Avelumab in patients with metastatic adrenocortical carcinoma (mACC): Results from the JAVELIN solid tumor trial

C Le Tourneau1, C Zarwan2, C Hoimes3, D.J. Wong4, S. Bauer5, M. Wermke6, H.J. Grote7, A. von Heydebreck8, K. Chin9, J. Gulley10

1Department of Medical Oncology, Institut Curie, Paris, France, 2Medical Oncology, Lahey Hospital and Medical Center, Burlington, MA, USA, 3Hematology and Oncology, Case Western Reserve University and University Hospitals Seidman Cancer Center, Cleveland, OH, USA, 4Department of Medicine, University of California, Los Angeles Medical Center, Los Angeles, CA, USA, 5Department of Medical Oncology, University Hospital Essen Westdeutsches Tumourzentrum, Essen, Germany, 6Early Clinical Trial Unit, Universitätsklinikum Dresden, Dresden, Germany, 7Oncology, Merck KGaA, Darmstadt, Germany, 8Biostatistics, Merck KGaA, Darmstadt, Germany, 9Immune-Oncology, EMD Serono, Inc, Billerica, MA, USA, 10Genitourinary Malignancies Branch, National Cancer Institute, Bethesda, MD, USA

Background: Avelumab is a human anti–PD-L1 IgG1 antibody that has shown promising clinical activity in multiple tumor types, and is approved in the US for the treatment of metastatic Merkel cell carcinoma. Here, we report an updated analysis of avelumab in patients with mACC, representing the largest prospective monotherapy study performed to date in this rare cancer with limited therapeutic options.

Methods: In a phase 1b cohort (NCT01772004), pts with mACC and prior platinum-based therapy received avelumab at 10 mg/kg IV Q2W until progression, unacceptable toxicity, or withdrawal. Prior and ongoing treatment with mitotane was permitted. Tumors were assessed every 6 wks (RECIST v1.1). Endpoints included safety (NCI-CTCAE v4.0), best overall response, objective response rate (ORR), progression-free survival (PFS), and overall survival (OS).

Results: As of Dec 31, 2016, 50 pts from 6 countries received avelumab for a median of 3.4 mos (0.5–24.8). Median follow-up was 16.5 mos (11.7–27.6); 5 pts (10.0%) remained on treatment. Median age was 50 y (range 21–71) and median time since diagnosis of metastatic disease was 14.5 mos. 24 pts (48.0%) had received ≥2 prior lines of treatment for advanced disease (median 1, range 0–6). 41 pts (82.0%) had a treatment-related adverse event (TRAE) of any grade; the most common (>15%) were nausea (20.0%) and fatigue (18.0%). 8 pts (16.0%) had a grade ≥3 TRAE, of which only increased ALT (4.0%) occurred in >1 pt. 12 pts (24.0%) had an immune-related AE of any grade. Confirmed ORR was 6.0% (3 partial responses; 95% CI 1.3–16.5); response was ongoing in 1 pt at data cutoff. 21 pts (42.0%) had stable disease as best response.

Conclusion: Avelumab had a manageable safety profile and demonstrated clinical activity in pts with platinum-treated mACC.

Clinical trial identification: NCT: NCT01772004 Protocol: EMR 100070-001

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