Investor News

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Results of pivotal Phase III study in patients with metastatic colorectal cancer:

Positive Phase III Data on Bayer's Investigational Drug Regorafenib Show Significant Increase in Overall Survival

First presentation of data from CORRECT trial as "Late Breaking Abstract" at the 2012 Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (ASCO-GI)

Leverkusen, January 18, 2012 – Bayer HealthCare today announced positive data on its investigational drug regorafenib from the Phase III CORRECT (Colorectal cancer treated with regorafenib or placebo after failure of standard therapy) trial that will be presented as a late breaking abstract in an oral abstract session at the 2012 Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (ASCO-GI). The study evaluated regorafenib plus best supportive care (BSC) versus placebo plus BSC in patients with metastatic colorectal cancer (mCRC) whose disease has progressed after approved standard therapies. The study met its primary endpoint of significantly improving overall survival (OS) by 29% (HR=0.77, p=0.0052). The CORRECT trial also met two secondary efficacy endpoints, including a significant improvement in progression-free survival (PFS) (HR=0.49, p<0.000001), and a significant improvement in the disease control rate (DCR) (p<0.000001). The difference in the objective response rate (ORR) between the two arms did not reach statistical significance. These data will be presented at ASCO-GI in San Francisco, U.S. on Saturday, January 21, 2012, 2:30 PM – 4:00 PM Pacific Time, Level 3 Ballroom, Moscone Center West (LBA No. 385).

"These data are noteworthy because they demonstrate that regorafenib can stabilize disease, even at an advanced stage, and prolong life in patients with metastatic colorectal cancer who have no other treatment options available," said Prof. Eric van Cutsem, University Hospital Leuven, Belgium, who shares the role of the coordinating investigator of the study. "To date regorafenib is the only oral multi-kinase inhibitor as

monotherapy that has demonstrated in a large Phase III trial the ability to improve clinical outcomes in patients with advanced refractory colorectal cancer. The data suggest that regorafenib may provide a new standard of care for the treatment of refractory metastatic colorectal cancer."

The efficacy analyses showed that patients who were treated with regorafenib had the following outcomes:

- A median OS of 6.4 months compared to 5.0 months for the placebo group (HR=0.77, p=0.0052)
- A median PFS of 1.9 months compared to 1.7 months for the placebo group (HR= 0.49, p<0.000001)
- A DCR of 44.8% compared to 15.3% for the placebo group (p<0.000001)
- An ORR of 1.0% compared to 0.4% for the placebo group (p=0.188)

The overall safety and tolerability profile for regorafenib was consistent with results from previous studies. The most common drug-related, treatment-emergent adverse events (occurring in at least 25% of patients) 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%), voice changes (29.4% vs. 5.5%), 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.

The CORRECT trial was unblinded in late 2011 following a pre-planned interim analysis that determined that the regorafenib arm showed significant improvement in overall survival, and patients on the placebo arm were offered treatment with regorafenib.

"We are excited by these results because there is a high unmet medical need for patients with mCRC and these data show that regorafenib could make a positive impact on overall survival in patients who currently have no other options," said Kemal Malik, MD, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "We look forward to generating further data for this compound, including results from our other Phase III trial of regorafenib in gastrointestinal stromal tumors".

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

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, 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 angiogenic, stromal and oncogenic kinases. Regorafenib inhibits several angiogenic VEGF receptor tyrosine kinases which play central roles in tumor neoangiogenesis and lymphangiogenesis. It also inhibits various oncogenic and stromal kinases including KIT, RET, PDFGR, and FGFR thereby helping to stop the proliferation of selected cancer cells. Regorafenib has shown antitumor activity in preclinical studies by inhibiting tumor growth in multiple xenograft models via tumor neoantiangiogenic and tumor cell 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 Fast Track designation by the U.S. 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.

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 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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