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

Background

- Cutaneous squamous cell carcinoma (CSCC) is considered the second most common malignancy in the US, although its exclusion from non-cancer clinical trials has presented a bias against biomarker and epidemiologic characterization.
- Estimates suggest an incidence of around 1.5 million cases per year in the US.
- The incidence of CSCC is increasing yearly in the US.
- Most CSCC patients have a favorable prognosis, but for the patients who are not amenable to curative surgery, palliative systemic therapy has been administered.
- Cemiplimab is a programmed cell death-1 (PD-1) inhibitor that is indicated for treatment of CSCC in patients with metastatic (mCSCC) or locally advanced (laCSCC) disease not amenable to curative surgery or radiation.
- Cemiplimab demonstrated a robust clinical response and a safety profile consistent with other checkpoint inhibitors in a recent Phase 2 trial (NCT03794898).

Objective

- This post hoc exploratory analysis examined the QLQ-C30 data from a Phase 2 clinical trial to assess the effects of cemiplimab treatment on HRQL and pain.

Methods

- For inclusion in the Phase 2, non-randomized, global, pivotal trials of Cemiplimab for locally advanced or metastatic CSCC, patients were required to have not been amenable to curative surgery or curative radiotherapy according to the investigator.
- Patients were administered cemiplimab at a dosage of 3 mg/kg every 2 weeks (Q2W; mCSCC n=59; laCSCC n=78), 3 mg/kg every 3 weeks (Q3W; mCSCC n=56) or 350 mg every 3 weeks (Q3W; mCSCC n=56) for 12 treatment cycles or 350 mg every 3 weeks (Q3W; mCSCC n=56) for 12 treatment cycles or 350 mg every 8 weeks.
- Treatment cycle length was 8 weeks for Groups 1 and 2 and 9 weeks for Group 3.

Results

- A total of 193 adult patients were enrolled in the study, and demographic characteristics were generally similar across the treatment groups.

Conclusions

- This was a non-randomized, single-arm, open-label study.
- The 10-point threshold considered indicative of a clinically meaningful change was not validated for this specific patient population (i.e., advanced CSCC).
- In advanced CSCC patients, treatment with cemiplimab resulted in clinically meaningful reduction in pain as early as cycle 4 with statistically significant improvement observed after cycle 12.
- Cemiplimab demonstrated clinically meaningful improvement or stability in global health status/HRQL and pain.
- These results further support cemiplimab as a new standard of care option in the treatment of advanced CSCC.

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