Bizengri Approved to Treat Some Lung and Pancreatic Cancers

The FDA approved Bizengri (zenocutuzumab) to treat lung and pancreatic cancers that have an NRG1 fusion, a rare genetic change.

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By Linda Wang

The Food and Drug Administration (FDA) has given an accelerated approval to zenocutuzumab (Bizengri), making it the first drug that targets tumors with a very rare genetic alteration called an NRG1 fusion. Under the approval, zenocutuzumab can be used to treat people with pancreatic or non-small-cell lung cancer (NSCLC) whose tumors have an NRG1 fusion and whose disease has gotten worse despite standard treatments.

The approval was based on the results of a clinical trial in which one-third of patients treated with zenocutuzumab had sustained tumor shrinkage of at least 30% that lasted a median of 11 months. Most of the patients in the study had either NSCLC or pancreatic cancer.

“This is a patient population that has a very high unmet need,” said the study’s lead investigator, Alison Schram, MD, of the Memorial Sloan Kettering Cancer Center. “This approval gives these patients, who have very few effective therapeutic options, a new treatment option.”

Because it’s an accelerated approval, Partner Therapeutics, which licensed zenocutuzumab from Merus, must conduct additional studies to confirm that the drug helps patients clinically, which can include helping them live longer than with other treatments.

Shrinking tumors without causing serious side effects

NRG1 gene fusions happen when part of the NRG1 gene becomes joined with part of another gene. This new gene produces an NRG1 fusion protein that activates the binding of two other proteins that sit on the surface of cells, HER2 and HER3. The HER2/HER3 complex generates signals that drive cells to constantly grow and divide.

Zenocutuzumab turns off these cancer-promoting signals by blocking the NRG1 fusion protein from promoting the HER2/HER3 complex in the first place.

The phase 2 clinical trial included adults with advanced or metastatic solid cancers that had an NRG1 gene fusion. Patients received zenocutuzumab intravenously once every 2 weeks, until their disease got worse.

The accelerated approval was based on data from 158 patients, of whom 93 had advanced NSCLC and 36 had advanced pancreatic cancer. The rest of the patients had breast, colorectal, bile duct, and other types of cancer.

Although the treatment shrank tumors in people with different cancers, those with NSCLC and pancreatic cancer were most likely to respond. Nearly 30% of patients with NSCLC experienced tumor shrinkage, with responses lasting a median of 12.7 months. And 42% of patients with pancreatic cancer had tumors shrink, with responses lasting a median of 7.4 months. One patient had a complete disappearance of their tumors.

Side effects were mostly mild and included diarrhea, fatigue, nausea, and anemia. Only one patient stopped treatment because of a drug-related side effect.

Improving the response rate

Stephen V. Liu, MD, of the Lombardi Comprehensive Cancer Center at Georgetown University, who was a co-investigator, said that this study is “an important advance” but pointed out that a response rate of 30% is still relatively low. Nevertheless, he said, zenocutuzumab has some real advantages.

“These are tumors that don’t do well with standard treatment,” he said. “Having zenocutuzumab now gives us a targeted drug that has a better chance of working. While we certainly would want the response rate to be higher, I do feel that more patients derive benefit from the drug, and, importantly, with very little toxicity.”

Dr. Schram agreed that zenocutuzumab is a very good option.

“Zenocutuzumab is extremely well tolerated, and patients often feel better within weeks,” Dr. Schram said.

The study team is already conducting studies to understand why some patients respond to the treatment whereas others don’t, as well as what leads to resistance to the drug.

The researchers hope that, as zenocutuzumab is tested in more people with other cancer types, the approval can be expanded to additional cancer types. Other drugs—including afatinib (Gilotrif), which blocks HER2 activity—are being studied in people with tumors with NRG1 fusions.

Because NRG1 fusions are primarily identified through RNA testing—rather than DNA testing, which is less sensitive for detecting these alternations—Dr. Schram encourages clinicians to incorporate RNA testing into the diagnostic workup “to make sure we’re not missing patients who

could benefit from this therapy."

Dr. Liu agreed: "This is an important advance, but to really see the impact of [zenocutuzumab], we need to do a better job of testing for alterations like this."

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