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Investor News

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U.S. FDA Grants Priority Review to the New Drug Application for Bayer's Regorafenib to Treat Patients with Metastatic Colorectal Cancer

Leverkusen, Germany, June 28, 2012 – Bayer HealthCare announced today that the U.S. Food and Drug Administration (FDA) has granted priority review to the New Drug Application (NDA) filed end of April 2012 for the oral multi-kinase inhibitor regorafenib for the treatment of patients with metastatic colorectal cancer (mCRC) whose disease has progressed after approved standard therapies.

The FDA grants priority review to medicines that offer major advances in care or that provide a treatment where no adequate therapy exists. Under the Prescription Drug User Fee Act (PDUFA), the FDA will complete its review within six months from the receipt of the NDA submission, rather than the standard 10-month review cycle.

"We welcome the priority review of regorafenib by the FDA as it supports our efforts to make regorafenib available as early as possible to patients who have exhausted available therapies and urgently need new options," said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

The submission was based upon data from the pivotal, global Phase III CORRECT study. The trial showed that oral regorafenib plus best supportive care (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. 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.

About the CORRECT Study

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

Patients were randomized to receive either regorafenib plus 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 study 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.

In October 2011, Bayer announced that the Phase III CORRECT study met its primary endpoint, following a pre-planned interim analysis, by significantly improving overall survival. Based on a recommendation from an independent Data Monitoring Committee (DMC), the study was unblinded and patients on the placebo arm have been offered treatment with regorafenib.

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 individually and collectively impact upon tumor growth, formation of a stromal microenvironment and disease 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 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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