FDA Approves Regorafenib (Stivarga) for Metastatic Colorectal Cancer

By Ian Ingram [2]

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The US Food and Drug Administration (FDA) has approved the multikinase inhibitor regorafenib (Stivarga) to treat patients with colorectal cancer that has metastasized following previous treatment.

“Stivarga is the latest colorectal cancer treatment to demonstrate an ability to extend patients’ lives, and is the second drug approved for patients with colorectal cancer in the past 2 months,” said Richard Pazdur, MD, director of the office of hematology and oncology products in FDA’s Center for Drug Evaluation and Research, in a press release.

In August, the FDA approved aflibercept (Zaltrap) to be used in combination with a FOLFIRI regimen for patients with metastatic colorectal cancer.

The trial that led to the approval of regorafenib, the CORRECT trial, was conducted from May 2010 to March 2011 and involved 760 patients with metastatic colorectal cancer whose disease had progressed following earlier treatment. Patients received best supportive care and were randomized two to one to either regorafenib or placebo.

The results were presented earlier this year at the 2012 American Society of Clinical Oncology Gastrointestinal Cancers Symposium. Results showed that patients treated with regorafenib had a median overall survival of 6.4 months vs 5 months for patients treated with placebo ($P = .005$). Median progression-free survival was 1.9 months for patients on regorafenib (95% CI: 1.88-2.17) vs 1.7 months for those taking placebo (95% CI: 1.68-1.74). The disease control rate for patients on regorafenib was 44.8% vs 15.3% for placebo ($P < .0001$).

Adverse events in the regorafenib arm, of grade 3 or higher, were fatigue (15%), hyperbilirubinemia (8%), diarrhea (8%), hand-foot skin reaction (17%), and hypertension (7%). Other common adverse events included loss of appetite and weight loss, infection, oral mucositis, and dysphonia.

The approval includes a boxed warning due to severe and fatal liver toxicity observed during the trial.

In 2012, 143,460 Americans will be diagnosed with colorectal cancer and 51,690 will die from the disease, according to estimates from that National Institutes of Health. Colorectal cancer is both the third most common cancer and third leading cause of cancer death in men and in women in the United States, according to the Centers for Disease Control and Prevention.

Regorafenib, reviewed under the FDA’s priority review program, was approved a month ahead of the projected date. The expedited review process, typically taking 6 months, is reserved for drugs that offer major therapeutic advances.
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