New Dosing Schedule Allows Patients to Receive Opdivo Every Four Weeks

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The U.S. Food and Drug Administration (FDA) has approved a new dosing schedule for Opdivo (nivolumab), allowing the medicine to be offered every four weeks in addition to the previously available every two-week schedule, Bristol-Myers Squibb announced.

The approval means that physicians now may choose to prescribe Opdivo either as a 480 mg dose given every four weeks or a 240 mg dose administered every two weeks. For both regimens, the treatment can be given in shorter 30-minute infusions, cutting previous infusion time by half.

“At Bristol-Myers Squibb, we are united in our mission to fight cancer from all angles and recognize every patient has unique needs. From the introduction of our first Immuno-Oncology agent through today’s approval of flexible dosing options at two- or four-week intervals, we are relentless in pursuing innovative options for the cancer community,” Johanna Mercier, head, U.S. Commercial, Bristol-Myers Squibb, said in a press release.

The approval was based on a study showing that the safety and effectiveness of the four-week schedule is comparable to dosing every two weeks across multiple tumor types.

The findings were presented during the American Association for Cancer Research Annual Meeting 2017, in an oral presentation titled "A model-based exposure-response (E-R) assessment of a nivolumab (NIVO) 4-weekly (Q4W) dosing schedule across multiple tumor types."

The study showed that patients with melanoma, advanced non–small cell lung cancer, or advanced renal cell carcinoma treated with the four-week regimen had highly similar predicted objective tumor responses, compared to patients treated with every-two-week dosing. The difference between both groups was less than 1 percent across the different tumor types.

Patients also showed similar survival rates at one and two years.

"We continuously learn new ways to individualize treatment with immuno-oncology therapies, and in my experience, what works for one patient may not be optimal for another," said Jeffrey S. Weber, MD, PhD, deputy director of the Perlmutter Cancer Center at NYU Langone Health and professor of medicine at NYU School of Medicine.

"For instance, some patients may need the support of two-week visits with their healthcare team, while for others, a four-week interval may be more appropriate and better suited to their treatment needs. With this approval, we now have additional ways to help tailor patient care," he added.

The new 480 mg four-week regimen is under further evaluation in two trials, one for advanced or metastatic non-small cell lung cancer (NCT02713867), and one for advanced melanoma (NCT02714218).

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