169 PRISM: Primary Efficacy Results of a Phase 2 Trial with Panitumumab Monotherapy as Second-Line Treatment in Patients with
Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (R/M SCCHN)

D. Rischin*[1], D. Spigel*[2], D. Adkins*[3], R. Wein*[4], S. Arnold*[5], M. L. Davis*[6], N. Singhal*[7], A. Xue*[8], B. Bach*[8]. , [1]*Peter MacCallum Cancer Centre, East Melbourne, Australia,* [2]*Sarah Cannon Research Institute, Nashville, TN,* [3]*Washington University School of Medicine, St. Louis, MO,* [4]*Tufts Medical Center, Boston, MA,* [5]*University of Kentucky, Markey Cancer Center, Lexington, KY,* [6]*Capital District Health Authority, QEII Health Sciences Centre, Halifax, NS, Canada,* [7]*Royal Adelaide Hospital, Adelaide, Australia,* [8]*Amgen Inc., Thousand Oaks, CA*

Purpose/Objective(s): Panitumumab is a fully human monoclonal antibody targeting the epidermal growth factor receptor (EGFR). PRISM evaluated the safety and efficacy of panitumumab as second-line monotherapy in patients with R/M SCCHN. **Materials/Methods:** This is an open-label, single-arm, multicenter trial that enrolled patients with histologically or cytologically confirmed SCCHN. Key eligibility criteria included: at least 18 years old and progressive disease (PD) or intolerance to first-line systemic chemotherapy for R/M SCCHN. Patients received panitumumab 9 mg/kg Q3W until PD or intolerability. Tumor response was evaluated using modified RECIST 1.0 criteria every 6 weeks +/- 1 week. The primary endpoint was objective response rate (ORR); secondary endpoints included disease control (DC) rate, overall survival (OS), progression-free survival (PFS), and safety. **Results:** 52 patients were enrolled and received at least 1 panitumumab dose; 69% were men; median age was 61 years; ECOG performance score was 0 (38%), 1 (60%), or 2 (2%). The distribution of the primary tumor sites were oral cavity (38%), oropharynx (35%), larynx (25%), and hypopharynx (2%). 79% of patients had metastatic disease and 21% had locoregionally recurrent disease only. 92% of patients received prior radiotherapy, 92% prior platinum-based chemotherapy, 65% prior taxane, 40% prior fluoropyrimidine, and 10% prior EGFR inhibitor therapy. 94% of patients ceased first-line chemotherapy treatment due to PD; 6% due to chemotherapy intolerance. The RECIST confirmed partial response (PR) rate was 4% (2/51 patients) and the DC rate was 39% (20/51 patients). Two patients had an unconfirmed PR and one patient had an unconfirmed complete response; all three were considered to have a best response of stable disease per study criteria. Median PFS was 1.4 months (95% CI, 1.3 - 2.4 months). Median OS was 5.1 months (95% CI, 4.3 - 8.3 months). One patient has prolonged and continued disease stabilization (N = 25 cycles). The most common adverse events (AEs) were rash/dermatitis acneiform (69%), fatigue (33%), dry skin (21%), and hypomagnesemia (21%). 18 patients (35%) had a worst grade 3 AE and 4 patients (8%) had a worst grade 4 AE. Five patients died on study; one was deemed treatment-related (angioedema). **Conclusions:** Panitumumab monotherapy was generally well tolerated and had activity in previously treated patients with R/M SCCHN in the second-line setting.

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