FDA Approves Injectable Keytruda for Many Types of Cancer

The new injection formulation of the blockbuster immunotherapy shortens treatment time to one or two minutes.

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On September 19, the Food and Drug Administration (FDA) approved Keytruda Qlex, an injectable formulation of the widely used immune checkpoint inhibitor pembrolizumab. The European Medicines Agency also recommended approval. The new version enables patients to receive a brief shot rather than a lengthy IV infusion. What's more, it facilitates administration outside of specialized centers—for example, in a doctor's office or community clinic—making treatment more accessible and convenient.

Like the original formulation, Keytruda Qlex is approved for multiple malignancies, including melanoma, non-small-cell lung cancer, bladder cancer, cervical cancer, colorectal cancer, kidney cancer, liver cancer, triple-negative breast cancer and tumors with certain biomarkers anywhere in the body.

"At Merck, we are committed to putting patients first as we work relentlessly to discover new options that may help patients manage their treatment in a way that fits their needs," Marjorie Green, MD, senior vice president and head of oncology global clinical development for Merck Research Laboratories, said in a news release.

Keytruda Qlex is indicated for adults and adolescents ages 12 and older. It is administered via a one-minute injection in the thigh or abdomen every three weeks or a two-minute injection every six weeks. In contrast, Keytruda infusions take about 30 minutes. For patients who do not require a port or whose veins are difficult to access, subcutaneous administration may simplify treatment administration, according to Merck. It also benefits hospitals, letting them free up limited infusion slots.

Until last year, all of the nearly dozen approved checkpoint inhibitors had to be administered via IV infusion, a time-consuming procedure that usually takes place at an infusion center. In September 2024, the FDA gave the green light to the first injectable checkpoint inhibitor, Roche/Genentech's Tecentriq Hybreza (injectable atezolizumab). Last December, the agency approved Bristol-Myers Squibb's Opdivo Qvantig (injectable nivolumab).

All three drugs are monoclonal antibodies that target an immune checkpoint that regulates immune function. Some cancers can hijack the PD-1 protein on T cells to turn off their 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.

To create injectable versions, the checkpoint inhibitors are combined with hyaluronidase, an enzyme that increases the permeability of tissue under the skin and enables the antibodies to be dispersed and absorbed into the bloodstream. Keytruda Qlex uses a modified version of the natural enzyme known as berahyaluronidase.

Approval of Keytruda Qlex was based on findings from the Phase III MK-3475A-D77 trial (NCT05722015), in which 377 patients with previously untreated metastatic non-small cell lung cancer were randomly assigned to receive either Keytruda Qlex administered by subcutaneous injection or the original Keytruda formulation administered by IV infusion, both every six weeks in combination with platinum chemotherapy. The study showed that Keytruda Qlex reached comparable pharmacokinetic exposure levels, and overall response rates (tumor shrinkage), progression-free survival and overall survival were similar with the injectable and infusion formulations.

Adverse reactions were also comparable between the two formulations. Therapies that increase immune activation to target cancer can also cause excessive inflammation. The prescribing information for Keytruda includes warnings about immune-mediated adverse reactions, hypersensitivity and administration-related reactions.

“This approval is significant for patients and health care providers like me who have been using immunotherapies for years to treat certain cancers. We now have a new option with a broad set of indications that has demonstrated comparability with intravenous pembrolizumab but in a subcutaneous injection that can be administered in one minute every three weeks or two minutes every six weeks,” said J. Thaddeus Beck, MD, of the Highlands Oncology Clinical Trials Office. “Subcutaneous pembrolizumab provides faster administration than IV pembrolizumab, offers two dosing options and gives patients more choices of health care settings in which they can receive their therapy.”

Keytruda is the world’s top-selling drug, with nearly $29.5 billion in sales in 2024. The injectable and infusion formulations are expected to have a similar cost, around $200,000 per year. As Merck eyes the expiration of its patent on the original version in 2028, approval of Keytruda Qlex will allow an extended period of exclusivity. As cheaper biosimilar versions of the IV formulation of pembrolizumab hit the market, many patients are likely to prefer the pricier patented injections.

Click here for full prescribing information for Keytruda.
Click here to learn more about cancer immunotherapy.
