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# Investor News

**Not intended for U.S. and UK Media**

## Phase III Trial of Regorafenib in Patients with Unresectable Liver Cancer Meets Primary Endpoint of Improving Overall Survival

**Leverkusen, Germany, May 4, 2016** – Bayer today announced that a Phase III trial evaluating its oncology compound regorafenib (Stivarga®) for the treatment of patients with unresectable hepatocellular carcinoma (HCC) has met its primary endpoint of a statistically significant improvement in overall survival. The study, called RESORCE, evaluated the efficacy and safety of regorafenib in patients with HCC whose disease has progressed after treatment with sorafenib. The safety and tolerability were generally consistent with the known profile of regorafenib. Detailed efficacy and safety analyses from this study are expected to be presented at an upcoming scientific congress.

“Effective treatment options are urgently needed for patients with liver cancer,” said Dr. Joerg Moeller, member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Development. “With sorafenib having been a major advance in the treatment of unresectable HCC, regorafenib could now become the second proven systemic option for the treatment of liver cancer. We would like to thank the patients and the study investigators for their contributions and participation in this study.”

Bayer plans to submit data from the RESORCE study as the basis for marketing authorization of regorafenib in the treatment of unresectable HCC in 2016.

**About the Phase III Study**

The RESORCE [REgorafenib after SORafenib in patients with hepatoCELlular carcinoma] clinical trial is a randomized, double blind, placebo controlled, multicenter Phase III study of regorafenib in patients with hepatocellular carcinoma (HCC) whose disease has progressed after treatment with sorafenib. The trial enrolled 573 patients who were randomized in a 2:1 ratio to receive either regorafenib plus best supportive care (BSC) or placebo plus BSC.

Patients received 160 mg regorafenib once daily, for 3 weeks on/1week off, or placebo 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. 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 (more than 395,000 in China, 52,000 in the European Union, 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 383,000 in China, 48,000 in the European Union, and 24,000 in the United States.

**About Regorafenib (Stivarga®)**

Regorafenib is an oral multi-kinase inhibitor that targets various kinases involved in tumor growth and progression – angiogenesis, oncogenesis and the tumor microenvironment. In preclinical studies, regorafenib inhibits several angiogenic VEGF receptor tyrosine kinases that play a role in tumor neoangiogenesis (the growth of new blood vessels). In addition to VEGFR 1-3 it also inhibits various oncogenic and tumor microenvironment kinases including TIE-2, RAF-1, BRAF, BRAFV600, KIT, RET, PDGFR, and FGFR, which individually and collectively impact upon tumor growth, formation of a stromal microenvironment and disease progression.

Regorafenib is approved under the brand name Stivarga® in 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 more than 70 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 now 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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