# Real-world data on clinical outcome and tolerability in patients with advanced cutaneous squamous cell carcinoma treated with cemiplimab in the Netherlands

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## Background

- Cutaneous squamous cell carcinoma (CSCC) is the second most common cutaneous malignancy and its incidence continues to rise[1,2]
- Patients with locally advanced or metastatic disease have a poor prognosis, as they are largely unresponsive to curative surgery or radiotherapy[3]
- Cemiplimab, a monoclonal anti-PD-1 antibody, has recently been approved by the FDA and EMA for this patient cohort based on single-arm phase 2 studies[4]
- Real-world data on clinical outcome and tolerability is still scarce[5]

- Aim: To examine clinical outcome and tolerability of cemiplimab in patients with advanced CSCC

## Patients & Methods

- Retrospective cohort study from 3 sites in the Netherlands
- Patients with unresectable locoregional or metastatic CSCC were included
- Treatment with flatdose cemiplimab 350mg Q3W between November 2018 until November 2020
- Minimum follow-up of 3 months
- Data cut-off was November 01, 2020
- Toxicity was graded according to CTCAE v4.03
- Response evaluation was done by CT, MRI, PET-CT or clinical assessment where imaging was not deemed reliable/feasible
- Progression-free survival (PFS) and overall survival (OS) were estimated using the Kaplan-Meier method

## References

[1]Rogers HW, et al. Arch Dermatol. 2010; [2]Tokez S, et al. AMA Dermatol. 2020; [3]Lee A, et al. Drugs 2020 ; [4]Migden MR, et al. N Engl J Med 2018; [5]Migden MR, et al. Future Oncol 2020.

## Author information

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## Results

| Table 1. Demographics and baseline characteristics (n=66) | N (%) |
|---|---|
| **Age, years** | |
| Median (range) | 75 (30-93) |
| > 65 | 55 (83.3) |
| > 80 | 19 (28.8) |
| **Gender** | |
| Male | 50 (75.8) |
| Female | 16 (24.2) |
| **ECOG performance status score** | |
| 0-1 | 58 (87.9) |
| 2-3 | 8 (12.1) |
| **Comorbidities*** | |
| Total | 58 (87.9) |
| Cardiovascular | 45 (68.2) |
| Pulmonary | 5 (7.56) |
| Renal insufficiency | 6 (9.1) |
| Organ/stemcell transplantation | 3 (4.5) |
| 2nd (hematologic) malignancy | 24 (36.4) |
| Inflammatory disorders/AI | 8 (12.1) |
| Other | 16 (24.2) |
| **Site primary CSCC** | |
| Head/neck | 52 (78.8) |
| Extremity | 9 (13.6) |
| Trunk | 3 (4.5) |
| Unknown | 2 (3.0) |
| **Disease stage** | |
| Locally advanced | 41 (62.1) |
| Distant metastases | 25 (37.9) |
| **Histological differentiation** | |
| Well differentiated | 10 (15.2) |
| Moderately differentiated | 25 (37.9) |
| Poorly differentiated | 16 (24.2) |
| Undifferentiated | 1 (1.5) |
| Unknown | 14 (21.2) |
| **Prior systemic therapy** | 7 (10.6) |
| **LDH** | |
| ≤ULN | 53 (80.3) |
| >ULN | 12 (18.2) |
| Unknown | 1 (1.5) |

*Patients could have had more than one type of comorbidity. *AI, autoimmune; ECOG, Eastern Cooperative Oncology Group performance score; LDH, lactatedehydrogenase; ULN, upper limit of normal.*

- In total, 66 patients with unresectable locoregional (41 (62.1%) patients) or metastatic (25 (37.9%) patients) CSCC were identified (Table 1)
- The most commonly reported adverse event (AE) was fatigue, occurring in 48.5% of patients (Table 2)
- 2 patients experienced grade 4 AE's; 1 patient with pneumonitis and 1 patient with pre-existing chronic lymphatic leukemia presented with an immune-related agranulocytosis
- In 57 (86.4%) of patients, response evaluation was performed by imaging with CT, MRI or PET-CT
- With a median follow-up of 11.7 months (95% CI 8.4-15.1 months), median PFS and median OS were not reached (Figure 1 and 2)
- An objective clinical response was seen in 33 (50%) patients, of whom 9 (13.6%) reached CR and 24 (36.3%) PR (Figure 3 and 4)
- A median of 6.5 doses of cemiplimab (range 1-31 doses) were administered
- In 41 (62.1%) patients treatment was discontinued, in 43.9% of patients due to disease progression
- In 8 (19.5%) patients with ongoing response, treatment was stopped after a median of 11.5 months (range 2.9-15.2 months)

