locally advanced and metastatic CSCC. Here, we provide the final analysis from the study Groups 1, 2 and 3.

Methods

Patients received cemiplimab 3 mg/kg IV every 2 weeks for up to 96 weeks (Group 1, metastatic CSCC; Group 2, locally advanced CSCC) or cemiplimab 350 mg IV every 3 weeks for up to 54 weeks (Group 3, metastatic CSCC). The primary endpoint was objective response rate (ORR; complete + partial response) per independent central review (ICR). This is the final analysis and the final database lock occurred on 01 Mar 2022.

Results

A total of 193 patients were enrolled (Group 1, n=59; Group 2, n=78; Group 3, n=56). Tumour response per ICR, median progression-free survival (PFS) and overall survival (OS) (Table) remain generally consistent with the previous update (data cut-off: 11 Oct 2020). OS at 48 months is 61.8% (95% CI: 54.0-68.7). Overall median duration of response (DOR) was 41.3 months (Table). Fatigue (34.7%) was the most common treatment-emergent adverse event (TEAE) of any grade; hypertension (4.7%) was the most common Grade ≥3 TEAE.

	Group 1 (mCSCC) 3mg/kg Q2W (n=59)	Group 2 (laCSCC) 3mg/kg Q2W (n=78)	Group 3 (mCSCC) 350mg Q3W (n=56)	Total (n=193)
Median duration of follow-up, months, (range)	18.5 (1.1–41.0)	15.5 (0.8–43.2)	17.3 (0.6–43.4)	15.7 (0.6–43.4)
ORR, %, (95% CI)	50.8 (37.5–64.1)	44.9 (33.6–56.6)	46.4 (33.0–60.3)	47.2 (39.9–54.4)
Complete response, n (%)	12 (20.3)	10 (12.8)	11 (19.6)	33 (17.1)
Partial response, n (%)	18 (30.5)	25 (32.1)	15 (26.8)	58 (30.1)
Median DOR, months (95% CI)	NR (20.7–NE)	41.9 (20.5–54.6)	41.3 (40.8–46.3)	41.3 (38.8–46.3)
Median PFS, months (95% CI)	18.4 (7.3–53.2)	18.5 (11.1–43.8)	21.7 (3.8–43.3)	22.1 (10.4–32.3)
Median OS, months (95% CI)	57.7 (29.3–NE)	NR (58.3–NE)	48.4 (29.5–NE)	NR (56.0–NE)

CI, confidence interval; DOR, duration of response; NE, not evaluable; NR, not reached; ORR, objective response rate; OS, overall survival; PFS, progression-free survival.

Conclusion

The final update confirms the durable response, safety and efficacy of cemiplimab in patients with advanced CSCC.
There were no new safety signals identified on longer follow-up. Cemiplimab remains a standard of care option for advanced CSCC.

This study was funded by Regeneron Pharmaceuticals, Inc., and Sanofi.

Zusammenfassung

Phase-II-Studie mit Cemiplimab bei Patient*innen mit fortgeschrittenem kutanen Plattenepithelkarzinom (CSCC): Finale Analyse der Gruppe 1, 2 und 3 der EMPOWER-CSCC 1-Studie

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Hintergrund

Frühere Analysen der Phase-II Studie EMPOWER-CSCC 1 (NCT02760498) zeigten einen erheblichen klinischen Nutzen und ein akzeptables Sicherheitsprofil von Cemiplimab bei Patient*innen mit lokal fortgeschrittenem und metastasiertem CSCC. Hier stellen wir die finale Analyse der Studiengruppen 1, 2 und 3 vor.

Methoden

193 Patient*innen wurden mit Cemiplimab 3 mg/kg i.v. alle 2 Wochen (Q2W) für bis zu 96 Wochen (Gruppe 1, metastasiertes CSCC; Gruppe 2, lokal fortgeschrittenes CSCC) oder Cemiplimab 350 mg i.v. alle 3 Wochen (Q3W) für bis zu 54 Wochen (Gruppe 3, metastasiertes CSCC) 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)
- Komplette Ansprechrate
- Sicherheit und Verträglichkeit

Wirksamkeit

- Die ORR bewertet durch ICR betrug in der gesamten Studienpopulation (über alle 3 Gruppen hinweg) 47,2 % (95 % Konfidenzintervall [KI]: 39,9–54,4) mit 33 Patient*innen mit vollständigem Ansprechen (17,1 %) und 58 Patient*innen mit partiellem Ansprechen (30,1 %).
- Die mediane DOR lag in der gesamten Studienpopulation bei 41,3 Monaten (95 % KI: 38,8–46,3).
- Das mediane PFS der gesamten Studienpopulation betrug 22,1 Monate (95 % KI: 10,4–32,3).
- Das mediane OS der gesamten Studienpopulation wurde nicht erreicht (95 % KI: 56,0 Monate – nicht auswertbar).

