To present efficacy and safety data from a metastatic cutaneous squamous cell carcinoma (mCSCC) registration-enabling expansion cohort from a phase 1, open-label, global, multicenter trial of cosibelimab in patients with advanced cancers (NCT03124114).

**INTRODUCTION**

- Cutaneous squamous cell carcinoma is one of the most common human cancers in the United States, and advanced or metastatic disease is associated with substantial morbidity and mortality.
- PD-L1 is a high-affinity, fully human programmed death-ligand 1 (PD-L1)-binding monoclonal antibody with a functional humanized Fc domain, enabling ADCC and CDC and supporting clinical activity across multiple tumor types.

**MATERIALS AND METHODS**

- **PATIENTS**
  - Key eligibility criteria for patients included in the study are shown in Table 1. A total of 78 patients with mCSCC received cosibelimab 800 mg Q2W.
  - Median duration of follow-up was 15.2 months.

- **STUDY DESIGN**
  - Patients with mCSCC received cosibelimab 600 mg administered intravenously (IV) until disease progression, treatment-related adverse events (TRAEs), or study withdrawal. Complete responses (CR) were defined after radiographic confirmation of disease-free status, or clinical deterioration followed by deterioration of at least 25% in tumor diameters. Ten CRs were confirmed as of March 2022.
  - After patients stopped treatment and completed up to 3 follow-up visits, they were contacted to update tumor status until death.

**RESULTS**

- **PATIENT POPULATION**
  - Overall, 78 patients with mCSCC received cosibelimab 600 mg Q2W and comprised the safety and interim ITT (n=78). 2 of the 78 patients died because of corneal disease in 2019 (COVID-19) before conduct of any baseline response assessment or confirmed treatment discontinuation derived from the initial ITT population (n=76).
  - Patients were predominantly male (57%), aged 65 years (11%), with initial mCSCC (56%) and Eastern Cooperative Oncology Group performance status (ECOG PS) ≥1 (39%).

- **EFFICACY**
  - As of November 14, 2021, confirmed CR by ICR in the initial ITT population was 26% (95% CI: 16%-40%); Table 2.
  - Robust and durable reductions in target lesions were observed (Figures 2 and 4).
  - 13 of 26 patients achieved a CR or target lesions.
  - Median duration of follow-up was 16.2 months.
  - Kaplan-Meier–estimated probability of maintaining a response at 24 months was 98% (95% CI: 88%-100%).

- **SAFETY**
  - Treatment-related adverse events (TRAEs) were reported in 55 patients (70.5%; Table 3).
  - 4 patients (5.1%) experienced treatment-related serious adverse events (SAEs); no treatment-related SAEs occurred in >1 patient.
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**OUTCOME MEASURES**

- **Key endpoints assessed in the study are shown in Table 2.**

**CONCLUSIONS**

- Treatment with cosibelimab once every 2 weeks (Q2W) resulted in a robust objective response rate (ORR) with durable responses and demonstrated a predictable and manageable safety profile in patients with mCSCC, supporting its use in the treatment of this cancer.

- NCT03124114 is continuing enrollment of a registration-enabling cohort of patients with locally advanced cutaneous squamous cell carcinoma and a cohort of patients with mCSCC treated with a dosing regimen of 120 mg cosibelimab every 3 weeks.

**REFERENCES:**
