# FDA Approves First Injectable Checkpoint Inhibitor

The new injectable formulation of Tecentriq reduces treatment time to seven minutes compared with up to an hour for IV infusions.

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The Food and Drug Administration last week approved the first injectable version of an immune checkpoint inhibitor, which will reduce administration time to about seven minutes compared with 30 to 60 minutes for intravenous infusions. The new formulation, Tecentriq Hybreza, is approved for the same indications as Tecentriq infusions. The injections are administered subcutaneously in the thigh every three weeks.

Tecentriq (atezolizumab) is a monoclonal antibody that targets an immune checkpoint that plays a role in regulating 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. Tecentriq is approved for small-cell lung cancer, non-small-cell lung cancer (NSCLC), liver cancer, melanoma and soft tissue sarcoma.

Until now, 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.

Tecentriq Hybreza uses Halozyme Therapeutics' Enhanze drug delivery technology, which adds a hyaluronidase enzyme to Tecentriq to increase the permeability of tissue under the skin and allow the drug to be rapidly dispersed and absorbed into the bloodstream.

The approval of Tecentriq Hybreza was based on findings from IMscin001 (NCT03735121), an open-label trial that included 371 adults with locally advanced or metastatic NSCLC who experienced disease progression following chemotherapy. They were randomly assigned to receive subcutaneous injections of Tecentriq Hybreza or the original formulation of Tecentriq by IV infusion. Pharmacokinetic analysis showed that drug levels were similar with the two formulations, and there were no notable differences in overall response rate, progression-free survival, overall survival or safety profiles.

In a second study (IMscin002), 71% of participants said they preferred Tecentriq Hybreza over IV administration, citing less time in the clinic, increased comfort during treatment and reduced emotional distress.

“This approval represents a significant option to improve the patient experience,” Ann Fish-Steagall, RN, senior vice president of patient services for the LUNGevity Foundation, said in a Genentech news release. “When patients have options, they feel empowered to be vital participants in their own care and choose their preferred treatment option.”

Genetech was the first company to win approval for an injectable checkpoint inhibitor, but others aren’t far behind.

Researchers recently reported that people with advanced kidney cancer who received an injectable formulation of Opdivo (nivolumab) had drug concentrations, response rates and safety profiles similar to those of patients who received the drug by IV infusion. The injections cut treatment time from 30 minutes to less than five minutes. Studies have also yielded promising results for an injectable version of Keytruda (pembrolizumab).

Click here for full prescribing information for Tecentriq Hybreza.

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