Sicherheit und Verträglichkeit

- Die häufigsten Behandlungs-assoziierten unerwünschten Ereignisse (UE) jeglichen Grades waren Fatigue (34,7 %), Diarrhö (27,5 %), Nausea (23,8 %) sowie Pruritus (21,2 %).
- Insgesamt trat bei 19 Patient*innen (9,8 %) mindestens ein UE Grad ≥ 3 auf.
  Die häufigsten immunvermittelten UE waren Pneumonitis (3,1 %), Diarrhö (1,0 %) und autoimmune Hepatitis (1,0 %).

Fazit

Das finale Update bestätigte das dauerhafte Ansprechen, die Sicherheit und die Wirksamkeit von Cemiplimab bei Patient*innen mit fortgeschrittenem CSCC. Es wurden keine neuen Sicherheitsbedenken im längeren Nachbeobachtungszeitraum festgestellt.
Cemiplimab bleibt eine Standardtherapieoption für Patient*innen mit fortgeschrittenem CSCC.

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WISSENSCHAFTLICHE INFORMATION

CSCC
kutanes Platten-epithelkarzinom

CEMIPLIMAB
beim **CSCC**

ESMO 2022

Phase-II-Studie mit Cemiplimab bei Patient*innen mit fortgeschrittenem kutanen Plattenepithelkarzinom (CSCC): Finale Analyse der Gruppe 1, 2 und 3 der EMPOWER-CSCC 1-Studie

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Phase 2 study of cemiplimab in patients with advanced cutaneous squamous cell carcinoma (CSCC): Final analysis from EMPOWER-CSCC 1 Groups 1, 2 and 3

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Introduction

- CSCC is the second most common malignancy in the USA, with approximately 186,000–420,000 cases diagnosed each year.[1]
- While most cases of CSCC are cured by complete surgical excision, a small but substantial number of patients develop advanced disease, including locally advanced (laCSCC) or metastatic (mCSCC) disease.[2,3]
- Cemiplimab is a high-affinity, fully human, hinge-stabilised, immunoglobulin G4 anti–programmed cell death-1 (PD-1) antibody that blocks the interaction of the PD-1 receptor with its ligands, PD-L1 and PD-L2.[4]
- Cemiplimab is approved in the US and Europe, and by multiple other health authorities, for the treatment of patients with metastatic or locally advanced CSCC who are not candidates for curative surgery or curative radiation.[5–8] Additionally, cemiplimab is recommended for the treatment of patients with metastatic or locally advanced CSCC not amenable to curative surgery or curative radiation by the European Association of Dermato-Oncology, European Organisation for Research and Treatment of Cancer, and the National Comprehensive Cancer Network.[9,10]
- In the primary and follow-up analysis from the EMPOWER-CSCC 1 Phase 2 study, cemiplimab demonstrated substantial clinical benefit and an acceptable safety profile in patients with advanced CSCC (NCT02760498).[11–14]
  - Cemiplimab achieved an objective response rate (ORR) of 46.1% in patients with advanced CSCC, with complete response rates of 20.3%, 12.8% and 16.1% for groups 1, 2 and 3, respectively.[11]
- Here, we provide the final update from study Groups 1, 2 and 3.

Objectives

- Primary objective: To assess the clinical benefits of cemiplimab as measured by ORR (complete + partial response) per independent central review (ICR).
- Key secondary objectives: Duration of response (DOR), progression-free survival (PFS), overall survival (OS), complete response rate, and safety and tolerability.

Methods

- EMPOWER-CSCC 1 is an open-label, non-randomised, multicentre, international Phase 2 study of patients with advanced CSCC (NCT02760498).
- Patients with histologically confirmed mCSCC or unresectable laCSCC received cemiplimab 3 mg/kg intravenous (IV) every 2 weeks for up to 96 weeks (Group 1, mCSCC; Group 2, laCSCC) or cemiplimab 350 mg IV every 3 weeks for up to 54 weeks (Group 3, mCSCC) **(Figure 1)**.
- This is the final analysis and the data cutoff was 1 March 2022.

Figure 1. Study design

Key inclusion criteria
- ECOG performance status of 0 or 1
- Adequate organ function
- Groups 1 and 3: – At least one lesion measurable by RECIST version 1.1
- Group 2: – At least one lesion measurable by digital medical photography
  – CSCC lesion that is not amenable to surgery or radiation therapy per investigators' assessment

Key exclusion criteria
- Ongoing or recent (within 5 years) autoimmune disease requiring systemic immunosuppression
- Prior treatments with anti-PD-1 or anti-PD-L1 therapy
- History of solid organ transplant, concurrent malignancies (unless indolent or not considered life threatening; for example, basal cell carcinoma) or hematologic malignancies

†Retreatment optional for patients with disease progression during follow-up. ‡Confirmatory scans performed no sooner than 4 weeks following initial documentation of tumour response. The severity of TEAEs was graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (version 4.03). CSCC, cutaneous squamous cell carcinoma; ECOG, Eastern Cooperative Oncology Group; PD-1, programmed cell death-1; PD-L1, programmed cell death-ligand 1; Q2W, every 2 weeks; Q3W, every 3 weeks; RECIST 1.1, Response Evaluation Criteria In Solid Tumors version 1.1; TEAE, treatment-emergent adverse event.

