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Investor News

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Bayer's Stivarga® (regorafenib) Tablets Approved in Japan for the Treatment of Advanced or Recurrent Colorectal Cancer

Leverkusen, Germany, March 25, 2013 – Bayer HealthCare announced today that the Ministry of Health, Labor and Welfare (MHLW) in Japan has approved Stivarga® (regorafenib) tablets for the treatment of patients with unresectable, advanced/recurrent colorectal cancer (CRC). The approval of Stivarga by the MHLW is based on results from the pivotal Phase III CORRECT study that demonstrated a statistically significant improvement in overall survival and progression-free survival compared to placebo in patients with metastatic CRC (mCRC) whose disease had progressed after approved standard therapies. Stivarga 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.

"The approval of Stivarga in Japan is significant, as it provides an important treatment avenue for patients with advanced colorectal cancer whose cancer has returned despite treatment with other approved therapies," said Kemal Malik, MD, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "Bayer is committed to developing new therapies for patients and their physicians in hard to treat diseases like mCRC where there continues to be an unmet medical need for additional treatments, and we are delighted that Stivarga provides a potential new option for Japanese physicians to offer their patients."

"The incidence of colorectal cancer is increasing in Japan and we are limited in the number of treatment options available to patients with advanced disease," said Takayuki Yoshino, M.D., Chief of Department of Gastroenterology and Gastrointestinal Oncology at the National Cancer Center Hospital East, Japan. "Regorafenib has been shown to

prolong overall survival and slow the progression of cancer and provides an important treatment advance for patients with mCRC who have no further treatment options."

The international multicenter Phase III CORRECT (Colorectal cancer treated with regorafenib or placebo after failure of standard therapy) trial evaluated regorafenib plus best supportive care (BSC) versus placebo plus BSC in patients with mCRC, whose disease has progressed after approved standard therapies. The CORRECT study also included 20 sites in Japan. The study results showed that regorafenib plus BSC significantly improved both overall survival (OS) (HR=0.774, 1-sided p-value=0.005178) and progression-free survival (PFS) (HR=0.494, 1-sided p-value <0.000001) compared to placebo plus BSC in patients with mCRC whose disease had progressed after approved standard therapies. The data also showed a survival benefit (OS and PFS) in the regorafenib arm across nearly all subgroups analyzed. In the study, median OS was 196 days with regorafenib versus 151 days with placebo; median PFS was 59 days with regorafenib versus 52 days with placebo.

The most frequently observed adverse drug reactions (equally or greater than 30%) in patients receiving regorafenib were asthenia/fatigue, decreased appetite and food intake, hand-foot-skin reaction/ palmar-plantar erythrodysesthesia, diarrhea, mucositis, weight loss, infection, hypertension, and dysphonia. The most serious adverse drug reactions in patients receiving regorafenib were hepatotoxicity, hemorrhage and gastrointestinal perforation.

Full results from the CORRECT study were presented at the 48th Annual Meeting of the American Society of Clinical Oncology (ASCO) in June 2012 and published online in the journal The Lancet in January 2013.

In Japan, CRC is the third most common cause of cancer death, with over 40,000 people dying every year and almost 100,000 newly diagnosed cases per year. Research also shows that the incidence of CRC has risen dramatically in Japan in the last 20 years.

About the CORRECT trial

The Phase III study CORRECT randomized 760 patients with mCRC whose disease had progressed after currently approved standard therapies to receive regorafenib plus best supportive care (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 overall survival. Secondary endpoints

included progression-free survival, objective tumor response rate and disease control rate. The safety and tolerability of the two treatment groups were also compared.

About Stivarga® (regorafenib)

Stivarga® (active substance 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 inhibits 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 also approved under the name Stivarga® in the U.S. for the treatment of mCRC in September 2012 and for the treatment in gastrointestinal stromal tumors (GIST) in February 2013. Bayer has also submitted for marketing approval of regorafenib for the treatment of metastatic CRC in the EU in May 2012.

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 Oncology at Bayer

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

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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