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Investor News

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Bayer Initiates Phase III Trial of Regorafenib in Patients with Colorectal Cancer after Resection of Liver Metastases

Leverkusen, February 20, 2014 – Bayer HealthCare today announced that the company has begun to enroll patients in the COAST trial studying regorafenib (Stivarga®) tablets in colorectal cancer (CRC) patients with resected liver metastases. The randomized, double-blind, placebo-controlled Phase III trial is evaluating regorafenib as adjuvant treatment of colorectal cancer following resection of liver metastases with curative intent.

"The COAST trial is another step forward in Bayer's ongoing commitment to explore the full clinical potential of regorafenib for colorectal cancer patients across different stages of this disease," said Dr. Jörg Möller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "Many patients with advanced colorectal cancer that has metastasized to the liver experience disease recurrence despite curative surgery and are in need of new treatment options."

Phase III Trial Design

The COAST (Patients with Stage IV **CO**lorectal Cancer treated with **A**djuvant Regorafenib Versus Placebo after Curative Treatment of Liver Metastases in A Randomized, Double-blind, Placebo-controlled Phase-III **St**udy) clinical trial is studying regorafenib in patients with colorectal cancer after curative resection of liver metastases and completion of all planned chemotherapy. The study will investigate whether providing oral regorafenib in the adjuvant setting increases disease-free survival (DFS) and overall survival (OS). The trial will enroll approximately 750 patients who will be randomized in a 1:1 ratio to receive either 160 mg regorafenib or placebo. Safety and tolerability of the treatment groups will be continuously monitored.

The study will be conducted in North America, Brazil, Europe, Asia, Israel and Australia. For further information about the study, please visit www.clinicaltrials.gov.

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 Stivarga®

Stivarga® (regorafenib) 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, Stivarga 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.

Stivarga is approved in the United States, Europe, Japan, and in several other countries for the treatment of metastatic CRC. For the treatment of gastrointestinal stromal tumors (GIST), Stivarga is also approved in the United States, Japan and in several other countries. In September 2013, Bayer submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for the treatment of patients with GIST.

Stivarga 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 Stivarga 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 18.6 billion (2012), 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 54,900 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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