Background

Cemiplimab (PD-1 inhibitor with high avidity) is one of the most common cancers worldwide and is viewed in nodules or lesions by both basal and squamous cell carcinoma (BCC). In this phase 2b study, we examined the clinical activity of cemiplimab in patients with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC).

Methods

Adult patients with metastatic or locally advanced CSCC who fulfilled the criteria for advanced CSCC (metastatic or locally advanced, derived durable clinical benefit from prior treatments) were eligible for enrollment. The primary endpoint of the trial was clinical activity as per independent central review (ICR). Secondary endpoints included overall survival (OS), progression-free survival (PFS), and safety assessment. The trial was conducted at 104 sites in 21 countries (clinicaltrials.gov #NCT02826242).

The data cut-off for this analysis was September 20, 2018.

Results

Baseline characteristics, disposition, and treatment exposure

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<th>Group</th>
<th>Baseline characteristics</th>
<th>Disposition</th>
<th>Treatment exposure</th>
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<tbody>
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<td>Group 1 (metastatic CSCC; n = 45)</td>
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<td>Group 2 (locally advanced, n = 30)</td>
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Clinical activity

- **ORR:** 45.6% (95% CI: 32.9–58.2) with complete response (CR) in 9.3% of patients (95% CI: 3.6–15.1)
- **PFS:** 18.4 months (95% CI: 7.3–not evaluable) with a median follow-up of 12 months
- **OS:** not reached (95% CI: 57.0–80.6)

Treatment-emergent adverse events

- **Grade ≥3 TRAEs:** 10.2% of patients with serious TRAEs including pneumonitis (n=3; 5.1%) and aseptic meningitis, confusional state, hypercalcemia, new primary CSCC, pleural effusion, and pneumonia
- **6 patients (10.2%) experienced serious grade ≥3 TRAEs:** Pneumonitis (n=3; 5.1%) and aseptic meningitis, confusional state, hypercalcemia, new primary CSCC, pleural effusion, and pneumonia

Conclusions

- The clinical activity of cemiplimab in patients with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) was durable with manageable safety. Cemiplimab 3 mg/kg Q2W had an acceptable safety profile in metastatic CSCC. There were no new TEAEs resulting in death in this 12-month follow-up analysis.

References