PD-1 Inhibitor Pembrolizumab Provides Long-Term Survival Benefit for Patients With Advanced Melanoma

First Report of 36-month Overall Survival Data from Patients in Early-Stage Study
May 18, 2016

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Note: Summary contains data updated not included in the abstract

ASCO Perspective

“New therapies that block the PD-1 are extending survival for many patients, and for some may offer the prospect of living longer than ever after a diagnosis with advanced melanoma. In a matter of a few years, these therapies have truly transformed the outlook for patients with melanoma and many other hard-to-treat cancers,” said Don S. Dizon, MD, FACP, ASCO spokesperson and moderator of today’s presscast.

ALEXANDRIA, Va. – Long-term follow-up from a phase 1b trial (KEYNOTE-001) in newly diagnosed and previously treated patients with advanced melanoma, showed that 40% of patients were alive three years after starting pembrolizumab, with similar 36-month overall survival rates in both groups. The study was featured in a press briefing today and will be presented at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.

Under accelerated review in the United States, pembrolizumab was initially approved in September 2014 for the treatment of advanced melanoma, based on data from KEYNOTE-001. Additional clinical studies (KEYNOTE-002 and KEYNOTE-006) have also shown a survival benefit with pembrolizumab in patients with advanced melanoma when compared with chemotherapy or ipilimumab.

Notably, 15% of patients in this study experienced complete remissions according to immune-related response criteria; of these patients, 89% remain in remission. Before 2011, when ipilimumab was approved as the first drug to extend survival, patients with advanced melanoma
had a median overall survival of less than one year.

“Advanced melanoma is still a very challenging cancer, which is why it is so remarkable that such a large proportion of patients see a long-term survival benefit from this therapy,” said lead study author Caroline Robert, MD, PhD, Head of the Dermatology Unit at the Institut Gustave-Roussy in Paris, France. “The results of this study further demonstrate the potential for long-term benefit with pembrolizumab.”

About the Study

The phase I study included 655 patients diagnosed with advanced melanoma. Seventy-five percent of patients had previously received other treatments, including ipilimumab. Study participants received pembrolizumab at 2 or 10 mg/kg every three weeks, or 10 mg/kg every two weeks. During the trial, 2 mg/kg every three weeks was determined to be the optimal dose. Patients remained on treatment until disease progression, intolerable toxicity or investigator decision.

Key Findings

The three-year overall survival rate for patients treated with pembrolizumab was 40%, and the median overall survival was 24.4 months.

Survival rates differed slightly, however, based on prior melanoma therapy. Among patients who had not received any prior treatment, survival was slightly higher, at 45%. Three-year survival rates were the same among patients who had previously received ipilimumab and those who had not (41% in both groups). The average time on pembrolizumab was 11.3 months. A total of 61 (9%) patients stopped pembrolizumab after a complete response was achieved, and 97% remained in remission at time of analysis. For patients who remained in remission after stopping pembrolizumab, the median time they remained in remission after stopping pembrolizumab was 10 months and ongoing. According to the researchers, while it is difficult to make any definitive conclusions based on this single-arm, early phase trial, these encouraging survival data suggest that patients can benefit from pembrolizumab regardless of whether they received previous treatments.

Overall, pembrolizumab was well tolerated, with safety and tolerability consistent with that observed in other large-scale clinical trials. The most common adverse events related to pembrolizumab were fatigue (40%), itchiness (28%) and rash (23%) and only 8% of patients stopped the treatment because of side effects related to pembrolizumab.
This study received funding and support from Merck, Kenilworth, NJ, USA.

**View the full abstract.**

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