579 EVALUATION OF CEMIPLIMAB TREATMENT DURATION: CLINICAL OUTCOMES IN ADVANCED CSCC

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Background Cutaneous squamous cell carcinoma (CSCC) is the second most common skin cancer in white-skinned populations. Advanced or metastatic disease is rare, less than 5% of patients (pts), but when it occurs, is difficult to treat and often has a poor prognosis. Immune checkpoint blockade with cemiplimab, a PD-1 inhibitor, has been approved for advanced/metastatic CSCC[1] were is getting excellent results.[2] However, unlike what is already standard pratice for melanoma skin cancer,[3] [4] we do not know yet which is the optimal treatment duration. The aim of this study is to evaluate the minimum treatment period with cemiplimab in order to guarantee a durable clinical benefit.

Methods In this retrospective study was evaluated the duration standard treatment with cemiplimab 350 mg every 3 weeks (Q3W) in 95 pts with CSCC, on which 22 were discontinued not by clinical decision (figure 1). Demographic and clinical data were tabulated using descriptive statistics. PFS was calculated as the time from randomization until objective tumor progression or death, whichever occurs first; OS was calculated from randomization until death by any cause.

Results Overall, 95 pts were enrolled. Demographic and clinical characteristics are reported in table 1. The median age was 75 years (range, 32–96 years), and 68 (72%) pts were males. Cemiplimab was administered as first-line therapy in 45 (47%) pts and as second-line in 50 (53%) subjects; The most frequent comorbidities were blood hypertension (51%) and angina/coronary artery disease (23%). At the first follow-up visit, 10 (11%) pts achieved CR, 25 (26%) PR, 35 (37%) reached SD, and 25 (35%) were in progression. Twenty-two stopped cemiplimab treatment due to comorbidity (n=7), toxicity (n=3), no compliant (n=9) and complete response (n=3). No significant difference was observed in this cohort compared to general population (figure 2) in terms of OS (p=0.47; HR 0.80 (95% CI 0.42 to 1.48)) and PFS (p=0.29; HR 0.72 (95% CI 0.39 to 0.32). In the swimmer plot cartoon (figure 3), we observed 10 death events in pts treated for less than a year (n=12), only 1 death in pts treated at least 1 year (n=10) and 0 death in pts treated at least 2 years (n=5) (figure 4).

Conclusions From a patients, healthcare, and economic perspective, shorter treatment duration is preferred, and overtreatment should be prevented. In these preliminary result we showed that at least one year of treatment with cemiplimab appears to be a valid option. Further investigations are needed to get additional information.

REFERENCES

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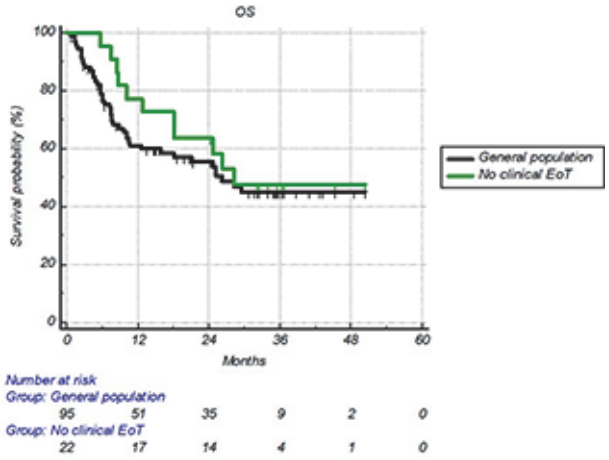
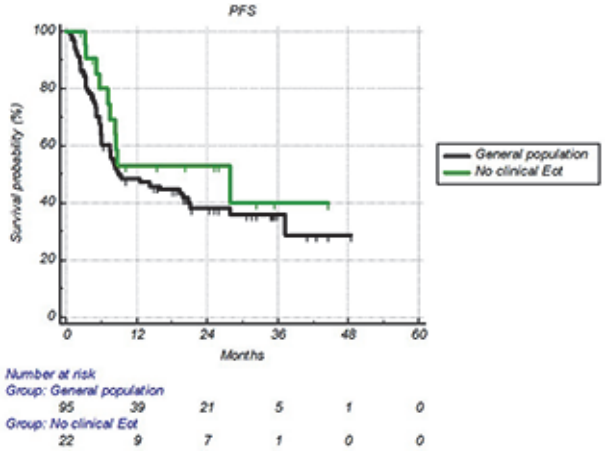
Ethics Approval This study was approved by the Ethics Committee of National Cancer Institute—IRCCS—Fondazione "G. Pascale", Naples, Italy, protocol number 32/22 oss. All patients provided their written informed consent to participate in this study.

