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Investor News

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Bayer Initiates Phase III Trial of Regorafenib in Patients with Advanced Liver Cancer

Leverkusen, Germany, May 15, 2013 – Bayer HealthCare today announced that the company has started to enroll patients in an international Phase III trial to evaluate the efficacy and safety of regorafenib for the treatment of patients with hepatocellular carcinoma (HCC) who have progressed on sorafenib treatment. Regorafenib is an oral multi-kinase inhibitor that inhibits various kinases within the mechanisms involved in tumor growth and progression – angiogenesis, oncogenesis and maintenance of the tumor microenvironment.

“With sorafenib being a major advance in the treatment of unresectable HCC, Bayer remains committed to developing other treatment options, as there is a high unmet medical need for patients with advanced liver cancer whose disease has progressed after treatment with sorafenib,” said Kemal Malik, MD, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “This international Phase III trial further broadens Bayer’s extensive and ongoing clinical development program for regorafenib and underscores Bayer’s commitment to developing novel treatment options, particularly for patients with difficult-to-treat cancers.”

About the Phase III Study

The RESORCE [REgorafenib after SORafenib in patients with hepatoCEllular carcinoma] clinical trial is a randomized, double blind, placebo controlled, multicenter Phase III study of regorafenib in patients with hepatocellular carcinoma whose disease has progressed after treatment with sorafenib. The trial will enroll approximatehly 530 patients who will be randomized in a 2:1 ratio to receive either regorafenib plus best supportive care (BSC) or placebo plus BSC.

Patients will receive 160 mg regorafenib once daily, for 3 weeks on/1week off, or placebo. The primary endpoint of the study is overall survival, and secondary endpoints are time to progression, progression-free survival, objective tumor response rate and disease control rate. Safety and tolerability of the treatment groups will also be continously monitored.

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

About Hepatocellular Carcinoma

Hepatocellular carcinoma (HCC) is the most common form of liver cancer and is responsible for approximately 90 percent of the primary liver cancers in adults. Liver cancer is the seventh most common cancer in the world and the third leading cause of cancer-related deaths globally.

Major risk factors that can lead to the development of HCC include alcohol abuse, hepatitis B, hepatitis C, the use of anabolic steroids and some hereditary diseases. HCC is often hard to detect early because signs and symptoms do not usually appear until it is in its later stages, and thus the majority of patients diagnosed with HCC have advanced disease, and may not be eligible for potentially curative therapies.

About Regorafenib

Regorafenib is an oral multi-kinase inhibitor that targets oncogenesis, tumor angiogenesis and maintenance of the tumor microenvironment signaling by inhibiting multiple protein kinases. In preclinical studies, regorafenib has been shown to inhibit several angiogenic VEGF receptor tyrosine kinases that play a role in tumor neoangiogenesis (the growth of new blood vessels). It also inhibits various oncogenic and tumor microenvironment kinases including VEGFR 1-3, KIT, RET, PDGFR and FGFR, which individually and collectively impact upon tumor growth, formation of a stromal microenvironment and disease progression.

Regorafenib was approved under the name Stivarga® by the U.S. Food and Drug Administration (FDA) for the treatment of metastatic colorectal cancer (mCRC) in September 2012 and for the treatment of gastrointestinal stromal tumors (GIST) in February 2013. It was also approved in Japan for the treatment of advanced or recurrent CRC in March 2013. Bayer has also submitted for marketing approval of regorafenib for the treatment of mCRC in the EU in May 2012. In December 2012, Bayer submitted a

filing in Japan for regorafenib for the treatment of GIST and has received priority review for this indication.

Regorafenib is a Bayer compound developed by Bayer and jointly promoted by Bayer and Onyx in the U.S. In 2011, Bayer entered into an agreement with Onyx, under which Onyx receives a royalty on all 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, 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 55,300 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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