Health-Related Quality of Life (HRQL) in Patients with Advanced Squamous Cell Carcinoma (SCC) Treated with Cemiplimab: Post Hoc Exploratory Analysis of a Phase 2 Clinical Trial

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Abstract

Purpose: To explore whether two independent multicenter, randomized Phase 2 clinical trials of cemiplimab in patients with advanced squamous cell carcinoma (SCC) of the skin demonstrated a clinically meaningful improvement in health-related quality of life (HRQL) and functional status (FS) in key domains of HRQL as measured by the EORTC QLQ-C30 and QLQ-C30 subscales.

Methods: The two Phase 2 trials were of patients with advanced squamous cell carcinoma of the skin (CSCC) treated with cemiplimab intravenous bolus 3 mg/kg every 2 weeks (Q2W; n=193) or every 3 weeks (Q3W; n=56) for 12 treatment cycles. A responder analysis was also conducted at cycle 6 and cycle 12 based on the change from baseline in the primary objective.

Results: Baseline scores for QLQ-C30 indicated generally moderate to high levels of functioning and moderate to low levels of symptom burden (Table 1). The mean improvements from baseline to cycle 12 in QLQ-C30 scale scores were 12.9±11.5 (cyclin) and 16.1±11.8 (globe) across all domains (p<0.001). Ninety-five percent of patients (95%) reported a meaningful improvement (≥10 points) in pain score at cycle 3 (LS mean change −12.8±28.0; n=59). Social function and fatigue showed lower improvement, with 82% of patients showing a meaningful improvement (≥10 points). The most common malignancy in the US, although its exclusion from national cancer registries has presented a barrier to epidemiologic characterization. Treatment cycle length was 8 weeks for Groups 1 and 9 weeks for Group 2. No new safety signals emerged with longer follow-up. The most common malignancy in the US, although its exclusion from national cancer registries has presented a barrier to epidemiologic characterization. Treatment cycle length was 8 weeks for Groups 1 and 9 weeks for Group 2. No new safety signals emerged with longer follow-up. The most common malignancy in the US, although its exclusion from national cancer registries has presented a barrier to epidemiologic characterization. Treatment cycle length was 8 weeks for Groups 1 and 9 weeks for Group 2. No new safety signals emerged with longer follow-up. The most common malignancy in the US, although its exclusion from national cancer registries has presented a barrier to epidemiologic characterization. Treatment cycle length was 8 weeks for Groups 1 and 9 weeks for Group 2. No new safety signals emerged with longer follow-up.

References