Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

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Bayer Receives Approval for Stivarga® in Japan for Second-Line Treatment of Hepatocellular Carcinoma

- Stivarga® (regorafenib) is the first and only systemic treatment to demonstrate significant improvement in overall survival in second-line hepatocellular carcinoma (HCC) patients and the first treatment advance in nearly a decade
- Pivotal trial RESORCE defines a new treatment plan in hepatocellular carcinoma (HCC) with Stivarga directly after Nexavar® (sorafenib)

Leverkusen, Germany, June 26, 2017 – Bayer announced today that the Ministry of Health, Labour and Welfare (MHLW) in Japan has granted marketing authorization for Stivarga® (regorafenib) tablets for the second-line treatment of patients with unresectable hepatocellular carcinoma (HCC) who have progressed after treatment with cancer chemotherapy. Stivarga, an oral inhibitor of multiple kinases involved in normal cellular functioning and in pathological processes such as oncogenesis, tumor angiogenesis, metastasis and tumor immunity, is the first and only treatment to demonstrate significant improvement in overall survival in second-line HCC patients who previously had no other options.

“The number of patients suffering from liver cancer continues to increase in Japan and for years Nexavar was the first and only approved systemic treament option with proven overall survival benefit to help address this unmet need”, said Robert LaCaze, Executive Vice President and Head of the Oncology Strategic Business Unit at Bayer. ”The approval of Stivarga in Japan for second-line HCC is a significant step forward for patients and their treating doctors. For the first time, patients have a proven treatment plan involving Stivarga directly after Nexavar which could establish a new standard of care.”

Since 1990, the annual mortality rate of liver cancer in Japan has increased by over 50%. Globally it is the second leading cause of cancer-related deaths.

The approval of Stivarga in HCC in Japan marks the third time that this therapy has been granted MHLW approval based on priority review, which is an expedited program given to medicines on the basis of their clinical usefulness and severity of the disease. The product is already approved in more than 90 countries worldwide for metastatic colorectal cancer (CRC), including Japan, and in more than 80 countries globally for the treatment of metastatic gastrointestinal stromal tumors (GIST), including Japan. Additional regulatory filings for Stivarga in HCC are under review in countries around the world and Stivarga in HCC has been approved by the FDA in the U.S.

The HCC approval is based on data from the international, multicenter, placebo-controlled Phase III RESORCE trial, which investigated patients with unresectable HCC whose disease had progressed during treatment with sorafenib. In the trial, regorafenib plus best supportive care (BSC) was shown to provide a statistically significant and clinically meaningful improvement in overall survival (OS) versus placebo plus BSC (HR 0.63; 95% CI 0.5-0.79; p<0.0001), which translates to a 37% reduction in the risk of death over the trial period.

The most common treatment-emergent adverse events (regorafenib vs. placebo group) were palmar-plantar erythrodysesthesia syndrome (53% vs. 8%), diarrhea (41% vs. 15%), fatigue (40% vs. 32%) and hypertension (31% vs. 6%).

About Hepatocellular Carcinoma

Hepatocellular carcinoma, or 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, 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). It was recently approved in the U.S. for second-line treatment of HCC and is now approved in Japan in this indication as well. Additional regulatory filings for Stivarga in HCC are under review in countries around the world, including the EU and China.

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 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.

Bayer AG, Investor Relations contacts:

Oliver Maier (+49-214-30-81013)
Dr. Jürgen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)
Constance Spitzer (+49-214-30-33021)
Prof. Dr. Olaf Weber (+49-214-30-33567)