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Investor News

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Phase III Trial of Regorafenib in Patients with Metastatic Gastrointestinal Stromal Tumors (GIST) Meets Primary Endpoint of Improving Progression-Free Survival

Leverkusen, Germany, April 3, 2012 – Bayer HealthCare today announced positive results from its Phase III trial GRID (GIST – Regorafenib In Progressive Disease) evaluating its investigational compound regorafenib (BAY 73-4506) for the treatment of patients with metastatic and/or unresectable gastrointestinal stromal tumors (GIST) whose disease has progressed despite prior treatment with imatinib and sunitinib. The trial met its primary endpoint of statistically significantly improving progression-free survival. In this trial, the safety and tolerability of regorafenib were generally as expected. Detailed data from the study are expected to be presented at an upcoming scientific meeting. The GRID study was sponsored by Bayer with academic leadership from the principal investigator George Demetri, M.D., Director of the Ludwig Center at the Dana-Farber Cancer Institute and Harvard Medical School, Boston, MA, U.S.A. The study started in January 2011 and completed enrollment by July 2011.

“Additional treatment options are needed for GIST patients after failure of approved drugs,” said Kemal Malik, MD, Head of Global Development and member of the Bayer HealthCare Executive Committee. “These findings may represent important progress in this difficult-to-treat disease with high unmet patient need.”

Bayer plans to submit regorafenib for marketing authorization in the treatment of metastatic and/or unresectable GIST based on these data.

Regorafenib has also shown positive results in a Phase III trial for the treatment of patients with metastatic colorectal cancer (mCRC) whose disease has progressed after approved standard therapies. Bayer plans to submit regorafenib for marketing authorization in mCRC in the first half of 2012.

About the GRID Study
GRID (GIST – Regorafenib In Progressive Disease) was a randomized, double-blind, placebo-controlled, multi-center, cross-over Phase III study of regorafenib for the treatment of GIST. It enrolled 199 patients whose disease has 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 best supportive care (BSC) or placebo plus BSC to evaluate efficacy and safety. Subjects receiving placebo who experienced disease progression were offered regorafenib treatment. The primary endpoint of this trial is progression-free survival, and secondary endpoints include overall survival, time to progression, disease control rate, tumor response rate, and duration of response.

About GIST
GIST is the most common form of sarcoma (a type of cancer that develops from certain tissues, like bone or muscle) involving the gastrointestinal tract. GIST represents a potentially life-threatening malignancy if the disease has spread to other parts of the body (metastasized) or is unable to be surgically removed with curative intent. The incidence of GIST is estimated to be 11 to 20 patients per million per year. In the U.S., it is estimated that there are approximately 4,500-6,000 new cases of GIST diagnosed each year, of which about 1,500 have already metastasized upon diagnosis. GIST is difficult to diagnose and is usually found incidentally when the doctor is looking for other problems.

GIST has become a paradigm of personalized cancer medicine in the past decade when it was discovered that most GIST are caused by activating mutations in the KIT or PDGFR-α receptor, which lead to uncontrolled signaling inside the tumor cells. Based on this knowledge, available therapeutic approaches to GIST focus on inhibiting these mutated receptor molecules (referred to as molecular targeted therapy). Imatinib and sunitinib, which inhibit oncogenic KIT, are currently the only two drugs approved for first and second-line treatment of metastatic and/or unresectable GISTs, respectively. Eventually, patients stop responding to these drugs due to the emergence of secondary mutations in KIT or PDGFR-α, or in alternative signaling cascades such as RAF.

About Regorafenib
Regorafenib is an investigational oral multi-kinase inhibitor targeting angiogenic, tumor microenvironment and oncogenic kinases. Regorafenib inhibits several angiogenic VEGF receptor tyrosine kinases which play a role in tumor neoangiogenesis and

lymphangiogenesis. It also inhibits various oncogenic and tumor microenvironment kinases including KIT, RET, PDGFR, and FGFR. 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 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 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.

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 Regorafenib in Colorectal Cancer (CORRECT trial)
Regorafenib has also shown positive results in a Phase III trial for the treatment of patients with metastatic colorectal cancer (mCRC) whose disease has progressed after approved standard therapies. The CORRECT (Colorectal cancer treated with regorafenib or placebo after failure of standard therapy) trial met its primary endpoint of statistically significantly improving overall survival as well as the secondary endpoint of statistically significantly improving progression-free survival. In this trial, the safety and tolerability of regorafenib were generally as expected and did not show any new or unexpected toxicities. Data from this trial were presented as a late breaking abstract in an oral abstract session at the Annual Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (ASCO-GI) in January 2012.

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.

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