Health-related quality of life in patients with metastatic basal cell carcinoma treated with cemiplimab: Analysis of a phase 2 open-label clinical trial

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Background

Patients with metastatic basal cell carcinoma (mBCC) who are not candidates for surgery or radiation therapy are generally treated with targeting signaling pathways inhibitors (HHIs).1

However, intolerance and resistance to HHIs are common.1

– Intolerance and resistance are generally treated with hedgehog signaling pathway inhibitors (HHIs).1

Response to HHIs was based on histologic confirmation of distant BCC metastases to lung, liver, bone, or lymph node, and included patients with both local and distant metastatic disease.

At baseline and Day 1 of each treatment cycle, patients were administered the European Organisation for Research and Treatment of Cancer Quality of Life-C30 (EORTC QLQ-C30) and Skindex-16 questionnaires (Table 1).

Objective

To evaluate HRQoL in patients with mBCC who were treated with cemiplimab in the phase 2 clinical trial.

Methods

In the phase 2 trial, non-randomized, open-label, single-arm, phase II trial of mBCC adults (≥18 years old) with mBCC and Eastern Cooperative Oncology Group performance status (CPS) ≤ 1 received cemiplimab 3 mg/kg every 3 weeks for up to 9 treatment cycles.

– Cemiplimab was based on histologic confirmation of distant BCC metastases to lung, liver, bone, or lymph node, and included patients with both local and distant metastatic disease.

Analyses were conducted on the full analysis set, which consisted of all enrolled patients who were deemed eligible for the study.

Follow-up assessment was conducted 28–42 days after the last study treatment administration if a patient discontinued early.

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Responder analyses were conducted in patients with non-missing data to determine the proportions with clinical meaningful improvement, maintenance, or clinically meaningful deterioration on the Skindex-16 at Cycles 2, 6, and 9.

– Similar results were generally observed at Cycles 2 and 6.

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In MMRM analysis, overall changes from baseline across the study period indicated maintenance of HRQoL and functioning items.

– In the responder analysis, clinically meaningful improvement or maintenance on all QLQ-C30 scales was reported by 80.6% of patients at Cycle 9 (Figure 4).

Results

Table 1. EORTC QLQ-C30 and Skindex-16 assessments

The EORTC QLQ-C30 is a standard instrument in oncology to evaluate the health-related quality of life (HRQoL) of patients to provide comprehensive assessment of QoL before, during, and after treatment.

The Skindex-16 assesses impact of skin diseases on HRQoL, over the past week with weights on 1 (least bothersome) to 7 (most bothersome) for the past week.

– Scores range from 0 to 100; higher scores on functional domain scales and lower scores on symptom scales reflect better outcomes.

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– Responders analyses were conducted in patients with non-missing data to determine the proportions with clinically meaningful improvement or deterioration, or maintenance from baseline on QLQ-C30 and Skindex-16 at Cycles 2, 6, and 9.

– Maintenance was defined as either improvement not deterioration that was clinically meaningful.

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– The patient population was 61.6% male, with a mean (SD) age of 61.0 (11.0) years (Table 2).

– Two-thirds of the patients (67%) had ECOC performance status of 0, and disease progression was the primary reason for discontinuation of prior HHI therapy.

– The small sample sizes (≤10 patients) in the later cycles (Cycle 8 and 9) limit data interpretability.

Table 2. Patient characteristics at baseline (N=54)

In contrast to the QLQ-C30, to the best of our knowledge reference values have not been determined for the Skindex-16.

– Changes from baseline were neither clinically meaningful nor statistically significant relative to baseline.

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– Change from baseline ≥10 points was considered clinically meaningful (change ≥10 points).

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– Limitations

– This was a single-arm, non-randomized, open-label study.

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– Clinically meaningful changes were based on prior literature and anchor-based approaches to derive clinically meaningful changes.

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Conclusions

– Results of this pivotal clinical trial (this study) showed that, in addition to providing clinically meaningful antitumour activity and durable responses in patients with mBCC, cemiplimab reported HRQoL was maintained during the study.

– From baseline to Cycle 9, most patients treated with cemiplimab reported: Maintenance of HRQoL in QLQ-C30 (54.5%) and functioning while maintaining a low symptom burden.

– Maintenance across all 3 scales in the Skindex-16.

References