Results

Patients

- A total of 193 patients were enrolled (Group 1, n=59; Group 2, n=78; Group 3, n=56) with a median age of 72.0 years (range, 38–96). Most patients had a primary cancer site of the head and neck (n=131, 67.9%) **(Table 1)**.
- Median duration of follow up was 15.7 months (range, 0.6–43.4) and median duration of exposure was 51.1 weeks (range, 2.0–109.3).

Response

- Tumour response per ICR, median PFS and OS remained generally consistent with the previous update (data cutoff: 11 October 2020) **(Table 2)**.
- Median PFS was 22.1 months (95% confidence interval [CI], 10.4–32.3) and the overall median DOR was 41.3 months (95% CI, 38.8–46.3) **(Figures 2 and 3A)**.
- Median OS was not reached. The Kaplan–Meier estimated probability of OS at 48 months was 61.8% (95% CI, 54.0–68.7) **(Figure 3B)**.

Table 1. Patient demographics and baseline characteristics

	Advanced CSCC (n=193)
Age, median (range), years	72.0 (38–96)
Male, n (%)	161 (83.4)
ECOG performance status, n (%)	
0	86 (44.6)
1	107 (55.4)
Primary CSCC site: head and neck, n (%)	131 (67.9)
mCSCC, n (%)	115 (59.6)
laCSCC, n (%)	78 (40.4)
Patients with cemiplimab as first-line therapy, n (%)	128 (66.3)
Patients with prior systemic therapy, n (%)†	65 (33.7)
Duration of exposure to cemiplimab, weeks, median (range)	51.1 (2.0–109.3)
Number of cemiplimab doses administered, median (range)	18.0 (1–48)

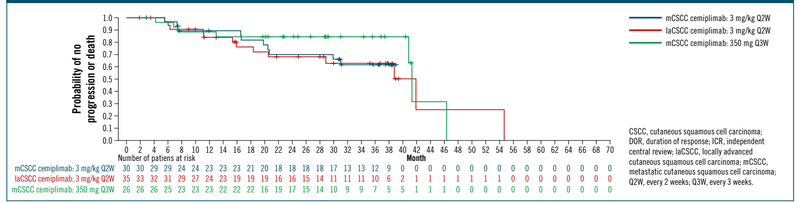
†Settings for prior lines of therapy included metastatic disease, adjuvant, chemotherapy with concurrent radiation, or other, and the most common types of prior systemic therapy were platinum compounds (n=46/65, 70.8%) and monoclonal antibodies (n=18/65, 27.7%). CSCC, cutaneous squamous cell carcinoma; ECOG, Eastern Cooperative Oncology Group; laCSCC, locally advanced cutaneous squamous cell carcinoma; mCSCC, metastatic cutaneous squamous cell carcinoma.

Table 2. Tumour response per ICR

	Group 1 (mCSCC) 3 mg/kg Q2W (n=59)	Group 2 (laCSCC) 3 mg/kg Q2W (n=78)	Group 3 (mCSCC) 350 mg Q3W (n=56)	Total (n=193)
Duration of follow-up, months, median (range)	18.5 (1.1–41.0)	15.5 (0.8–43.2)	17.3 (0.6–43.4)	15.7 (0.6–43.4)
ORR, % (95% CI)	50.8 (37.5–64.1)	44.9 (33.6–56.6)	46.4 (33.0–60.3)	47.2 (39.9–54.4)
Complete response, n (%)	12 (20.3)	10 (12.8)	11 (19.6)	33 (17.1)
Partial response, n (%)	18 (30.5)	25 (32.1)	15 (26.8)	58 (30.1)
DOR, months, median (95% CI)	NR (20.7–NE)	41.9 (20.5–54.6)	41.3 (40.8–46.3)	41.3 (38.8–46.3)
PFS, months, median (95% CI)	18.4 (7.3–53.2)	18.5 (11.1–43.8)	21.7 (3.8–43.3)	22.1 (10.4–32.3)
OS, months, median (95% CI)	57.7 (29.3–NE)	NR (58.3–NE)	48.4 (29.5–NE)	NR (56.0–NE)

