Primary Analysis of Phase 2 Results for Cemiplimab, a Human Monoclonal Anti-PD-1, in Patients with Metastatic Cutaneous Squamous Cell Carcinoma

**Background**

Cutaneous squamous cell carcinoma (CSCC) is prevalent in incidence only to basal cell carcinoma as the most common cancer in the US. Basal cell carcinoma accounts for 80% of nonmelanoma skin cancers, and metastatic (nodal and/or distant) CSCC is the 6th most common cancer in the US. More than 95% of CSCC patients are cured with surgery; however, current therapies are effective only in a limited proportion of patients whose disease has spread beyond the primary tumor. Cemiplimab (MedCorbitt CR-80176), a human monoclonal anti-PD-1 antibody, demonstrated antitumor activity in patients with advanced CSCC.

**Methods**

- **Primary endpoint:** Best overall response Rate (ORR).
- **Secondary objectives:** Included overall response rate (ORR), duration of response (DoR), progression-free survival (PFS), and overall survival (OS) in patients with advanced CSCC.

**Results**

- **Baseline characteristics:** The median age was 71 years (range 18–96), 54% were female, and 91% had a Performance Status (PS) of 0 or 1. Most patients (74%) had prior radiotherapy.
- **ORR:** The ORR was 52% (95% CI: 37.0–65.8) with a median duration of response of 7.9 months (range: 1.1–15.6).
- **PFS:** The median PFS was 52.5% (95% CI: 37.0–65.8) with a median duration of response of 7.9 months (range: 1.1–15.6).

**Conclusion**

- Cemiplimab showed an acceptable risk/benefit profile in this metastatic CSCC population, which is likely to be extended to first-line with medical oncologists.
- With an outcome of death (including death due to metastatic disease), overall survival was 91.9% (95% CI: 85.9–96.8). The median duration of response was 7.9 months (range: 1.1–15.6).

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**References**