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Investor News

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Bayer Receives EU Approval for Stivarga® (regorafenib) for the Second-Line Systemic Treatment of Liver Cancer

- Approval marks first treatment advance in nearly a decade and is based on data from the Phase III RESORCE study, in which Stivarga® (regorafenib) demonstrated significant improvement in overall survival in hepatocellular carcinoma (HCC) patients previously treated with Nexavar® (sorafenib)
- Nexavar is the only approved first-line treatment and Stivarga the only approved second-line therapy in Europe and the United States for patients with HCC

Leverkusen, Germany, August 7, 2017 – Bayer today announced the European Commission (EC) has granted marketing authorization for Stivarga® (regorafenib) for the treatment of adult patients with HCC who have been previously treated with Nexavar® (sorafenib). Stivarga is the first and only treatment that has demonstrated a significant improvement in overall survival (OS) in second-line HCC. This marks the third major approval in five months for Stivarga, with the product also gaining approval in the U.S. and Japan for second-line treatment of HCC in April and June, respectively.

“Until now, there was no effective second-line systemic treatment option for liver cancer patients and their treating physicians in Europe. With the EU approval of Stivarga in HCC, the outlook could significantly improve for patients with HCC, as they have now for the first time, a treatment plan with two approved therapies involving the use of Stivarga directly after Nexavar,” said Dr. Jordi Bruix, lead investigator for the RESORCE trial, BCLC Group, Liver Unit, Hospital Clinic, University of Barcelona, IDIBAPS, CIBEREHD, Spain.

The approval is based on data from the international, multicenter, placebo-controlled Phase III RESORCE [REgorafenib after SORafenib in patients with hepatoCEllular carcinoma; NCT 01774344] trial, which investigated patients with HCC whose disease had progressed during treatment with Nexavar. In the trial, regorafenib plus best supportive care (BSC) was shown to provide a statistically significant and clinically

meaningful improvement in OS versus placebo plus BSC (10.6 vs. 7.8 months, respectively, (HR 0.63; 95% CI 0.50-0.79; p<0.0001)), which translates to a 37% reduction in the risk of death over the trial period. Adverse events observed in the RESORCE trial were generally consistent with the known safety profile of regorafenib. The most common treatment-emergent adverse events were hand-foot skin reaction, diarrhea, fatigue and hypertension.

“Liver cancer is often diagnosed late and difficult to treat, but the EU approval of Stivarga for HCC marks the first treatment advance for patients in nearly a decade. Bayer continues to support the liver cancer community and is committed to ongoing research in the field, as well as continuing to pursue additional regulatory filings for Stivarga across the world,” said Robert LaCaze, Executive Vice President and Head of the Oncology Strategic Business Unit at Bayer.

Liver cancer is often more difficult to treat than other cancers with an annual mortality rate of 48,000 in the EU. Globally, it is the second leading cause of cancer-related deaths.

Additional regulatory filings for Stivarga in HCC are under review in other countries around the world, including China. The product was approved in the U.S. and Japan for second-line treatment of HCC in April and June, respectively. Stivarga is already approved in more than 90 countries worldwide, including the U.S., Japan, China and countries in the EU, for the treatment of metastatic colorectal cancer. Stivarga is also approved in more than 80 countries globally, including the U.S., Japan, China and countries in the EU, for the treatment of metastatic gastrointestinal stromal tumors.

About Hepatocellular Carcinoma

Hepatocellular carcinoma, or HCC, is the most common form of liver cancer representing 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).

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 115,200 people and had sales of EUR 46.8 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.7 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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