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Investor News

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Bayer Submits Regorafenib for the Treatment of Gastrointestinal Stromal Tumors in Japan

Leverkusen, Germany, December 21, 2012 – Bayer HealthCare today announced that Bayer Yakuhin, Ltd., Osaka, Japan, has submitted for marketing authorization the oral multi-kinase inhibitor regorafenib for the treatment of metastatic and/or unresectable gastrointestinal stromal tumors (GIST) to the Ministry of Health, Labour and Welfare (MHLW) in Japan. This follows the submission of regorafenib to MHLW for the treatment of colorectal cancer (CRC) which received priority review at the end of August 2012.

“The submission of regorafenib for the treatment of GIST in Japan shortly after the submission in metastatic colorectal cancer is an important step towards meeting a significant medical need of patients in Japan,” said Kemal Malik, M.D., member of the Bayer HealthCare Executive Committee and Head of Global Development.

The submission to the MHLW is based on the positive results from the pivotal Phase III GRID (GIST – Regorafenib In Progressive Disease) trial which took place across the globe, including eight sites in Japan. The study evaluated regorafenib plus best supportive care (BSC) versus placebo plus BSC in patients with metastatic and/or unresectable GIST whose disease had progressed despite prior treatment with imatinib and sunitinib. Regorafenib plus BSC significantly improved progression-free survival compared to placebo plus BSC. The overall safety and tolerability profile for regorafenib in the GRID study was consistent with results from previous studies. Results from the study were presented at the Annual Meeting of the American Society of Clinical Oncology (ASCO) in June 2012 and were published online on November 22, 2012 in the journal The Lancet.

Regorafenib was approved by the FDA in mCRC in September under the name Stivarga® and received priority review for the treatment of GIST in the U.S. in October 2012

following the submission for marketing approval in August 2012. Regorafenib has also been submitted to the regulatory authorities in the EU for the treatment of mCRC.

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. Each treatment cycle 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 Japan, it is estimated that there are 1,000 to 1,500 patients with unresectable or recurrent GIST diagnosed every year.

The discovery of oncogenic KIT kinase mutations in GISTs and the introduction of kinase inhibitor therapies have led to a rapid evolution in the understanding of these tumors. It is now established that 70–80% of GISTs harbour a KIT gene mutation, that these mutations lead to the continued activation of the kinase and that mutant KIT is a clinically important therapeutic target in GIST.

About Regorafenib

Regorafenib is an oral multi-kinase inhibitor that targets oncogenesis, angiogenesis and tumor microenvironment signaling by inhibiting multiple protein kinases. In preclinical studies, Stivarga has been shown to inhibit several angiogenic VEGF receptor kinases that play a role in tumor neoangiogenesis (the growth of new blood vessels). It also inhibits various oncogenic and tumor microenvironment kinases including KIT and PDGFR, which play a key role in the development and recurrence of GIST tumors.

Regorafenib is a Bayer compound developed by Bayer and jointly promoted by Bayer and Onyx Pharmaceuticals, Inc. in the U.S.. In 2011, Bayer entered into an agreement with Onyx, under which Onyx receives a royalty on all future 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 Yakuhin, Ltd.

Bayer Yakuhin Ltd., headquartered in Osaka, is a healthcare company which combines business activities of pharmaceuticals, dermatology, Consumer Care (OTC product) and Animal Health (companion and food animal products). Pharmaceuticals business is focused on the following areas: Diagnostic Imaging, General Medicine, Oncology, Specialty Medicine and Women's Healthcare. Bayer Yakuhin aims to be one of leading pharmaceutical companies, which responds to Japanese patients' unmet medical needs, with the spirit of Bayer's corporate slogan "Science For A Better Life".
Bayer Yakuhin homepage: http://www.bayer.co.jp/byl

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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