CemiplimAb-rwlc Survivorship and Epidemiology (CASE): A prospective, non-interventional study of the safety and effectiveness of cemiplimab in immunocompromised/immunosuppressed patients with advanced cutaneous squamous cell carcinoma at 2 years' follow-up

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SYNOPSIS

- While surgery and/or radiation are definitive treatments for CSCC, many patients progress to locally advanced and metastatic disease and require systemic therapy.[1,2]
- Cemiplimab was the first programmed cell death-1 inhibitor approved for the treatment of patients with m/la CSCC who are not candidates for curative surgery or radiation.[3,4]
- Despite the high prevalence of CSCC in IC/IS patients, they are often excluded from registration studies because of potentially reduced treatment efficacy and potentially increased toxicity.[5–7]
- Prior retrospective observational research indicated similar OS between those with IC/IS conditions versus without.[8]

OBJECTIVE

- To present the safety and effectiveness of cemiplimab in IC/IS patients with advanced CSCC from the CASE study in the real-world setting, at 2 years' follow-up.

METHODS

- CASE (NCT03836105) is a phase 4, multicenter, prospective, non-interventional study evaluating the effectiveness and safety of cemiplimab 350 mg every 3 weeks in patients with m/la CSCC.
- Effectiveness outcomes included ORR, PFS, and OS.
  - Tumor response was evaluated as per standard clinical practice at the individual centers.
  - Missing data was included in the denominator for ORR calculations.
- Safety outcomes included treatment-related irAEs, IRRs, and treatment-related SAEs.
- As this is an exploratory analysis, all *P* values are nominal.

RESULTS

- As of March 2025, 254 patients with m/la CSCC had received ≥1 dose of cemiplimab. Of these, 42 (16.5%) were IC/IS and 212 (83.5%) were non-IC/IS.
- The distribution of categories of IC/IS in this population and the locations of target lesions are shown in **Figures 1** and **2**.
- The median (Q1:Q3) duration of study follow-up in IC/IS patients was 116.2 (60.1:160.1) weeks and that of non-IC/IS patients was 128.3 (44.1:156.7) weeks.
- The median (Q1:Q3) duration of treatment exposure was 43.9 (24.7:82.0) weeks for IC/IS patients and 31.9 (15.0:60.7) weeks for non-IC/IS patients.
- Demographics and baseline disease characteristics are presented in **Table 1**.

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ABBREVIATIONS

CASE, CemiplimAb-rwlc Survivorship and Epidemiology; CR, complete response; CSCC, cutaneous squamous cell carcinoma; ECOG PS, Eastern Cooperative Oncology Group performance status; IC, immunocompromised; irAE, immune-related adverse event; IRR, infusion-related reaction; IS, immunosuppressed; m/la, metastatic/locally advanced; NE, not evaluable; ORR, objective response rate; OS, overall survival; PFS progression-free survival; PR, partial response; SAE, serious adverse event.

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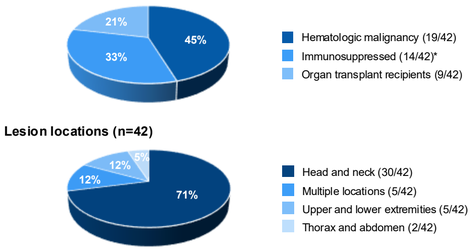
DISCLOSURES

SJP reports consulting/advisory roles for Replimune, Regeneron, and Sun Pharma and research funding from Bristol Myers Squibb Foundation. **GR** reports consulting/advisory roles for Coherus, Fennec Pharmaceuticals, and Merus. **MJK** reports research funding from Regeneron, Mirati, and Bristol Myers Squibb Foundation. **ESR** reports consulting/advisory roles with Regeneron, Leo Pharma, Checkpoint Therapeutics, and Genentech and research funding from Regeneron and Pellepharm. **FW** reports consulting/advisory roles with Bayer, Bristol Myers Squibb, Eisai, Exelixis, Loxo, Merck, and Regeneron; research funding (institutional) from Bristol Myers Squibb, CUE Biopharma, Eisai, Lilly, Loxo/Lilly, and Merck; travel/accommodation expense compensations from Bayer and Merck Sharp & Dohme; and honoraria from Bristol Myers Squibb, Eisai, EMD Serono, Exelixis, and Regeneron. **CZ**, **DAGM**, **RGWQ**, **JW**, **KT**, **SN**, and **JFP** are employees and shareholders of Regeneron.

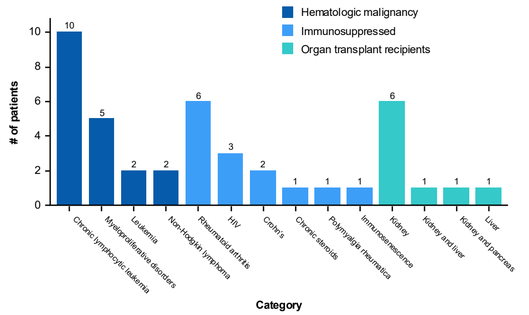
RESULTS

Figure 1. IC/IS analysis set.



*As defined by the investigator.

Figure 2. Distribution across IC/IS categories.



- Tumor response by IC/IS category and comparison with non-IC/IS patients are shown in **Figure 3**.

