Cemiplimab (REGN2810) is a human immunoglobulin G4 monoclonal antibody directed against PD-L1.

**Background**

- Cemiplimab (REGN2810) is a human immunoglobulin G4 monoclonal antibody directed against PD-L1.
- Phase 1 results from the first 48 patients with advanced solid tumors showed no dose-limiting toxicities.
  - The most common treatment-related adverse events were fatigue (38%), anemia (12%), and nausea (12%).
  - The overall response rate was 18%.
  - Cemiplimab 3 mg/kg every 2 weeks (Q2W) was selected for further study in Expansion Cohorts.
  - Research biopsies were performed at baseline and at Day 29.

**Objectives**

- To characterize the safety and tolerability of intravenous cemiplimab 3 mg/kg.
- To assess clinical activity in advanced CSCCs.
- To evaluate PD-L1 expression by immunohistochemistry.

**Methods**

- Study design: CSCC expansion cohorts
- Cohort 1 enrolled 10 patients with mCSCC; cohort 2 enrolled 10 patients with intermediate- and locally advanced CSCC.

**Results**

- **PD-L1 expression**:
  - Five patients were evaluable by immunohistochemistry:
    - Three of 5 patients with confirmed responses (60%) were positive (≥1%) for PD-L1 by immunohistochemistry.
    - One patient had negative PD-L1 expression.

**Patient characteristics**

- **Cohort 1**: 10 patients with mCSCC.
- **Cohort 2**: 10 patients with intermediate- and locally advanced CSCC.

**Tumor response**

- **Complete response (CR)**: 0/20 (0%)
- **Partial response (PR)**: 2/20 (10%)
- **Stable disease (SD)**: 14/20 (70%)

**Stable disease**

- **Number of patients with confirmed responses**: 11
- **Number of patients with evaluable lesions**: 11
- **Number of patients with lesions with measurable change**: 9

**Treatment-emergent adverse events (TEAEs)**

- **Any grade**:
  - Fatigue: 14/20 (70%)
  - Dyspnea: 6/20 (30%)
  - Hypertension: 5/20 (25%)
  - Anemia: 4/20 (20%)
  - Constipation: 3/20 (15%)
- **Grade 3 or 4**:
  - Hypertension: 1/20 (5%)
  - Fatigue: 2/20 (10%)

**Disclosure**

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- **Marta Gil Martin**: no disclosures.
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**Figure 3.** Change in target lesion over time

**Figure 4.** Case response to cemiplimab in an 86-year-old male with metastatic CSCC (Figure 3)

**Table 1.** Patient characteristics and response to cemiplimab

**Table 2.** Tumor PD-L1 expression (immunohistochemistry, using two biomarkers)

**Table 3.** Best overall tumor response rate by cohort

**Table 4.** Impact of baseline PD-L1 expression on tumor response.