In both subgroups, there was a numerical trend in TTD in GHS/QoL favouring cemiplimab (squamous: Functioning, symptom and GHS/QoL scales from the EORTC QLQ-C30 and QLQ-LC13 are presented in this paper).

Statistical analysis

• Mixed-model repeated-measures (MMRM) analyses were performed to compare overall change from baseline between the two treatments, while controlling for baseline characteristics.

• TTD was based on a 10 point threshold was identified using a stratified log rank test and Cox proportional hazards model.

Results

Baseline characteristics

• There were 925 patients with PD-L1 TPS ≥50%. Approximately 43% of patients had squamous cell histology (cemiplimab, n=392; chemotherapy, n=433), and 57% of patients had non-squamous cell histology (cemiplimab, n=161; chemotherapy, n=159). Most patients were males (92% and 89.2% respectively), with a median age of 63-64 years (Supplementary Table 1).

• For every cycle from baseline to Cycle 6, most patients in the cemiplimab and chemotherapy arms (>97% and >96% respectively) completed at least one question each on the EORTC QLQ-C30 and QLQ-LC13 questionnaires.

MMRM analysis

• A statistically significant difference in overall change from baseline in GHS/QoL favouring cemiplimab was found in physical and social functioning, fatigue, nausea/vomiting and appetite loss, and peripheral neuropathy and alopecia (QLQ-LC13) (Figure 1).

TTD analysis

• In both subgroups, there was a numerical trend in TTD in GHS/QoL favouring cemiplimab (squamous: Physical functioning, Fatigue, Dyspnoea, Constipation, Constipation; and peripheral neuropathy and alopecia for QLQ-C30; and peripheral neuropathy and alopecia for QLQ-LC13). When comparing treatment arms, no analysis revealed statistically significant MMRM functions for favouring chemotherapy for any QLQ-C30 or QLQ-LC13 scale (Supplementary Figure 2).