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Investor News

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Bayer's Regorafenib Recommended for Approval in the European Union for the Treatment of Metastatic Colorectal Cancer

Regorafenib 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

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Leverkusen, Germany, June 28, 2013 – Bayer's oncology compound regorafenib has been recommended for approval by the European Committee for Medicinal Products for Human Use (CHMP) treatment of adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies. These include fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy. The decision of the European Commission on the approval is expected in the third quarter of 2013.

"The recommendation by the CHMP for regorafenib is an important milestone for Bayer and brings us one step closer to providing an innovative new treatment option for patients with metastatic colorectal cancer," said Kemal Malik, MD, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "Bayer is committed to developing new therapies in difficult-to-treat diseases like mCRC where there continues to be an unmet medical need for additional treatments, and we are delighted that regorafenib provides a potential new treatment option for patients and their physicians."

"The medical community constantly strives to find new and better treatment options in the fight against cancer. There are currently limited choices in mCRC so the potential approval of regorafenib in Europe can give patients and physicians new hope," said Eric Van Cutsem, Lead CORRECT investigator, University Hospital Gasthuisberg Leuven, Belgium. "In the pivotal Phase III CORRECT trial, regorafenib has been shown to prolong

overall survival and slow the progression of cancer in patients whose disease had progressed after treatment with currently available therapies. It is the first and only multikinase inhibitor to show an overall survival benefit in mCRC and we are very encouraged by the positive opinion from CHMP."

The CHMP recommendation was based on data from the pivotal Phase III CORRECT (Colorectal cancer treated with regorafenib or placebo after failure of standard therapy) trial. The study results showed that regorafenib plus BSC significantly improved both overall survival (OS) (HR=0.77, 1-sided p-value=0.0052) and progression-free survival (PFS) (HR=0.49, 1-sided p-value <0.000001) compared to placebo plus BSC in patients with mCRC whose disease had progressed after approved standard therapies. In the study, median OS was 6.4 months with regorafenib versus 5.0 months with placebo; median PFS was 1.9 months with regorafenib versus 1.7 months with placebo.

In the CORRECT study, the most frequently observed adverse drug reactions (equally or greater than 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.

Full results from the CORRECT study were presented at the 48th Annual Meeting of the American Society of Clinical Oncology (ASCO) in June 2012 and published in the journal The Lancet in January 2013.

Regorafenib is approved under the brand name Stivarga® in several countries, including the USA and Japan, for the treatment of mCRC. It has also received U.S. approval for the treatment of patients with gastrointestinal stromal tumors (GIST) in February 2013. The NDA for regorafenib for the treatment of GIST filed in Japan in December 2012 was granted priority review.

About Colorectal Cancer

CRC is the third 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).

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 regorafenib
Regorafenib 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, regorafenib 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 is a Bayer compound developed by Bayer and jointly promoted by Bayer and Onyx in the USA. In 2011, Bayer entered into an agreement with Onyx, 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.

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 18.6 billion (2012), 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 55,300 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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