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Investor News

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Bayer receives approval in China for Stivarga® (regorafenib) for the second-line systemic treatment of liver cancer

Approval based on data from the Phase III RESORCE study where Stivarga® (regorafenib) demonstrated significant improvement in overall survival in hepatocellular carcinoma (HCC) patients previously treated with Nexavar® (sorafenib)

Leverkusen, Germany, December 13, 2017 – Bayer announced today that the Chinese Food and Drug Administration (CFDA) approved Stivarga® (regorafenib) tablets for the second-line treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with Nexavar® (sorafenib). The data from the pivotal Phase III RESORCE study showed that Stivarga® (regorafenib) provided a statistically significant and clinically meaningful improvement in overall survival (OS) versus placebo; the median OS was 10.6 vs 7.8 months, (HR 0.62, 95% CI 0.50-0.78; p<0.0001). Exploratory analyses of the RESORCE trial showed that the median time from the start of prior sorafenib treatment to death was 26 months in patients receiving regorafenib versus 19.2 months in those receiving placebo. Regorafenib is the first drug approved for the second-line treatment of patients with HCC in China. The CFDA approval expands Bayer's leadership in liver cancer with a treatment plan in HCC involving use of Stivarga directly after progression on Nexavar.

"Following the approval of Stivarga for the treatment of metastatic colorectal cancer and gastrointestinal stromal tumors earlier this year in China, the approval in HCC brings new hope to Chinese patients with HCC who previously had no effective treatment options after being treated with Nexavar", said Robert LaCaze, Member of the Executive Committee of Bayer AG's Pharmaceuticals Division and Head of the Oncology Strategic Business Unit. "The product is already approved for the treatment of HCC in many countries around the world, including US, Japan and in the EU, and this milestone expands Bayer's global leadership in liver cancer."

Liver cancer is often more difficult to treat than other cancers with 466,000 new cases diagnosed and 422,000 deaths in China per year. Globally, it is the second leading cause of cancer-related deaths.

About Regorafenib (Stivarga®)

Regorafenib is an oral multi-kinase inhibitor that potently blocks multiple protein kinases involved in tumor angiogenesis (VEGFR1, -2, -3, TIE2), oncogenesis (KIT, RET, RAF-1, BRAF), metastasis (VEGFR3, PDGFR, FGFR) and tumor immunity (CSF1R).

Regorafenib is approved under the brand name Stivarga® in more than 90 countries worldwide, including the U.S., countries of the EU, China and Japan for the treatment of metastatic colorectal cancer (mCRC). The product is also approved in over 80 countries, including the U.S., countries of the EU, China and Japan, for the treatment of metastatic gastrointestinal stromal tumors (GIST). This year, it was also approved in the U.S., Japan and countries of the EU for second-line treatment of HCC.

In the EU, Stivarga is indicated as monotherapy for the treatment of adult patients with mCRC who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy, as well as for the treatment of adult patients with unresectable or metastatic GIST who progressed on or are intolerant to prior treatment with imatinib and sunitinib, and for the treatment of adult patients with HCC who have been previously treated with sorafenib.

Regorafenib is a compound developed by Bayer. In 2011, Bayer entered into an agreement with Onyx, now an Amgen subsidiary, under which Onyx receives a royalty on all global net sales of regorafenib in oncology.

About Oncology at Bayer

Bayer is committed to delivering science for a better life by advancing a portfolio of innovative cancer treatments. The oncology franchise at Bayer currently includes three oncology products and several other compounds in various stages of clinical development. Together, these products reflect the company’s approach to research, which prioritizes targets and pathways, with the potential to impact the way that cancer is treated.

Bayer: Science For A Better Life

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2016, the Group employed around 99,600 people and had sales of EUR 34.9 billion. Capital expenditures amounted to EUR 2.2 billion, R&D expenses to EUR 4.4 billion. For more information, go to www.bayer.com.

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