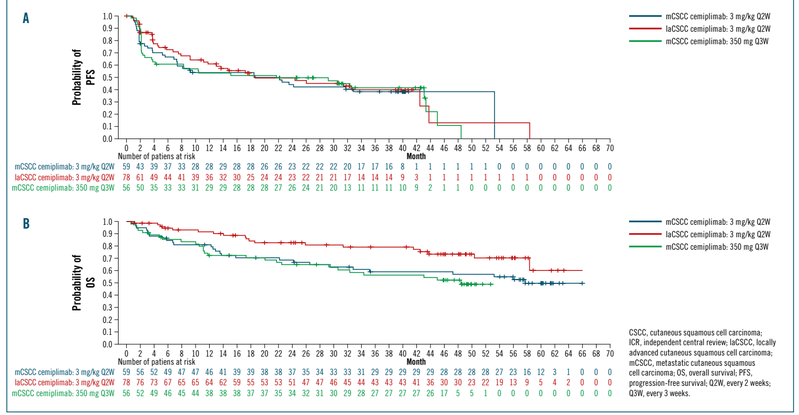
CI, confidence interval; DOR, duration of response; ICR, independent central review; laCSCC, locally advanced cutaneous squamous cell carcinoma; mCSCC, metastatic cutaneous squamous cell carcinoma; NE, not evaluable; NR, not reached; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; Q2W, every 2 weeks; Q3W, every 3 weeks.

Figure 2. Kaplan-Meier curve of DOR per ICR



CSCC, cutaneous squamous cell carcinoma; DOR, duration of response; ICR, independent central review; laCSCC, locally advanced cutaneous squamous cell carcinoma; mCSCC, metastatic cutaneous squamous cell carcinoma; Q2W, every 2 weeks; Q3W, every 3 weeks.

Figure 3. Kaplan-Meier curves of PFS and OS per ICR



CSCC, cutaneous squamous cell carcinoma; ICR, independent central review; laCSCC, locally advanced cutaneous squamous cell carcinoma; mCSCC, metastatic cutaneous squamous cell carcinoma; OS, overall survival; PFS, progression-free survival; Q2W, every 2 weeks; Q3W, every 3 weeks.

Safety

- All but one patient (n=192, 99.5%) 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=67, 34.7%), followed by diarrhoea (n=53, 27.5%), nausea (n=46, 23.8%) and pruritus (n=41, 21.2%)
- Grade ≥3 TEAEs were reported in 95 patients (49.2%). The most common Grade ≥3 TEAEs were hypertension (n=9, 4.7%), cellulitis and anaemia (each n=8, 4.1%), pneumonia (n=8, 4.1%), pneumonitis (n=6, 3.1%), sepsis (n=5, 2.6%) and fatigue (n=5, 2.6%).
- In total, 19 patients (9.8%) experienced at least one sponsor-identified Grade ≥3 immune-related adverse event (irAE). The most common Grade ≥3 irAEs were pneumonitis (n=6, 3.1%), diarrhoea and autoimmune hepatitis (each n=2, 1.0%).
- Twenty patients (10.4%) discontinued treatment due to TEAEs of any grade **(Supplementary Table 1)**.
- No new TEAEs resulting in death were reported compared with previous reports.[6–8]

Table 3. TEAEs†

	Advanced CSCC, n=193	
TEAEs, n (%)	Any grade	Grade ≥3
Any	192 (99.5)	95 (49.2)
Serious	75 (38.9)	60 (31.1)
Leading to discontinuation	20 (10.4)	13 (6.7)
Leading to death	5 (2.6)	5 (2.6)
Occurring in ≥10% of patients (any grade)		
Fatigue	67 (34.7)	5 (2.6)
Diarrhoea	53 (27.5)	2 (1.0)
Nausea	46 (23.8)	0
Pruritus	41 (21.2)	0
Constipation	28 (14.5)	1 (0.5)
Vomiting	25 (13.0)	1 (0.5)
Arthralgia	34 (17.6)	1 (0.5)
Cough	32 (16.6)	0
Rash	32 (16.6)	1 (0.5)
Anaemia	22 (11.4)	8 (4.1)
Hypothyroidism	22 (11.4)	0
Actinic keratosis	23 (11.9)	0
Rash, maculo-papular	23 (11.9)	1 (0.5)
Upper respiratory tract infection	21 (10.9)	0
Headache	21 (10.9)	0

†TEAEs occurring in ≥10% of patients are reported here. 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. RTI, respiratory tract infection; TEAE, treatment-emergent adverse event.

Conclusions

- The EMPOWER-CSCC 1 study confirms the efficacy, durability, and safety profile of cemiplimab in patients with advanced CSCC.
- No new safety concerns were identified on longer follow-up.
- Cemiplimab remains a standard-of-care option for metastatic or locally advanced CSCC patients who are not candidates for curative surgery or radiation.

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Disclosure

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Scan for supplementary appendix and a copy of the poster.

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