Consent Written informed consent was obtained from the patient for publication of this abstract and any accompanying images. A copy of the written consent is available for review by the Editor of this journal

Abstract 579 Figure 1



Abstract 579 Figure 2



Abstract 579 Figure 3

Abstract 579 Table 1

Patient characteristics	N = 95
Median age	75 (range 32-96)
Gender: female/male, n (%)	27 (28)/68 (72)
CNS metastases at baseline, n (%)	9 (9)
Type of anti-PD-1 agent	
Cemiplimab, n (%)	95 (100)
Line of treatment	Anti-PD1
1st line treatment, n (%)	45 (47)
2nd line treatment or more, n (%)	50 (53)
Type of previous therapy	
Chemotherapy	35 (37)
Chemotherapy+radiotherapy	12 (13)
Immunotherapy	1 (1)
Target therapy	2 (2)
Response rate at 1st assessment	
Complete response , n (%)	10 (11)
Partial response , n (%)	25 (26)
Stable disease , n (%)	35 (37)
Progression disease , n (%)	25 (26)
ORR, n (%)	35 (37)
DCR, n (%)	38 (40)

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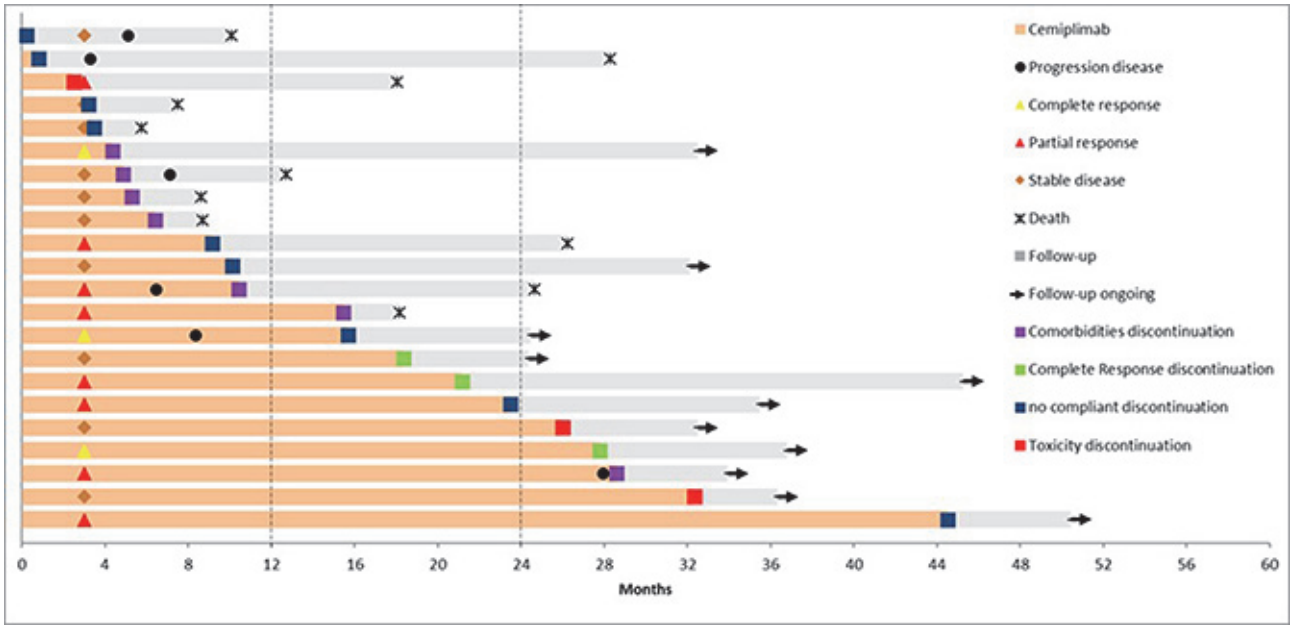

Abstract 579 Figure 4