A pooled analysis of clinical outcomes with anti-PD1-based neoadjuvant immunotherapy (NeoIT) in cutaneous squamous cell carcinoma (cSCC).

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Background

- Anti-PD1 immunotherapy has shown improved clinical outcomes in patients with advanced cSCC[1,2], and recently, in the neoadjuvant setting for resectable disease[3].
- Pathological response is predictive of recurrence in melanoma[4] and recent NeoIT trials suggests the same in cSCC[3]; however, an analysis of clinical outcomes in patients with resectable cSCC treated with intended anti-PD1-based NeoIT in larger datasets remains unknown.

Objectives

We sought to:

1) Study the recurrence-free survival based on pathological response.
2) Assess the clinical outcomes for those patients who did not proceed with surgery after immunotherapy with neoadjuvant intention.

Methods

- 134 patients with resectable cSCC treated with intended anti-PD1-based NeoIT from 17 cancer centres globally were included.
- Demographics, disease characteristics, pathological response, recurrence-free survival (RFS) or progression-free survival (PFS) were examined.
- Pathological response was assessed according to Tetzlaff *ne* .[5]
- Survival outcomes were described using Kaplan-Meier method and log rank test to evaluate the difference in survival curves between groups.

Results

TABLE 1. Baseline characteristics.

Variables (N, %)[1]	Cohort (n=134)
Age	
Median (range)	75 (39 – 97)
Sex	
Male	97 (72%)
Immunocompromised	29 (22%)
ECOG PS[2]	
≥1	58 (43%)
Known primary	125 (93%)
Head & Neck	102 (82%)
Not head & neck,	23 (18%)
Stage	
III/IV	106 (79%)
Treatment	
PD1	122 (91%)
PD1 +/- investigational agent	12 (9%)

[1] Except for Age (reported in median, range), all other variables are reported with N and %.
[2] ECOG PS, Eastern Cooperative Oncology Group Performance Status

Results

In this real-world study, anti-PD-1 based NeoIT in resectable cSCC is associated with high clinical response and major pathologic response rates.

66 (49%) patients underwent surgery

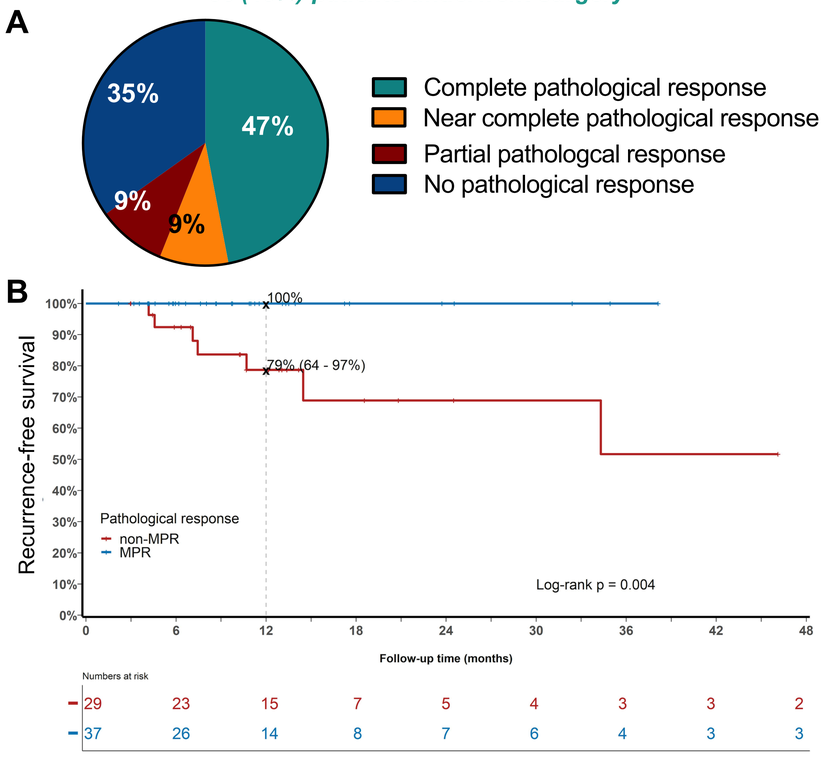

FIGURE 1. Clinical outcomes of patients treated with neoadjuvant immunotherapy followed by surgery. (A) Pathological response (complete pathological response [pCR], near complete pathological response [near-pCR], pathological partial response [pPR], and no pathological response [pNR]). **(B)** Recurrence-free survival in MPR (pCR + near-pCR; n=37; *blue*) *versus.* non-MPR (pPR and pNR; n=29; *red*) patients.

68 (51%) patients did not have surgery

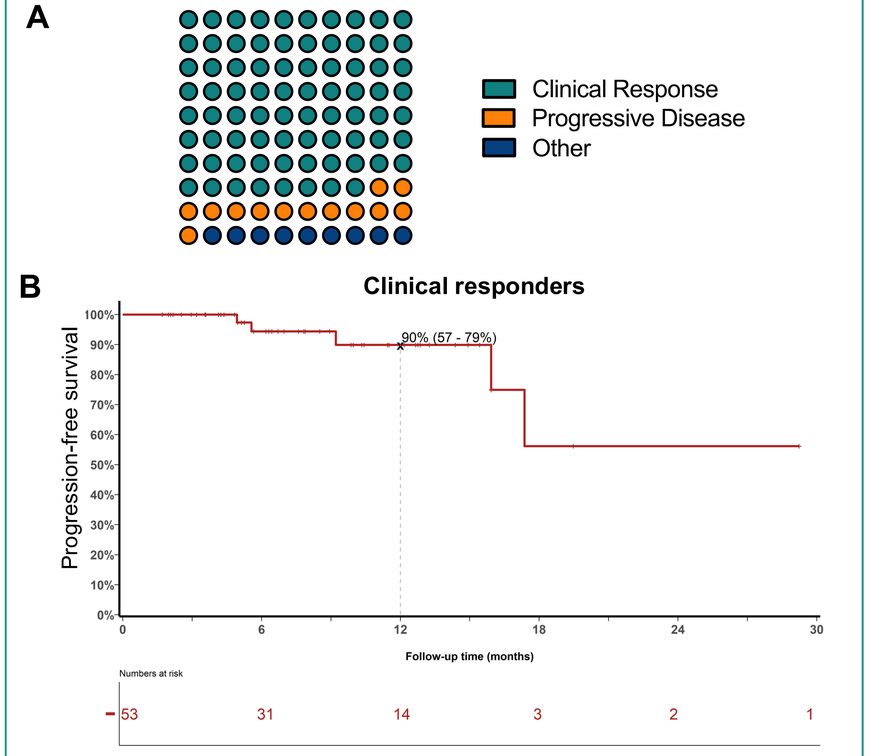

FIGURE 2. Clinical outcomes of patients treated with intended neoadjuvant immunotherapy who did not proceed with surgery. (A) Reasons not to have proceeded with surgery. **(B)** Progression-free survival of those patients (n=53) who did not proceed with surgery due to clinical response (9% of these patients progressed).

Conclusions

- Anti-PD1-based NeoIT is an active regimen in resectable stage II-IV cSCC and is associated with high clinical response and MPR rates; none of the patients within this cohort with MPR from NeoIT has recurred to date.
- 9% of patients who did not have surgery due to clinical response eventually progressed.
- These findings highlight the importance of further research to investigate the role of surgery in this subgroup of patients.

References

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