Bayer

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Investor News

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Phase III Trial of Regorafenib in Metastatic Colorectal Cancer Meets Primary Endpoint of Improving Overall Survival

Trial stopped based on positive data from a pre-planned interim analysis

Leverkusen, October 26, 2011 – Bayer HealthCare today announced positive results from its Phase III trial evaluating its investigational compound regorafenib (BAY 73-4506) for the treatment of patients with metastatic colorectal cancer (mCRC) whose disease has progressed after approved standard therapies: The trial met its primary endpoint of statistically significantly improving overall survival. This is the result of a pre-planned interim analysis conducted by an independent Data Monitoring Committee (DMC) of the CORRECT (Patients with metastatic colorectal cancer treated with regorafenib or placebo after failure of standard therapy) trial. Per the recommendation of the DMC, the study has been unblinded and patients in the placebo arm will be offered treatment with regorafenib. In this trial, the safety and tolerability of regorafenib were generally as expected and did not show any new or unexpected toxicities. Data from the study are expected to be presented at a forthcoming scientific meeting.

“These data are significant because they demonstrate that regorafenib increases overall survival in patients with heavily pretreated mCRC, an area of high unmet medical need,” said Kemal Malik, MD, Head of Global Development and member of the Bayer HealthCare Executive Committee. “We are extremely encouraged by the result of this analysis and we are hopeful about the potential of regorafenib to fill this unmet treatment need.”

Bayer will continue discussions with health authorities worldwide, including the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) regarding next steps in filing for approval of regorafenib in the treatment of mCRC.

Bayer recently 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 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 study was conducted in North America, Europe, 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 varies very much 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 of angiogenic, stromal and oncogenic receptor tyrosine kinases (TK). Regorafenib inhibits angiogenic kinases like receptors for VEGF which play central roles in angiogenesis. It also inhibits various oncogenic kinases including RAF, RET as well as stromal kinases such as KIT and PDGFR, 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 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.

Regorafenib was granted orphan drug designation by the FDA for the treatment of patients with gastrointestinal stromal tumors (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.

Regorafenib was granted Fast Track designation by the U.S. FDA for the treatment of patients with metastatic and/or unresectable GIST whose disease has progressed despite at least imatinib and sunitinib as prior treatments, as well as for the treatment of patients with mCRC who have progressed after approved standard therapies. 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.

About Oncology at Bayer

Bayer is committed to advancing the science of cancer, and translating this science into therapies that can help people with cancer live longer. With several potential first- and best-in-class compounds in clinical development, Bayer's oncology portfolio demonstrates the Company's commitment to improving the lives of people living with cancer.

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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