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Investor News

Not intended for U.S. and UK Media

Regorafenib from Bayer Granted Priority Review in the U.S. for Second-Line Treatment of Liver Cancer

Leverkusen, January 4, 2017 – Bayer today announced that the U.S. Food and Drug Administration (FDA) has granted priority review designation to the supplemental New Drug Application (sNDA) for regorafenib for the second-line treatment of patients with unresectable hepatocellular carcinoma (uHCC) in the U.S.

“Liver cancer is one of the leading cancer-related causes of death world-wide and more than 30,000 cases of liver cancer are diagnosed in the U.S each year. As the first and only approved systemic treatment for HCC, Nexavar was a significant step in addressing the unmet need in this field, but effective second-line treatment options are urgently needed for patients”, said Dr. Joerg Moeller, member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Development. “The priority review for regorafenib in the U.S. is great news for patients as it supports our efforts to make this treatment available as early as possible in the second-line setting for HCC in the U.S.”

The FDA grants priority review to medicines that if approved, would be significant improvements in the safety or effectiveness of the treatment for serious conditions. Under the Prescription Drug User Fee Act (PDUFA), the FDA aims to complete its review within six months (compared to 10 months under standard review).

Regorafenib is already approved under the brand name Stivarga® in many countries, including the U.S., to treat metastatic colorectal cancer and unresectable and/or metastatic gastrointestinal stromal tumors.

The regulatory submission for regorafenib is based on data from the international, multicenter, placebo-controlled Phase III RESORCE [REgorafenib after SORafenib in patients with hepatoCEllular carcinoma] trial. The trial investigated regorafenib in patients with unresectable hepatocellular carcinoma (HCC) whose disease had progressed during

treatment with sorafenib (Nexavar®) tablets. Results showed that regorafenib significantly improved overall survival (OS) compared to placebo (HR 0.63; 95% CI 0.50-0.79; p<0.001), which over the trial period represents a 37 percent reduction in the risk of death for patients who received regorafenib plus best supportive care (BSC) compared to patients treated with placebo plus BSC. The median OS was 10.6 months in patients treated with regorafenib, compared to 7.8 months in patients who received placebo plus BSC. The safety and tolerability was generally consistent with the known profile of regorafenib, with no clinically meaningful differences in health-related quality of life (HRQoL) between the regorafenib and placebo plus BSC groups. Data from the study were first presented at the 18th World Congress on Gastrointestinal Cancer (WCGC) in June 2016 and published online on December 5, 2016 in the peer-reviewed journal *The Lancet*.

Regorafenib has also been submitted to regulatory authorities in Japan and the EU for the treatment of second-line HCC and submissions in additional countries are in progress.

About the RESORCE trial

The Phase III RESORCE [**RE**gorafenib after **SOR**afenib in patients with hepato**CE**llular carcinoma] clinical trial enrolled 573 patients whose disease had progressed during treatment with sorafenib. Patients were randomized in a 2:1 ratio to receive either regorafenib or placebo plus best supportive care.

Patients received 160 mg regorafenib once daily or placebo, for 3 weeks on/1week off, with 28 days constituting one full treatment cycle. The primary endpoint of the study was overall survival, and secondary endpoints were time to progression, progression-free survival, objective tumor response rate and disease control rate. Health-related quality of life was assessed by the FACT-Hep and EQ-5D questionnaires. Safety and tolerability were also continuously monitored.

About Hepatocellular Carcinoma

Hepatocellular carcinoma (HCC) is the most common form of liver cancer and represents approximately 70-85 percent of liver cancer worldwide. Liver cancer is the sixth most common cancer in the world and the second leading cause of cancer-related deaths globally. More than 780,000 cases of liver cancer are diagnosed worldwide each year (52,000 in the European Union, 501,000 in the Western Pacific region and 30,000 in the United States) and the incidence rate is increasing. In 2012, approximately 746,000

people died of liver cancer including approximately 48,000 in the European Union, 477,000 in the Western Pacific region and 24,000 in the United States.

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 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 and Japan, for the treatment of metastatic gastrointestinal stromal tumors (GIST). In the EU, Stivarga is indicated 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.

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 treatments. The oncology franchise at Bayer 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 2015, the Group employed around 117,000 people and had sales of EUR 46.3 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.3 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to www.bayer.com.

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