| Table 2. Adverse Events*(n=66) | N (%) |
|---|---|
| **Any grade** | 59 (89.4) |
| Grade 1-2 | 47 (71.2) |
| Grade 3-4 | 12 (18.2) |
| **Led to discontinuation of treatment** | |
| Total | 5 (7.5) |
| Hepatitis grade 3 | 2 (3.0) |
| Pruritus grade 2 | 1 (1.5) |
| Hematologic grade 3 | 1 (1.5) |
| Pneumonitis grade 4 | 1 (1.5) |
| **Most common AE's (all grades)†** | |
| Fatigue | 32 (48.5) |
| Pruritus | 20 (30.3) |
| AF increased | 17 (25.8) |
| AST increased | 14 (21.2) |
| GGT increased | 14 (21.2) |
| **Most common grade 3-4 AE's‡** | |
| ALT increased | 3 (4.5) |
| AST increased | 3 (4.5) |
| GGT increased | 2 (3.0) |
| Rash | 2 (3.0) |

*Treatment related adverse events (AE). †Occurring in >20% of patients. ‡Occurring in ≥3% of patients. Patients could have experienced more than one AE. *AF, Alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, gamma-glutamyltransferase.*

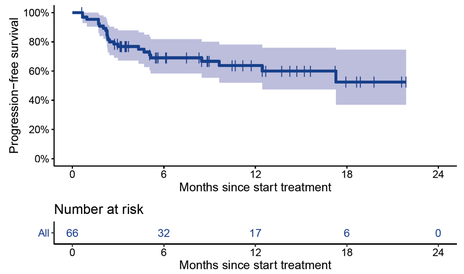


**Fig 1. Progression-free survival (PFS).** PFS was calculated as time between date of first cemiplimab dose and time of PD or date of death due to any cause.

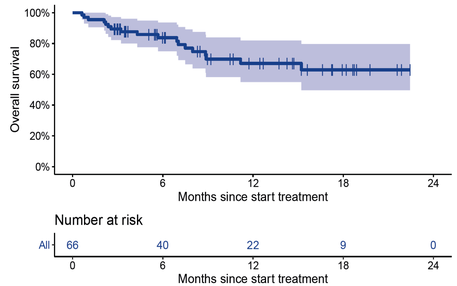


**Fig 2. Overall survival (OS).** OS was calculated as the time between the date of first cemiplimab dose and date of death due to any cause.

## CLINICAL CASE PRESENTATION

**Prior to cemiplimab treatment** **One year after treatment**

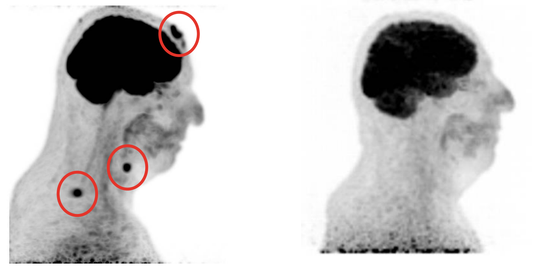

**Fig 3.** Example of complete radiologic response after one year of treatment (18 cycles of cemiplimab) in a 72-year old male patient with metastatic CSCC (frontal subcutaneous lesion of the scalp with damage to the tabula externa and interna and right-sided lymph node metastases in level IB and V).

**Prior to cemiplimab treatment** **After 2 cycles of cemiplimab**

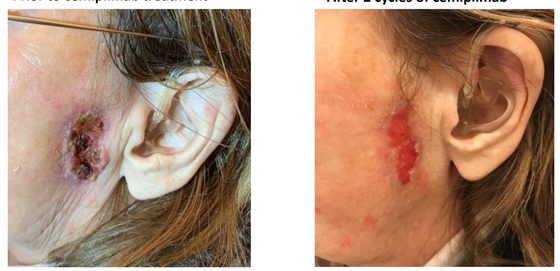

**Fig 4.** Example of a partial clinical response after 2 cycles of cemiplimab in a 86-year old female patient (ECOG performance status 3) with locally advanced stage III (T3N0M0), poorly differentiated CSCC. Surgical resection was not deemed possible due to the extent of surgery and risks of anesthesia.

## Conclusions

- In this real-world cohort of patients with advanced CSCC, cemiplimab demonstrated to be well-tolerated
- Treatment was feasible even in elderly patients with severe comorbidities
- An objective clinical response was observed in 50% of patients, which is comparable to the results of earlier prospective clinical trials
- Treatment with cemiplimab should be considered for the treatment of patients with locally advanced or metastatic CSCC

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