Background

A monoclonal antibody to PD-L1, cemiplimab (MR1), has been approved by the US Food and Drug Administration (FDA) for the treatment of advanced cutaneous squamous cell carcinoma (CSCC) based on a Phase 2 trial that demonstrated substantial antitumor activity (ORR 40.7%) with durable responses, and manageable toxicity. Cemiplimab is also being studied in several other cancer indications. This report provides additional, updated analysis of the Phase 2 trial for 78 patients with advanced CSCC.

Methods

A total of 78 patients with advanced CSCC (Group 1) from the Phase 2 study were included in this analysis. Efficacy was assessed according to Response Evaluation Criteria in Solid Tumors (RECIST 1.1) for scans; modified World Health Organization criteria (for photos) and Eastern Cooperative Oncology Group (ECOG) performance status. Patients were treated with cemiplimab 3 mg/kg intravenous administration every 2 weeks for up to 36 cycles or until disease progression.

Results

Baseline characteristics, disposition, and treatment exposure

A total of 78 patients were enrolled and treated with cemiplimab 3 mg/kg Q2W (Table 1, Figure 2). Ten patients had received one prior cancer-related systemic therapy and two had received ≥2 prior cancer-related systemic therapies. Disease control was observed in 50/78 (64.1%) patients, with 43/78 (55.1%) patients having confirmed complete or partial responses. The Kaplan-Meier estimated progression-free probability at 12 months was 79.5% (95% confidence interval [CI]: 66.6–88.3). The safety profile of cemiplimab was manageable, with grade ≥3 adverse events occurring in 25% of patients; no new safety signals emerged.

Conclusions

Cemiplimab produced substantial antitumor activity with durable responses in patients with advanced CSCC that was technically amenable to surgery but clinically inappropriate for surgery. The study was funded by Regeneron Pharmaceuticals, Inc., and Sanofi. Medical writing support was provided by Laura Bruno, MSc.

Acknowledgments

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References


Figure 2. Primary analysis of Phase 2 Results of Cemiplimab, a Human Monoclonal Anti–PD–1, in Patients with Locally Advanced Cutaneous Squamous Cell Carcinoma

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