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Investor News

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Bayer's Stivarga® (regorafenib) Tablets New Drug Application Granted Priority Review by U.S. FDA for the Treatment of Patients with Gastrointestinal Stromal Tumors

Berlin, October 29, 2012 – Bayer HealthCare announced today that the U.S. Food and Drug Administration (FDA) granted priority review to the New Drug Application (NDA) filed at the end of August 2012 for the oral multi-kinase inhibitor Stivarga® (regorafenib) tablets to treat patients with metastatic and/or unresectable gastrointestinal stromal tumors (GIST) whose disease has progressed despite prior treatment with other kinase inhibitors.

Stivarga was recently approved by the FDA for the treatment of patients with metastatic colorectal cancer (mCRC) who have been previously treated with currently available therapies.

The FDA grants priority review to medicines that offer advances in care or that provide a treatment where no adequate therapy exists. Under the Prescription Drug User Fee Act (PDUFA), the FDA will complete its review within six months, rather than the standard 10-month review cycle.

"We are pleased to receive priority review designation from the FDA for regorafenib in GIST as it reflects the pressing need for new therapies for this rare but aggressive tumor type and the potential for regorafenib to offer another option for patients," said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

The submission was based on data from the Phase III GRID (GIST – Regorafenib In Progressive Disease) study which showed that regorafenib plus best supportive care (BSC) significantly improved progression-free survival over placebo plus BSC. In this trial, the safety and tolerability profile of regorafenib was consistent with results from previous studies. Data from this trial were first reported at the Annual Meeting of the American

Society of Clinical Oncology (ASCO) in June 2012 and updated data were presented at the European Society for Medical Oncology (ESMO) congress in September 2012.

About the GRID Study

GRID was a randomized, double-blind, placebo-controlled, multi-center Phase III study of regorafenib for the treatment of GIST. It randomized 199 patients whose disease had progressed despite prior treatment with imatinib and sunitinib.

Patients were randomized in a 2:1 ratio to receive either regorafenib plus BSC or placebo plus BSC to evaluate efficacy and safety. Treatment cycles consisted of 160 mg regorafenib (or matching placebo) once daily for three weeks on / one week off plus BSC. The primary endpoint was progression-free survival, and secondary endpoints included overall survival, time to progression, disease control rate, tumor response rate, and duration of response. The safety and tolerability of the two treatment groups were also compared.

About Gastrointestinal Stromal Tumors (GIST)

GIST is the most common form of sarcoma arising from the muscle wall of the gastrointestinal tract. GIST represents a 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.

About 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 maintenance of the tumor microenvironment. In preclinical studies, regorafenib inhibited 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 and maintenance of a tumor microenvironment.

Stivarga was approved by the FDA in September 2012 for the treatment of patients with CRC who had been previously treated with currently available therapies (including

fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and if KRAS wild type, an anti-EGFR therapy). It was also submitted for the treatment of mCRC in the EU in May 2012. The NDA for regorafenib for the treatment of advanced CRC filed in Japan in July 2012 was granted priority review.

Regorafenib is a Bayer compound developed by Bayer and jointly promoted in the U.S. by Bayer and Onyx Pharmaceuticals, Inc. In 2011, Bayer entered into an agreement with Onyx, under which Onyx receives a royalty on all future global net sales of Stivarga 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 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. More information at www.healthcare.bayer.com.

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