FDA Approves Ramucirumab (Cyramza) for Gastric Cancer

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The FDA has approved the angiogenesis inhibitor ramucirumab for the treatment of gastric cancer and gastroesophageal junction adenocarcinoma.

The US Food and Drug Administration has approved the angiogenesis inhibitor ramucirumab (Cyramza) for the treatment of advanced gastric cancer and adenocarcinoma of the gastroesophageal junction. The new drug is intended as a second-line agent for patients with unresectable or metastatic disease following treatment with a fluoropyrimidine- or platinum-containing therapy.

The trial that led to the approval, the REGARD trial, was an international phase III trial that included 355 patients with unresectable or metastatic gastric or gastroesophageal junction cancer. Patients were randomized 2:1 to either treatment with ramucirumab (n = 238) or placebo (n = 117). The primary endpoint was overall survival. Results of the trial found that patients who received treatment with ramucirumab saw an improvement in overall survival (5.2 months vs 3.8 months) and progression-free survival. In the REGARD trial, common adverse events experienced by patients in the ramucirumab arm included diarrhea and hypertension.

Results from another clinical trial, the RAINBOW trial, which studied the efficacy of ramucirumab plus paclitaxel vs paclitaxel alone, also showed an improvement in overall survival for patients treated with ramucirumab.

In 2014, an estimated 22,220 Americans will be diagnosed with gastric cancer and an estimated 10,990 will die from the disease, according to the National Cancer Institute.

“Although the rates of stomach cancer in the United States have decreased over the past 40 years, patients require new treatment options, particularly when they no longer respond to other therapies,” 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. “[Ramucirumab is a] new treatment option that has demonstrated an ability to extend patients’ lives and slow tumor growth.”
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