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# The Medical Letter®

## on Drugs and Therapeutics

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### IN BRIEF

## Avelumab (*Bavencio*) for Metastatic Merkel Cell Carcinoma

The FDA has approved the fully-human programmed death ligand 1 (PD-L1) blocking antibody avelumab (*Bavencio* – EMD Serono/Pfizer) for treatment of metastatic Merkel cell carcinoma (MCC) in patients  $\geq 12$  years old. Avelumab is the first drug to be approved in the US for this rare skin cancer. About 1600 people in the US, most commonly older adults (mean age at presentation is 75 years), are diagnosed each year with MCC. Most of these patients can be treated with surgical resection, but ~50% will have a recurrence and >30% will eventually have metastatic disease. Median progression-free survival in patients with metastatic disease has been about 3 months with chemotherapy. MCC tumors, which often express PD-L1, have been treated off-label with the PD-1 inhibitors pembrolizumab (*Keytruda*)<sup>1</sup> and nivolumab (*Opdivo*).<sup>2</sup>

In an ongoing single-arm trial (JAVELIN Merkel 200), 88 patients with metastatic MCC (58 with PD-L1 positive tumors, 16 PD-L1 negative, 14 not assessable) who were previously treated with at least one chemotherapy regimen received at least one dose of avelumab; 75% of patients were 65 years or older. An objective response occurred in 28 patients (32%); 8 patients had a complete response. Tumor PD-L1 expression did not affect response rates. The duration of response was  $\geq 6$  months in 92% of responders.<sup>3</sup>

The most common adverse effects of avelumab in clinical trials were fatigue (50%), musculoskeletal pain (32%), diarrhea (23%), nausea (22%), rash (22%), and infusion-site reactions (22%). Serious treatment-related adverse events occurred in 6% of patients. Grade 3 or 4 adverse events (lymphopenia, elevation of creatine kinase, transaminase increases) occurred in 5% of patients. As with PD-1 inhibitors, immune-mediated adverse effects including pneumonitis, colitis, nephritis, hepatitis, and endocrinopathies (hypothyroidism, adrenal insufficiency, type 1 diabetes) can occur.

The recommended dosage of *Bavencio* is 10 mg/kg infused IV over 60 minutes every 2 weeks. The cost of one 10-mL vial containing 200 mg of the drug is \$1504; three months' treatment for a 60-kg patient would cost \$27,072.<sup>4</sup>

1. PT Nghiem et al. PD-1 blockade with pembrolizumab in advanced Merkel-cell carcinoma. *N Engl J Med* 2016; 374:2542.
2. K Mantripragada and A Birnbaum. Response to anti-PD-1 therapy in metastatic Merkel cell carcinoma metastatic to the heart and pancreas. *Cureus* 2015; 7:e403.
3. HL Kaufman et al. Avelumab in patients with chemotherapy-refractory metastatic Merkel cell carcinoma: a multicentre, single-group, open-label, phase 2 trial. *Lancet Oncol* 2016; 17:1374.
4. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: *AnalySource® Monthly*. June 5, 2017. Reprinted with permission by First Databank, Inc. All rights reserved. ©2017. [www.fdbhealth.com/policies/drug-pricing-policy](http://www.fdbhealth.com/policies/drug-pricing-policy).

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