1290P Avelumab in European patients (pts) with metastatic Merkel cell carcinoma (mMCC): Experience from an ad-hoc expanded access program (EAP)

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Background: Avelumab—a human anti–PD-L1 IgG1 monoclonal antibody—showed favorable efficacy and safety in pts with mMCC in the phase 2 JAVELIN Merkel 200 trial (NCT02155647), leading to its approval in multiple countries. Here, we describe real-world experience with avelumab in European pts with mMCC.

Methods: European pts participating in the EAP (NCT03089658) had stage IV mMCC and progressive disease (PD) on/after chemotherapy or were ineligible for either chemotherapy or participation in clinical trials. In contrast to JAVELIN Merkel 200, pts could have ECOG PS $\geq$ 2, treated brain metastases, or immunosuppressive conditions. Pts received a 3-mo supply of avelumab (administered 10 mg/kg IV Q2W until PD or unacceptable toxicity); resupply was allowed for pts with complete response (CR), partial response (PR), stable disease, or clinical benefit per physician assessment. No central imaging was obtained.

Results: As of April 30, 2018, of 521 requests for avelumab across 37 countries, 343 were received in Europe: 305 were approved (including 20 for immunocompromised [IC] pts), 29 were medically rejected, and 9 were withdrawn. Most requests were from France (n = 96) and Italy (n = 87). 275 European pts received avelumab. Median age was 73 y (range, 28-95 y), and 69% of pts were male. Of 250 pts on treatment >3 mo, 145 (58%) had either unevaluable tumors or no data reported (including 11 IC pts). Of 105 evaluable pts, physician-assessed objective responses were observed in 54.3% (57 pts; including 3 IC pts [2 CR and 1 PR]) with 25.7% CR (27 pts) and 28.6% PR (30 pts). Median duration of treatment in pts with response was 195 d (range, 30-570 d). The disease control rate in evaluable pts was 75%. No new safety signals were reported. The EAP is ongoing but closing in 2018 as required postapproval.

Conclusions: The avelumab EAP provides an alternative treatment option for pts with mMCC with PD on/after chemotherapy or who are ineligible for either chemotherapy or clinical trials. In a real-world setting, avelumab showed efficacy and safety consistent with JAVELIN Merkel 200.

Clinical trial identification: Trial Protocol Number: NCT03089658.

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