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Investor News

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Adjuvant Treatment of Colorectal Cancer after Resection of Liver Metastases:

Phase III Trial of Regorafenib Shows Insufficient Patient Recruitment

- Enrolment will be halted before the study endpoints can be assessed
- No new safety signals from study

Leverkusen, Germany, March 5, 2015 – Bayer HealthCare today announced that it is suspending enrolment into a Phase III trial with regorafenib (Stivarga®) in colorectal cancer patients with resected liver metastases due to insufficient patient recruitment. The randomized, double-blind, placebo-controlled Phase III trial is evaluating regorafenib as an adjuvant treatment of colorectal cancer following resection of liver metastases with curative intent. As a result of slow patient accrual, the study will be closed to further enrolment before the study endpoints can be assessed. Importantly, there were no new safety signals from the study.

“We are disappointed that the extensive measures to increase recruitment did not have the desired outcome. We would like to thank the patients and the study investigators for their contributions and participation in this study,” said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “Importantly, this decision does not affect our commitment for Stivarga in the approved as well as potential additional indications. We will continue to evaluate regorafenib in a number of tumor types with significant unmet medical needs, including colorectal cancer.”

Bayer is informing Health Authorities and investigators on the planned enrolment suspension. The company is actively working with the Data Monitoring Committee, the Study Steering Committee and investigators with regard to the appropriate disposition of patients who have entered into the trial. A summary of the findings will be disclosed to the public as available.

Phase III Trial Design

The COAST (Patients with Stage IV COlorectal Cancer treated with Adjuvant Regorafenib Versus Placebo after Curative Treatment of Liver Metastases in a Randomized, Double-blind, Placebo-controlled Phase-III Study) clinical trial is studying regorafenib in patients with colorectal cancer after curative resection of liver metastases and completion of all planned chemotherapy. The study investigates whether providing 160 mg oral regorafenib in the adjuvant setting increases disease-free survival (DFS) and overall survival (OS) compared to placebo. From the original 750 patients planned to enroll in the study, to date about 25 patients have been enrolled.

About Colorectal Cancer

Colorectal Cancer (CRC) is the third most common cancer worldwide, with over one million cases occurring every year. 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 (Stivarga®)

Regorafenib (Stivarga®) is an oral multi-kinase inhibitor that inhibits various kinases within the mechanisms involved in 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 (the growth of new blood vessels). In addition to VEGFR 1-3 it also inhibits various oncogenic and tumor microenvironment kinases including TIE-2, RAF-1, BRAF, BRAFV600, KIT, RET, PDGFR, and FGFR, which individually and collectively impact upon tumor growth, formation of a stromal microenvironment and disease progression.

Regorafenib has been approved under the brand name Stivarga® in more than 70 countries worldwide, including the U.S., Europe and Japan, for the treatment of metastatic colorectal cancer (mCRC). In more than 50 countries worldwide, including the U.S., Europe and Japan, the product has also been approved for the treatment of patients with gastrointestinal stromal tumors (GIST).

Regorafenib is a compound developed by Bayer. In 2011, Bayer entered into an agreement with Onyx Pharmaceuticals, Inc., an Amgen subsidiary, under which Onyx receives a royalty on all global net sales of regorafenib in oncology.

About Oncology at Bayer

Bayer is committed to delivering *science for a better life* by advancing a portfolio of innovative treatments. The oncology franchise at Bayer now includes three oncology products and several other compounds in various stages of clinical development. Together, these products reflect the company's approach to research, which prioritizes targets and pathways with the potential to impact the way that cancer is treated.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 20,0 billion (2014), 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 60,700 employees (Dec 31, 2014) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

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