SKIN CANCER (OTHER THAN MELANOMA)

DURATION OF RESPONSE (DOR) ANALYSIS OF CEMIPLIMAB, A HUMAN MONOCLONAL ANTI-PD-1, IN THE PHASE 2 STUDY OF PATIENTS WITH ADVANCED CUTANEOUS SQUAMOUS CELL CARCINOMA (CSCC)

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Background: Cemiplimab showed substantial antitumour activity in patients with advanced CSCC from two Phase 2 study groups.

Objective: To assess DoR to cemiplimab in the Phase 2 study of patients with advanced CSCC (NCT02760498).

Materials and Methods: Patients with metastatic CSCC (mCSCC; Group 1) or locally advanced CSCC (laCSCC; Group 2) received cemiplimab 3 mg/kg IV over 30 minutes Q2W. Tumour measurements were performed per RECIST 1.1 Q8W. This analysis included patients with mCSCC or laCSCC who started study treatment at least 6 or 9 months, respectively, before Oct 27, 2017 (data cut-off date).

Results: Eighty-two patients were eligible (median age: 70 years [range: 38–96]; 59 mCSCC and 23 laCSCC; ECOG performance status: 0 and 1 in 36 and 46 patients, respectively). Thirty-nine patients (47.6%) had received prior systemic therapy and 64 (78.0%) had received prior radiotherapy. Median duration of follow-up was 8.6 months (range: 0.8–15.9). Overall response rate by central review was 46.3% (95% CI: 35.3–57.7; 4 complete responses and 34 partial responses). Median DoR has not been reached. At the time of data cut-off, the longest DoR was 12.9+ months and was consistent between patient groups. Among the 38 responding patients, 32 (23 mCSCC and 9 laCSCC) continued treatment and maintained response at the time of data cut-off. DoR exceeded 6 months in 23 (60.5%) patients. Only 3 responding patients (all with mCSCC) had subsequent disease progression at the time of data cut-off. Median time to response was 1.9 months (range: 1.7–7.6). Updated response data will be analysed in October 2018. The most common treatment-emergent adverse events (any grade) regardless of attribution were diarrhoea and fatigue (each 28.0%).

Conclusions: In this analysis, cemiplimab showed substantial activity with responses ongoing at the time of data cut-off. The safety profile was comparable with other anti-PD-1 agents.