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CemiplimAb-rwlc Survivorship and Epidemiology (CASE): Safety and effectiveness of cemiplimab in patients with advanced cutaneous squamous cell carcinoma in a real-world setting: 2 years' follow-up of a prospective observational study

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BACKGROUND

- While surgery is the most common first-line treatment for cutaneous squamous cell carcinoma (CSCC), patients with advanced and metastatic disease require systemic therapy.¹
- Cemiplimab is the first approved programmed cell death-1 inhibitor for the treatment of adult patients with locally advanced or metastatic CSCC not amenable to curative surgery or radiation.^{2,3}
- Limited data exist on the clinical characteristics, management, disease progression, and survivorship of patients with advanced CSCC in real-world clinical practice.
- Here, we present real-world evidence from the CemiplimAb-rwlc Survivorship and Epidemiology (CASE) study (NCT03836105).

OBJECTIVE AND METHODS

- CASE is a phase 4, multicenter, prospective, noninterventional, observational study of patients with advanced CSCC who are receiving cemiplimab 350 mg every 3 weeks (Figure 1).
- Effectiveness outcomes included objective response rate (ORR) and progression-free survival (PFS).
- Tumor response was evaluated as per standard clinical practice at the individual centers
- PFS was defined as time from the date of the first administration of cemiplimab to progression or death
- Safety outcomes included treatment-related immune-related adverse events (irAEs), infusion-related reactions, and treatment-related serious adverse events (SAEs).

RESULTS

- As of March 24, 2025, 254 patients with advanced CSCC received ≥1 dose of cemiplimab.
- The mean (SD) duration of study follow-up was 105.5 (60.85) weeks.
- The median duration of exposure was 35.0 weeks (Q1-Q3, 15.0-65.9).
- Demographics and disease characteristics are presented in **Table 1**.
- The locations of tumors are described in **Figure 2**.
- ORR was observed in 112/254 patients (44.1%; 95% CI: 37.9–50.4) included in the trial. When considering only patients with ≥1 response evaluation, 112/203 responded (55.2%; 95% CI: 48.1–62.1) (Figure 3).
- Median PFS was 15.7 (95% CI: 12.8–23.7) months. Median overall survival (OS) was not statistically significant.
- While not statistically significant, some numerical differences in PFS and OS can be observed between the different CSCC subpopulations (Figure 4).

Figure 1. Study design



*Patients are excluded if they have a condition that may interfere with study evaluations, restrict adherence to the treatment plan, or prevent completion of scheduled assessments. CSCC, cutaneous squamous cell carcinoma; irAE, immune-related adverse event; ORR, objective response rate; PFS, progression-free survival; Q3W, every 3 weeks.

Table 1. Baseline characteristics

	All patients (N=254)
Age (years)	76.0 (20–99)
Median (Min-Max)	
Age group, years, n (%)	
≥65	210 (82.7)
Male, n (%)	199 (78.3)
Race, n (%)	
White	226 (89.0)
Other	10 (3.9)
Unknown/missing	18 (7.1)
ECOG PS, n (%)	
0	56 (22.3)
1	108 (42.5)
2	23 (9.1)
Missing	4 (1.6)
600 (2.8)	
Cancer stage, n (%)	
Locally advanced	163 (64.2)
Metastatic	91 (35.8)
Immunocompromised/immunosuppressed, n (%)	42 (16.5)

Figure 2. Localization of skin lesions

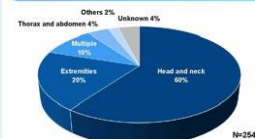
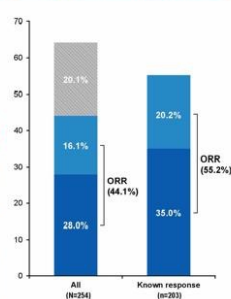


Figure 3. Tumor response



■ Partial response ■ Complete response ■ Missing
ORR, objective response rate.

SAFETY

- Safety was evaluated in all patients included in the study (N=254).
- A total of 76 (29.9%) patients experienced ≥1 treatment-related irAE (Table 2), the most common were hypothyroidism (21 [8.3%]), fatigue (11 [4.3%]), pruritus (9 [3.5%]), rash (8 [3.1%]), diarrhea (8 [3.1%]), rash maculo-papular (6 [2.4%]), and arthralgia (5 [2.0%]).
- Two deaths were attributed to a treatment-related SAE: 1 acute cardiac failure and 1 pneumonitis.

Figure 4. PFS and OS in key subgroups

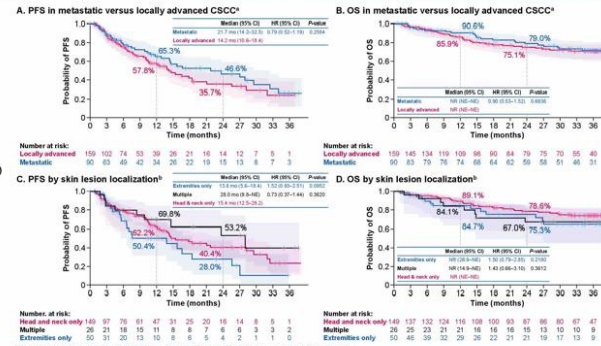


Table 2. Summary of AEs

	Participants with ≥1, n (%)	All patients (N=254)
Treatment-related irAE		76 (29.9)
Any grade		24 (9.4)
Grade ≥3		0
IRR		1 (0.4)
Any grade		0
Grade ≥3		0
Treatment-related SAE		19 (7.5)
Any		19 (7.5)
Leading to treatment discontinuation		2 (0.8)
Resulting in death		2 (0.8)

irAE, immune-related adverse event; IRR, infusion-related reaction; SAE, serious adverse event.

CONCLUSIONS

- After 2 years of follow-up, this phase 4 study shows that the efficacy of cemiplimab in patients with advanced CSCC in real-world practice is comparable to that observed in the EMPOWER-CSCC-1 trial.
- The safety profile of cemiplimab in patients with advanced CSCC was generally acceptable, with no new safety signals.
- This study confirms the utility of cemiplimab for treating advanced CSCC outside of controlled clinical trial settings.

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ACKNOWLEDGMENTS

This study (NCT03836105) was funded by Regeneron Pharmaceuticals, Inc. Writing assistance was provided by Elizabeth Smith, MD, of Alpha 4 division of Prime, Knoxville, TN, funded by Regeneron Pharmaceuticals, Inc.

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