FDA Approves Injectable Opdivo for Many Types of Cancer

The new injectable immunotherapy formulation shortens treatment time to about five minutes.

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On December 27, the Food and Drug Administration approved Opdivo Qvantig, an injectable formulation of the PD-1 checkpoint inhibitor nivolumab, which will reduce administration time from about 30 minutes to about five minutes and may allow patients to receive treatment in more settings.

“Receiving a cancer diagnosis can be frightening and stressful,” said Audrey Davis, LPC, of the Cancer Support Community. “Having a treatment option that may offer patients flexibility to receive treatment outside of traditional hospital settings and reduce the administration time is important. It’s exciting to see these continued advancements with immunotherapy administration that may offer another choice for patients and caregivers navigating this difficult journey.”

Opdivo, from Bristol-Myers Squibb, is a monoclonal antibody that targets an immune checkpoint that regulates immune function. Some cancers can hijack the PD-1 protein on T cells to turn off response to malignant cells. Drugs that block the interaction between PD-1 and its binding partner on tumors, known as PD-L1, can release the brakes and restore T-cell activity.

The original IV infusion formulation of Opdivo is approved for the treatment of 11 different types of cancer. The new injectable formulation is indicated—alone or in combination regimens—for most of the same malignancies, including melanoma, bladder cancer, colorectal cancer, esophageal cancer, kidney cancer, liver cancer and non-small-cell lung cancer.

Until recently, all of the nearly dozen approved checkpoint inhibitors had to be administered via intravenous infusion, a time-consuming procedure that usually takes place at an infusion center. Injectable formulations could potentially be administered at a doctor’s office, making treatment more accessible and convenient. The first injectable checkpoint inhibitor, Roche/Genentech’s Tecentriq Hybreza (injectable atezolizumab), was approved in September. Merck has also reported good results for an experimental injectable version of Keytruda (pembrolizumab).

Opdivo Qvantig and Tecentriq Hybreza both use Halozyme Therapeutics’ Enhanze drug delivery technology, which adds a hyaluronidase enzyme to increase the permeability of tissue under the skin and enables the checkpoint antibodies to be dispersed and absorbed into the bloodstream.

The approval of Opdivo Qvantig was based on findings from the randomized Phase III CheckMate-67T trial (NCT04810078), which compared the two formulations in people with previously treated advanced kidney cancer. The study showed that the injectable formulation was noninferior to the intravenous infusion, meaning it worked at least as well. Pharmacokinetic analysis showed that drug concentrations were comparable, and the overall response rate was statistically similar (24% versus 18%, respectively). The safety profiles of the two formulations were also similar.

“This approval of subcutaneous nivolumab gives our patients a new option that can deliver consistent efficacy and comparable safety expected from IV nivolumab and offers a patient-centric treatment experience,” sadi Saby George, MD, of Roswell Park Comprehensive Cancer Center, in a news release. “Opdivo Qvantig offers faster administration, delivered in three to five minutes. It may allow patients, in consultation with their doctors, to choose another treatment method and the flexibility to receive treatment closer to home.”

Click here to learn more about cancer immunotherapy.
