Regorafenib Approved to Treat Metastatic Colorectal Cancer

Main Bullet points:

- On September 27, 2012 the FDA approved Regorafenib, as the brand name Stivarga, to treat metastatic colorectal cancer.
- On October 29, 2012 Bayer received priority review by the FDA for the use of Stivarga tablets to treat patients with gastrointestinal stromal tumors.
- Sales of Stivarga are estimated to be over 1.25 billion a year.
- Colorectal cancer is the third most commonly diagnosed cancer and the third leading cause of cancer death in the United States for men and women.
- 29 percent of the patients who received Regorafenib in the Phase III CORRECT trial had an increased survival rate.

On May 23, 2012 Bayer HealthCare announced their submission for approval of a potential blockbuster cancer drug - Regorafenib. Only several months later the FDA approved Regorafenib, and Bayer’s novel cancer treatment prospect became a reality. With a quicker than normal approval from the FDA, Bayer was set up to ramp up their late-stage development process, setting the stage for potential sales upwards of $1.25 billion a year. Coined Stivarga, Regorafenib is a powerful treatment with both antiangiogenic and antineoplastic activity, Regorafenib binds to and inhibits the vascular endothelial growth factor receptors 2 and 3, as well as Raf kinases. The ability of Regorafenib to inhibit tumor angiogenesis and tumor cell proliferation makes this multi-kinase inhibitor a novel and life extending option for patients with metastatic colorectal cancer.
Results from Bayer’s global Phase III CORRECT trial were presented at the Annual Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology in January 2012, and at the American Society of Clinical Oncology in June 2012. Bayer has also submitted an application for European marketing authorization for Regorafenib for the treatment of patients with metastatic colorectal cancer.

The CORRECT study was international, randomized, double-blind, and placebo-controlled consisting of 760 patients. All patients had metastatic colorectal cancer that had a disease progression despite standard therapies within three months of time. The unacceptable levels of toxicity, as well as the lack of improvement cause these patients to withdraw from their standard care. The patients in this Phase III CORRECT study received either Regorafenib plus supportive care or a placebo plus supportive care. The treatment cycles consisted of 160 mg of Regorafenib, or a matching placebo, once daily for three weeks in a row and one week off. All patients received best supportive care during this trial. With patients from a wide range of locales, including Australia, China, Europe, Japan and North America, this clinical trial proved to be successful. Overall survival rates improved for 29 percent of the patients who received Regorafenib. The patients who were administered Regorafenib had a median overall survival of 6.4 months as compared a 5 month survival for patients who received a placebo. The results offer a beacon of hope for patients who are in a position where every extra day of life they have is truly a gift.

Colorectal cancer is commonly found in the colon and rectum, and it is typically classified as adenocarcinomas. These adenocarcinomas make up more than 90 percent of all large bowel tumors. As the third most commonly diagnosed cancer and the third leading cause of cancer death in the United States for men and women, new treatments and therapies are crucial. The CRC estimates that more than 140,000 people will have been diagnosed with CRC in 2011, and almost 50,000 of these patients will ultimately lose their lives due to this disease. In addition, about 50 percent of colon cancer patients experience metastases, mainly to the liver.
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On October 29, 2012 Bayer received a priority review by the FDA for the use of Stivarga tablets to treat patients with gastrointestinal stromal tumors. Based on data from a global Phase III GRID study, this priority review is an essential step in finding treatment options for patients who suffer from metastatic and unresectable gastrointestinal stromal tumors who present with disease progression even after treatment with at least two other kinase inhibitors.

YES Pharma is proud to be a leading supply source for Regorafenib (CAS#: 755037-03-7) to several global pharmaceutical companies and academic research institutes, while recognizing that we play a significant part in the battle against cancer. The Regorafenib that YES Pharma supplies is intended for laboratory R&D use only.

References:

www.bayer.com
National Cancer Institute. “Stage IV and Recurrent Colon Cancer.”
http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm321378.htm

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