FDA Approves Aflibercept (Zaltrap) for Metastatic Colorectal Cancer

By Ian Ingram [2]

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The FDA has approved the angiogenesis inhibitor aflibercept (Zaltrap) to be used with the chemotherapy regimen FOLFIRI in the treatment of adults with colorectal cancer whose tumors have progressed after treatment with an oxaliplatin-containing regimen. The phase III trial that led to the approval showed an increase in overall survival for patients who received the new drug.

“This approval demonstrates the benefits of adding a biological agent, Zaltrap, to a commonly used chemotherapy drug regimen, FOLFIRI,” said Richard Pazdur, MD, director of the Office of Hematology and Oncology Products in the FDA’s Center for Drug Evaluation and Research, in a press release. “An improvement in median survival time was noted with the addition of Zaltrap to FOLFIRI, accompanied by an improvement in response rate and a delay in tumor progression and growth.”

Colorectal cancer is the third most common cancer and the second most common cause of cancer death in the United States. An estimated 143,460 Americans will be diagnosed with colorectal cancer and 51,690 will die from the disease in 2012, according to the National Institutes for Health.

The VELOUR Study

The safety and effectiveness of aflibercept was evaluated in the VELOUR trial, a multicenter, randomized, placebo-controlled phase III trial. The goal of the study was to compare the efficacy of aflibercept vs placebo in combination with the FOLFIRI regimen as a second-line treatment for patients with metastatic colorectal cancer previously treated with oxaliplatin. The primary endpoint of the trial was overall survival.

The trial included 1,226 patients with an Eastern Cooperative Oncology Group performance status between 0 and 2, whose colorectal cancer progressed while receiving an oxaliplatin-based combination chemotherapy. Participants received treatment until their cancer progressed or side effects became unacceptable. The FOLFIRI and aflibercept arm included 614 patients who were given aflibercept (4 mg/kg) intravenously every 2 weeks; the FOLFIRI and placebo arm included 612 patients.

Patients who were assigned to receive the aflibercept plus FOLFIRI combination had a median overall survival of 13.5 months compared to 12 months for those receiving FOLFIRI plus placebo. A reduction in tumor size occurred in 20% of patients receiving the aflibercept plus FOLFIRI combination vs 11% for those receiving FOLFIRI plus placebo.

In addition, the clinical trial demonstrated an improvement in progression-free survival, one of the secondary endpoints. The progression-free survival for patients receiving the aflibercept plus FOLFIRI combination was 6.9 months compared with 4.7 months for those receiving FOLFIRI plus placebo. The most common adverse events observed in patients receiving aflibercept plus FOLFIRI were febrile neutropenia, diarrhea, fatigue, weight loss, decreased appetite, stomatitis, headache, hypertension, and proteinuria. The drug can also cause severe and fatal bleeding, including gastrointestinal bleeding, and is being approved with a boxed warning from the FDA to alert patients and health care professionals.
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