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Investor News

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Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (ASCO-GI):

Phase III Data of Bayer's Regorafenib in Patients with Metastatic Colorectal Cancer to be Presented as Late Breaking Oral Presentation at 2012 ASCO-GI Congress

Late breaking abstract (LBA #385) of Phase III CORRECT study results to be presented on January 21, 2012

Leverkusen, January 10, 2012 – Results from the Phase III CORRECT study will be presented as a late breaking abstract in an oral abstract session on January 21 (2:30 PM – 4:00 PM Pacific Time, Level 3 Ballroom, Moscone Center West) at the 2012 Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (ASCO-GI), in San Francisco, CA, U.S. The pivotal Phase III CORRECT (Colorectal cancer treated with regorafenib or placebo after failure of standard therapy) study evaluated regorafenib plus best supportive care (BSC) versus placebo plus BSC in patients with metastatic colorectal cancer (mCRC) whose disease has progressed after standard therapies. The data will be presented by Axel Grothey, MD, Professor of Oncology, Mayo Clinic, Rochester, MN, U.S., who shares the role of the coordinating investigator of the study.

The full congress program can be found under:
http://www.gicasymposium.org/MeetingProgram.aspx

About the CORRECT Study

The CORRECT study is 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, 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.

Bayer plans to submit regorafenib for marketing authorization in mCRC in 2012.

About Regorafenib

Regorafenib is an investigational oral multi-kinase inhibitor targeting angiogenic, stromal and oncogenic kinases. Regorafenib inhibits angiogenic kinases such as receptors for VEGF which play central roles in angiogenesis. It also inhibits various oncogenic and stromal kinases including KIT, RET, PDGFR, FGFR, and RAF, thereby helping to stop the proliferation of cancer cells. Regorafenib has shown antitumor activity in preclinical studies by inhibiting tumor growth in multiple xenograft models via antiangiogenic and antiproliferative mechanisms. Based on these results, regorafenib is currently being investigated in clinical studies for its potential to treat patients with various tumor types.

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

Regorafenib was granted Fast Track designation by the FDA for the treatment of patients with mCRC who have progressed after approved standard therapies, as well as for the treatment of patients with metastatic and/or unresectable gastrointestinal stromal tumors (GIST) whose disease has progressed despite at least imatinib and sunitinib as prior treatments. Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious diseases and fill an unmet medical need.

Regorafenib was granted orphan drug designation by the FDA for the treatment of patients with GIST. Orphan drug designation aims to encourage the development of drugs involved in the diagnosis, prevention or treatment of a medical condition affecting fewer than 200,000 people in the country.

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 16.9 billion (2010), 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 and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2010) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

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