



News Release

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Phase III Data Show Bayer's Investigational Compound Regorafenib (BAY 73-4506) Met Primary Endpoint Showing Statistically Significant Improvement in Overall Survival in Patients with Metastatic Colorectal Cancer Refractory to Standard Approved Therapies

Pivotal trial data to be presented for the first time at the 2012 Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (ASCO-GI)

Wayne, NJ, January 17, 2012 – Bayer HealthCare today announced latest data on its investigational compound regorafenib (BAY 73-4506) from the Phase III CORRECT (Colorectal cancer treated with regorafenib or placebo after failure of standard therapy) trial. The study met its primary endpoint, showing statistically significant improvement in overall survival (OS) by 29% (HR=0.77, p=0.0052, median OS: 6.4 months vs. 5.0 months for the placebo group) in patients with metastatic colorectal cancer (mCRC) whose disease had progressed after approved standard therapies.¹ This late-breaking abstract, with these updated data, will be presented by Axel Grothey, MD, Professor of Oncology, Mayo Clinic and co-principal investigator of the CORRECT study, in an oral abstract session (LBA No. 385, January 21, 2012 from 2:30 p.m. – 4:00 p.m. PT, 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.

Additionally, findings from the secondary endpoints of the CORRECT study showed statistically significant improvement in progression-free survival (PFS) (HR=0.49, p<0.000001, median PFS: 1.9 months vs. 1.7 months) and an improvement in disease control rate (44.8% vs. 15.3%) in patients treated with regorafenib compared to those treated with placebo. The difference in objective response rate between the two arms (1.0% vs. 0.4%) did not reach statistical significance.¹

The most common drug-related, treatment-emergent adverse events included fatigue (47.4% vs. 28.1%), hand-foot skin reaction (46.6% vs. 7.5%), diarrhea (33.8% vs. 8.3%), anorexia (30.4% vs. 15.4%), hypertension (27.8% vs. 5.9%), oral mucositis (27.2% vs. 3.6%) and rash/desquamation (26.0% vs. 4.0%) for patients receiving regorafenib as compared to placebo.¹

Per the recommendation from an independent Data Monitoring Committee, the CORRECT study was unblinded in late 2011 following a pre-planned interim analysis that determined that the regorafenib arm showed significant improvement in overall survival; patients on the placebo arm were unblinded and offered treatment with regorafenib.

Bayer plans to submit regorafenib for marketing authorization in mCRC in 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 had progressed during or within 3 months following last administration of approved standard therapies, which must have included fluoropyrimidine, oxaliplatin, irinotecan, bevacizumab and cetuximab or panitumumab.¹

Patients who had withdrawn from standard treatment due to unacceptable toxicity warranting discontinuation of treatment and precluding retreatment with the same agent prior to progression of disease were also allowed into the study.

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.¹

The study was conducted in North America, Europe, China, Japan and Australia.

About Colorectal Cancer

Colorectal cancer 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.²

CRC is the third most commonly diagnosed cancer and the third leading cause of cancer death in the United States, in both men and women.³ It is estimated that more than 140,000 people will be diagnosed with CRC in 2011, and nearly 50,000 people will die from the disease.⁴ Approximately 50 percent of colon cancer patients will be diagnosed with metastases (most commonly to the liver) either at the time of diagnosis or due to recurrent disease.⁵

About Regorafenib

Regorafenib is an investigational oral multi-kinase inhibitor targeting angiogenic, stromal and oncogenic kinases⁶ and 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 FDA, EMA or other health authorities.

Regorafenib is one of several cancer compounds in Bayer's development pipeline. 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 Pharmaceuticals Inc.

Bayer HealthCare Pharmaceuticals Inc. is the U.S.-based pharmaceuticals business of Bayer HealthCare LLC, a subsidiary of Bayer AG. Bayer HealthCare is one of the world's leading, innovative companies in the healthcare and medical products industry, and combines the activities of the Animal Health, Consumer Care, Diabetes Care, and Pharmaceuticals divisions. As a specialty pharmaceutical company, Bayer HealthCare Pharmaceuticals provides products for Diagnostic Imaging, General Medicine, Hematology, Neurology, Oncology and Women's Healthcare. The company's aim is to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases.

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¹ A. Grothey, et al. Results of a randomized Phase 3 trial (CORRECT) of regorafenib plus best supportive care (BSC) versus placebo plus BSC in patients with mCRC who have progressed after standard therapies [January 17, 2012 ASCO-GI Presscast Presentation]. 2012 Gastrointestinal Cancers Symposium; January 19-21, 2012. San Francisco, CA.

² American Cancer Society. Colorectal Cancer Guide. Available from: <http://www.cancer.org/acs/groups/cid/documents/webcontent/003096-pdf.pdf>. Accessed on October 14, 2011.

³ American Cancer Society. Colorectal Cancer Facts & Figures 2011-2013. Available at: <http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-028323.pdf>. Accessed on October 24, 2011.

⁴ National Cancer Institute. Colon and Rectal Cancer. Available at: <http://www.cancer.gov/cancertopics/types/colon-and-rectal>. Accessed on October 24, 2011.

⁵ National Cancer Institute. Stage IV and Recurrent Colon Cancer. Available at: <http://www.cancer.gov/cancertopics/pdq/treatment/colon/HealthProfessional/page9>. Accessed on October 24, 2011.

⁶ S. Wilhelm, et al. Regorafenib (Bay 73-4506): A New Oral Multikinase Inhibitor of Angiogenic, Stromal, and Oncogenic Receptor Tyrosine Kinases with Potent Preclinical Antitumor Activity. *Online International Journal of Cancer*. December 17, 2010.