Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

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Results of two pivotal Phase III studies of regorafenib in gastrointestinal cancers:

Positive Phase III Data on Bayer's Investigational Drug Regorafenib Show Significant Increase in Progression-Free Survival in Patients with Gastrointestinal Stromal Tumors (GIST)

- First data from Phase III GRID trial for regorafenib in GIST presented as Late-Breaking Abstract in oral abstract session
- First presentation of subgroup analysis of Phase III CORRECT trial for regorafenib in metastatic colorectal cancer in oral abstract session; Data show positive trend in overall and progression-free survival across subgroups of patients

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LBA #10008, Abstract # 3502

Leverkusen, Germany, June 4, 2012 – Bayer HealthCare today announced positive data from the Phase III GRID (GIST – Regorafenib In Progressive Disease) trial evaluating its investigational drug regorafenib in patients with metastatic and/or unresectable gastrointestinal stromal tumor (GIST) whose disease had progressed despite prior treatment with imatinib and sunitinib. Regorafenib significantly improved progression-free survival (PFS) over placebo (HR=0.27, p<0.0001), which means a 73% reduction in the risk of progression or death. The median PFS was 4.8 months in the regorafenib arm versus 0.9 months in the placebo arm. Furthermore, regorafenib demonstrated a significantly greater disease control rate (DCR, defined as rate of partial response [PR] plus durable stable disease [SD] lasting for at least 12 weeks) compared to placebo (52.6% vs. 9.1%; p<0.000001). In addition, there was a positive trend in the regorafenib group in improving overall survival (OS) (HR=0.77, p=0.20). The OS results were not statistically significant, which was expected due to the cross-over design of the study.

These data will be presented as a late-breaking abstract in an oral abstract session at the 48th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, IL (USA) (LBA No. 10008).

“GIST continues to represent an area of unmet patient need, given the aggressive nature of the disease after resistance emerges to the standard targeted therapies,” said George Demetri, MD, Director of the Ludwig Center at the Dana-Farber Cancer Institute and Harvard Medical School, Boston, MA (USA), Principal Investigator and Chair of the Steering Committee for the GRID trial. “These data from the GRID study support regorafenib as an important advance in helping control this difficult-to-treat cancer in patients after failure of standard molecular targeted therapies.”

Additionally, new data from the Phase III CORRECT (Colorectal cancer treated with regorafenib or placebo after failure of standard therapy) trial analyzing the subgroups were presented in an oral abstract session at the 2012 ASCO Annual Meeting. 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 currently approved standard therapies. The study results showed that regorafenib plus BSC significantly improved both overall survival and progression-free survival, compared to placebo plus BSC. New data from CORRECT showed a positive trend of survival benefit (OS and PFS) in the regorafenib arm across nearly all subgroups analyzed. In particular, the benefit of regorafenib was demonstrated in both patients with KRAS wild-type tumor and those with KRAS mutant tumor (Abstract No. 3502).

“These data show regorafenib’s potential across various cancer types, first in CRC and now in GIST,” said Kemal Malik, MD, Head of Global Development and member of the Bayer HealthCare Executive Committee. “We are committed to researching treatments, particularly for patients who have exhausted available therapies and urgently need new options.”

Bayer has submitted a Marketing Authorization Application to the European Medicines Agency (EMA) and a New Drug Application to the U.S. Food and Drug Administration (FDA) for the oral multi-kinase inhibitor regorafenib for the treatment of patients with mCRC. Bayer plans the first submissions of regorafenib for marketing authorization in GIST in the second half of 2012.

About the GRID results

GRID was a randomized, double-blind, placebo-controlled, multi-center, cross-over Phase III study of regorafenib for the treatment of GIST. It randomized 199 patients whose disease had progressed despite prior treatment with imatinib and sunitinib. Patients were randomized in a 2:1 ratio to receive either regorafenib (160 mg once daily, 3 weeks on/1 week off) plus BSC or placebo plus BSC to evaluate efficacy and safety. The primary endpoint of this trial was PFS, and secondary endpoints included OS, time to progression, disease control rate, tumor response rate, and duration of response. Patients initially randomized to placebo were allowed to cross over to open-label regorafenib once the disease progressed, which 85% of the patients from the placebo arm did.

The overall safety and tolerability profile for regorafenib in the GRID study was consistent with results from previous studies. There were no new or unexpected safety concerns with regorafenib. The most common drug-related, treatment-emergent adverse events (occurring in at least 10% of patients) included hand-foot skin reaction (56.1% vs. 15.2%), hypertension (48.5% vs. 16.7%), diarrhea (40.9% vs. 7.6%), fatigue (38.6% vs. 27.3%), oral mucositis (37.9% vs. 9.1%), alopecia (23.5% vs. 3.0%), hoarseness (22.0% vs. 4.5%), anorexia (20.5% vs. 7.6%), rash maculopapular (18.2% vs. 3.0%), nausea (15.9% vs. 9.1%), constipation (15.2% vs. 7.6%), myalgia (13.6% vs. 9.1%), and voice alteration (11.4% vs. 3.0%) for patients receiving regorafenib as compared to placebo.

About the CORRECT results

The Phase III study CORRECT randomized 760 patients with metastatic colorectal cancer (mCRC) whose disease had progressed after currently approved standard therapies to receive regorafenib plus BSC or placebo plus BSC at a 2:1 ratio. 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 OS. Secondary endpoints included PFS, objective tumor response rate and disease control rate. The safety and tolerability of the two treatment groups were also compared. Primary efficacy and safety data for this trial were reported earlier this year at the Annual Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (ASCO-GI) in January 2012. The results presented at ASCO 2012 included new data from the subgroup analysis, including data on the patient’s tumor KRAS mutation status.

The detailed results from the KRAS subgroup analysis are as follows:

- KRAS wild-type: median OS 7.3 months vs. 5.0 months, HR=0.65; median PFS 2.0 months vs. 1.8 months, HR 0.48
- KRAS mutant: median OS 6.2 months vs. 5.1 months, HR=0.87; median PFS 1.9 months vs. 1.7 months, HR 0.53

KRAS status is an important biomarker in mCRC. Approximately 40% of colorectal cancers are characterized by mutations in the KRAS gene. KRAS mutations often predict lack of response to anti-EGFR therapy. A treatment that works despite the KRAS status would represent an advance in colorectal cancer therapy and address a significant unmet medical need.

There were no new or unexpected safety findings. The most common drug-related, treatment-emergent adverse events (occurring in at least 10% 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%), rash/desquamation (26.0% vs. 4.0%), nausea (14.4% vs. 11.1%), weight loss (13.8% vs. 2.4%), thrombocytopenia (12.6% vs. 2.0%), bleeding (11.4% vs. 2.8%), and fever (10.4% vs. 2.8%) for patients receiving regorafenib as compared to placebo.

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 U.S. Food and Drug Administration (FDA), 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.

Bayer AG, Investor Relations contacts:

Dr. Alexander Rosar (+49-214-30-81013)
Dr. Juergen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)
Dr. Olaf Weber (+49-214-30-33567)
Fabian Klingen (+49-214-30-35426)
Ute Menke (+49-214-30-33021)

Forward-Looking Statements

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