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Investor News

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Bayer's Stivarga® (regorafenib) Tablets Approved by U.S. FDA for Treatment of Metastatic Colorectal Cancer

Stivarga shown in a pivotal Phase III trial to extend overall survival in patients with metastatic colorectal cancer (mCRC) whose disease had progressed after previous treatments

Leverkusen, Germany, September 27, 2012 – Bayer HealthCare announced today that the U.S. Food and Drug Administration (FDA) approved Stivarga® (regorafenib) tablets for the treatment of patients with metastatic colorectal cancer (mCRC) who have been previously treated with currently available therapies (including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and if KRAS wild type, an anti-EGFR therapy). The approval of Stivarga is based on results from the pivotal Phase III study (CORRECT) that demonstrated a statistically significant improvement in overall survival (OS) and progression-free survival (PFS) compared to placebo in patients with mCRC whose disease had progressed after approved standard therapies. Stivarga is an oral multi-kinase inhibitor that inhibits various kinases within the mechanisms involved in tumor growth and progression – angiogenesis, oncogenesis and the tumor microenvironment.

"The U.S. approval of Stivarga is an important milestone for Bayer as it marks the first approval of this innovative cancer treatment to fulfill a significant unmet medical need in the treatment of metastatic colorectal cancer," said Dr. Jörg Reinhardt, Chief Executive Officer, Bayer HealthCare. "Bayer makes significant investments to provide patients and their physicians with groundbreaking therapies for a better life. With Stivarga we are expanding our product portfolio in oncology which will significantly contribute to the future growth of our company."

"The approval of regorafenib adds to the treatments we have for metastatic colorectal cancer, which is important for those patients who have no further options," said Heinz-

Josef Lenz, MD, FACP, CORRECT investigator and associate director for clinical research and co-leader of the Gastrointestinal Cancers Program at the USC Norris Comprehensive Cancer Center. “In the pivotal Phase III CORRECT trial, the drug has been shown to prolong survival and slow the progression of cancer in patients whose disease had progressed after treatment with currently available therapies. It provides patients another avenue to fight this cancer.”

In the Phase III CORRECT (Colorectal cancer treated with regorafenib or placebo after failure of standard therapy) trial, regorafenib plus best supportive care (BSC) significantly improved OS (HR=0.77, 2-sided p-value=0.0102) and PFS (HR=0.49, 2-sided p-value<0.0001) compared to placebo plus BSC. Median OS was 6.4 months with regorafenib versus 5.0 months with placebo; median PFS was 2.0 months with regorafenib versus 1.7 months with placebo. The data also showed a survival benefit (OS and PFS) in the regorafenib arm across nearly all subgroups analyzed. No difference in overall response rate was observed. Five patients (1%) in the regorafenib arm and one patient (0.4%) in the placebo arm experienced partial responses. History of KRAS evaluation was reported for 729 (96%) patients; 430 (59%) of these patients were reported to have KRAS mutation. The most frequently observed adverse drug reactions (≥30%) in patients receiving regorafenib were asthenia/fatigue, decreased appetite and food intake, hand-foot-skin reaction/ palmar-plantar erythrodysesthesia, diarrhea, mucositis, weight loss, infection, hypertension, and dysphonia. The most serious adverse drug reactions in patients receiving regorafenib were hepatotoxicity, hemorrhage and gastrointestinal perforation.

Primary efficacy and safety data for this trial were first reported at the Annual Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (ASCO-GI) in January 2012 and additional data were presented at the ASCO Annual Meeting in June 2012.

Stivarga was developed and reviewed under the fast track program and received priority review designation from the FDA. These designations are granted by the FDA to expedite the development and review of drugs to treat serious diseases and fill an unmet medical need (fast track), and given to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists (priority review).

About Colorectal Cancer

CRC is the fourth most common cancer worldwide, with over one million cases occurring every year. The mortality rate from CRC is approximately half of its global incidence. The five-year survival estimate for CRC on average is 55 percent, but is highly variable dependent on the stage of the disease (from 74 percent for patients with Stage I disease to only 6 percent for Stage IV patients).

In mCRC, KRAS status is an important biomarker and can be a predictor of treatment response. Approximately 40 percent of colorectal cancers are characterized by mutations in the KRAS gene. Some of the CRC therapies currently available have demonstrated efficacy only in patients without KRAS mutations.

About the CORRECT Study

CORRECT was an international, multicenter, randomized, double-blind, placebo-controlled Phase III study that enrolled 760 patients with mCRC whose disease had progressed during or within three months following last administration of approved standard therapies. Patients were randomized to receive regorafenib plus BSC or placebo plus BSC, respectively. Treatment cycles consisted of 160 mg of regorafenib (or matching placebo) once daily for three weeks on / one week off plus BSC.

About Stivarga® (regorafenib)

Stivarga® is an oral multi-kinase inhibitor that inhibits various kinases within the mechanisms involved in tumor growth and progression – angiogenesis, oncogenesis and the tumor microenvironment. In preclinical studies, Stivarga inhibits several angiogenic VEGF receptor tyrosine kinases that play a role in tumor neoangiogenesis (the growth of new blood vessels). It also inhibits various oncogenic and tumor microenvironment kinases including VEGFR 1-3, KIT, RET, PDGFR, and FGFR, which individually and collectively impact upon tumor growth, formation of a stromal microenvironment and disease progression.

Regorafenib was also submitted for marketing approval for the treatment of metastatic CRC in the EU in May 2012. The NDA for regorafenib for the treatment of advanced CRC filed in Japan in July 2012 was granted priority review.

Regorafenib is also under investigation in metastatic and/or unresectable gastrointestinal stromal tumors (GIST) for patients whose disease had progressed despite prior treatment with imatinib and sunitinib. Positive Phase III data showing a significant increase in PFS

has been presented at the ASCO 2012 Annual Meeting. Regorafenib has been granted orphan drug designation and Fast Track designation by the FDA for this tumor type. Bayer has submitted a New Drug Application to the FDA for regorafenib in GIST in August 2012.

Regorafenib is a Bayer compound developed by Bayer. In 2011, Bayer entered into an agreement with Onyx Pharmaceuticals, Inc., under which Onyx will receive a royalty on any future global net sales of Stivarga in oncology. Bayer and Onyx will jointly promote Stivarga in the U.S.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 17.2 billion (2011), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2011) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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Forward-Looking Statements

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