Figure 3. Tumor response by IC/IS category.

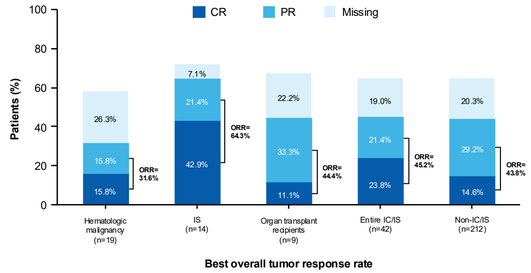
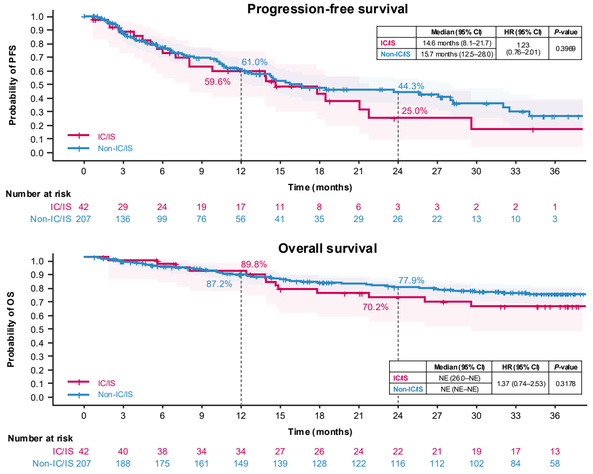


Figure 4. PFS and OS by IC/IS status.*



*HRs were calculated with the non-IC/IS group as the reference group.

Figure 5. PFS and OS by IC/IS category.

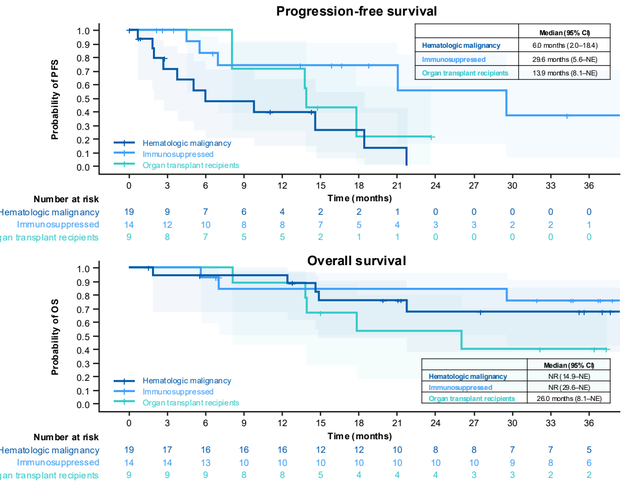


Table 1. Demographics and baseline characteristics.

	IC/IS (n=42)	Non-IC/IS (n=212)
Age, median (range), years	73.5 (50–90)	76.0 (28–99)
Aged ≥65 years, n (%)	37 (88.1)	173 (81.6)
Male, n (%)	32 (76.2)	167 (78.8)
Race, n (%)		
White	38 (90.5)	188 (88.7)
Other	0	10 (4.7)
Unknown/missing	4 (9.5)	14 (6.6)
ECOG PS, n (%)		
0	8 (19.0)	51 (24.1)
1	26 (61.9)	82 (38.7)
2+	3 (7.1)	24 (11.3)
Missing	5 (11.9)	55 (25.9)
Cancer grade, n (%)		
Locally advanced	24 (57.1)	139 (65.6)
Metastatic	18 (42.9)	73 (34.4)

- Survival probabilities for IC/IS and non-IC/IS patients are compared in **Figure 4**.
- Survival probabilities for the categories of IC/IS patients are shown in **Figure 5**.
- A comparison of adverse events in IC/IS and non-IC/IS patients is shown in **Table 2**.

Table 2. Summary of AEs.

Participants with ≥1, n (%)	IC/IS (n=42)	Non-IC/IS (n=212)
Treatment-related irAEs		
Any grade	13 (31.0)	63 (29.7)
Grade ≥3	5 (11.9)	19 (9.0)
IRRs		
Any grade	0	1 (0.5)
Grade ≥3	0	0
Treatment-related SAEs		
Any	3 (7.1)	16 (7.5)
Grade ≥3	3 (7.1)	14 (6.6)
Leading to treatment discontinuation	0	7 (3.3)
Resulting in death	1 (2.4)	1 (0.5)

- Of the 9 transplant patients, 2 (22.2%) had rejection episodes and lost their graft.

CONCLUSIONS

- After 2 years of follow-up, the results of this exploratory analysis of a phase 4 study suggest that the safety and efficacy of cemiplimab in IC/IS patients with m/la CSCC may be similar to those observed in non-IC/IS patients in real-world practice.
- While there are small variations in ORR and PFS, the results are generally comparable across IC/IS categories, with no observed differences in OS, although sample size limitations are noted.
- This study supports the potential of cemiplimab for treating advanced CSCC in a selected group of patients who are IC/IS; additional research is warranted.
- In this descriptive analysis, the differences in baseline prognostic factors between cohorts are not addressed. In addition, small sample sizes in the IC/IS cohort and subgroup categories warrant caution in interpretation of the results.

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