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Investor News

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Bayer's Regorafenib Submitted for EU and U.S. Marketing Authorization for the Treatment of Metastatic Colorectal Cancer

Leverkusen, Germany, May 23, 2012 – Bayer HealthCare has submitted a Marketing Authorization Application to the European Medicines Agency (EMA) and a New Drug Application to the U.S. Food and Drug Administration (FDA) for the oral multi-kinase inhibitor regorafenib for the treatment of patients with metastatic colorectal cancer (mCRC).

"These submissions of regorafenib for metastatic colorectal cancer are a significant development milestone for this agent and a step forward in bringing a potential new treatment to patients with metastatic colorectal cancer who currently have no other options," said Kemal Malik, MD, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "We are encouraged by the improved overall survival seen in the CORRECT study and look forward to continuing discussions with the regulatory authorities."

The submissions are supported by data from the pivotal, global Phase III CORRECT (Colorectal cancer treated with regorafenib or placebo after failure of standard therapy) trial. Results from the study were first presented at the Annual Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (ASCO-GI) in January 2012 and will be presented at the upcoming ASCO annual meeting in Chicago, IL (USA) in early June 2012. The study evaluated regorafenib plus best supportive care (BSC) versus placebo plus BSC in patients with mCRC whose disease has progressed after approved standard therapies. The CORRECT results showed that regorafenib plus BSC significantly improved both overall survival and progression-free survival, compared to placebo plus BSC. In this trial, the safety and tolerability of regorafenib were generally as expected and no new or unexpected toxicity was observed.

About the CORRECT Study
The CORRECT trial is an international, multicenter, randomized, double-blind, placebo-controlled study that enrolled 760 patients with mCRC whose disease has progressed after approved standard therapies. The CORRECT study was conducted in North America, Europe, Israel, China, Japan and Australia.

Patients were randomized to receive either regorafenib plus best supportive care (BSC) or placebo plus BSC. Treatment cycles consisted of 160 mg of regorafenib (or matching placebo) once daily for three weeks on / one week off plus BSC. The primary endpoint of this trial was overall survival. Secondary endpoints included progression-free survival, objective tumor response rate and disease control rate. The safety and tolerability of the two treatment groups were also compared.

About Colorectal Cancer
Colorectal cancer (CRC) is a disease in which malignant (cancer) cells form in the tissues of the colon or rectum. The majority of cancers occurring in the colon and rectum are adenocarcinomas, which account for more than 90 percent of all large bowel tumors.

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).

About Regorafenib
Regorafenib is an investigational, oral, multi-kinase inhibitor targeting three key mechanisms of 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 and lymphangiogenesis (the growth of new blood vessels and lymphatic vessels). It also inhibits various oncogenic and tumor microenvironment kinases including KIT, RET, PDGFR, and FGFR which control tumor growth, infrastructure and progression. Regorafenib is currently being investigated in clinical trials for its potential to treat patients with various tumor types.

Regorafenib is an investigational agent and is not approved by the United States Food and Drug Administration (FDA), the European Medicines Agency (EMA) or other health authorities.

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 regorafenib in oncology.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition 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. Find more information at www.bayerhealthcare.com.

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