

Avelumab safe and yields durable responses for patients with advanced Merkel cell carcinoma

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The immunotherapeutic avelumab (Bavencio) was well tolerated by patients with advanced Merkel cell carcinoma, and the majority of those whose cancer responded to avelumab treatment had durable responses, according to results from a phase II clinical trial presented here at the AACR Annual Meeting 2017, April 1-5.

"Merkel cell [carcinoma](#) is a rare type of cancer, with about 2,000 new cases diagnosed each year in the United States, but incidence has been increasing slowly over the past decade," said Howard L. Kaufman, MD, a surgical oncologist at Rutgers Cancer Institute of New Jersey in New Brunswick, New Jersey. "Patients with metastatic Merkel cell carcinoma are usually treated with chemotherapy, but the cancer nearly always recurs within six months, at which point life expectancy is only about three to six months.

"Given the lack of effective treatment options for [patients](#) with metastatic Merkel cell carcinoma whose cancer has recurred after chemotherapy, we are excited to see such a high objective response rate. It is also noteworthy that nearly all of the patients whose cancer initially responded to avelumab exhibited durable responses, with most ongoing for more than a year," continued Kaufman, who is also professor of surgery and medicine at the Rutgers Robert Wood Johnson Medical School. "Based on data from this clinical trial, avelumab became the first ever treatment approved by the U.S. Food and Drug Administration for

treating patients with this devastating disease."

Kaufman explained that avelumab targets the PD-L1 protein and that the rationale for treating patients with Merkel cell carcinoma with the immunotherapeutic came from studies showing that PD-L1 is found on tumor samples from nearly all patients with this form of [cancer](#).

Kaufman and colleagues enrolled 88 patients with metastatic Merkel cell carcinoma that had progressed after treatment with chemotherapy in the phase II clinical trial. All patients received 10 mg/kg avelumab as an intravenous infusion over one hour every two weeks.

Previously [reported](#) data showed that 28 patients had a response after 10.4 months of follow-up. Eight had a complete response and 20 partial responses.

The researchers are now reporting that after longer follow-up, the number of patients to have a response increased to 29, for an overall response rate of 33 percent after a median of 16.4 months of follow-up. In addition, the number of patients to have a complete response increased to 10 because one of the partial responses had improved to a complete response, and another patient newly recorded to have a response had a complete response.

At the time of data cutoff, 21 of the responses were ongoing and the median duration of response had not been reached. The researchers estimated that 74 percent of patients will have a response that lasts one year or longer.

Kaufman explained that the most common [treatment](#) side effects were fatigue and infusion reactions.

"The findings of long-term responses and well-tolerated safety profile

suggest that avelumab could be an important new agent for patients with Merkel cell carcinoma who have failed prior chemotherapy," said Kaufman. "Given these results, it will be interesting to determine whether response rates could be increased by giving avelumab prior to chemotherapy or in combination with other treatments."

More information: Howard L Kaufman et al. Avelumab in patients with chemotherapy-refractory metastatic Merkel cell carcinoma: a multicentre, single-group, open-label, phase 2 trial, *The Lancet Oncology* (2016). [DOI: 10.1016/S1470-2045\(16\)30364-3](https://doi.org/10.1016/S1470-2045(16)30364-3)

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