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Investor News

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New Drug Application for Bayer's Regorafenib to Treat Patients with Colorectal Cancer Granted Priority Review in Japan

Leverkusen, Germany, September 11, 2012 – Bayer HealthCare today announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has granted priority review to Bayer Yakuhin, Ltd., Osaka, Japan, for the New Drug Application (NDA) of Regorafenib filed at the end of July 2012 for the treatment of patients with unresectable, advanced/recurrent colorectal cancer (CRC). The MHLW grants priorty review to medicines on the basis of their clinical usefulness and severity of the disease.

"The number of patients suffering from colorectal cancer continues to increase in Japan and for patients with advanced disease, there are limited options. The improved overall survival seen in the CORRECT trial is encouraging and has the potential to provide Japanese physicians with a new option to offer these patients," said Kemal Malik, MD, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

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

The submission to MHLW is based upon the positive results from the pivotal, multinational Phase III CORRECT (Colorectal cancer treated with regorafenib or placebo after failure of standard therapy) trial which was conducted across the globe, including 20 sites in Japan. The study evaluated regorafenib plus best supportive care (BSC) versus placebo plus BSC in patients with metastatic CRC whose disease progressed after approved standard therapies. The CORRECT results showed that regorafenib plus BSC significantly improved both overall survival and progression-free survival, compared to placebo plus BSC. In this trial, the safety and tolerability of regorafenib were generally as

expected. Full results from the study were presented at the 48th Annual Meeting of the American Society of Clinical Oncology (ASCO) in June 2012.

Regorafenib was submitted for marketing approval for the treatment of metastatic CRC in the U.S. and EU in April and May 2012, respectively and was granted priority review by the FDA in June 2012.

About the CORRECT Study
The CORRECT trial is an international, multicenter, randomized, double-blind, placebo-controlled study that enrolled 760 patients with metastatic CRC whose disease has progressed after approved standard therapies, including 100 patients from Japan. The CORRECT study was conducted in North America, Europe, Israel, China, Japan and Australia.

Patients were randomized to receive either regorafenib plus best supportive care (BSC) or placebo plus BSC. 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 Colorectal Cancer
Colorectal cancer (CRC) is a disease in which malignant (cancer) cells form in the tissues of the colon or rectum. The majority of cancers occurring in the colon and rectum are adenocarcinomas, which account for more than 90 percent of all large bowel tumors.

CRC is the fourth most common cancer worldwide, with over one million cases occurring every year. The mortality rate from CRC is approximately half of its global incidence. 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 Regorafenib
Regorafenib is an investigational, oral, multi-kinase inhibitor targeting three key mechanisms of tumor growth and progression – angiogenesis, oncogenesis, and the tumor microenvironment. In preclinical studies, regorafenib inhibits several angiogenic VEGF receptor tyrosine kinases that play a role in tumor neoangiogenesis and

lymphangiogenesis (the growth of new blood vessels and lymphatic vessels). It also inhibits various oncogenic and tumor microenvironment kinases including KIT, RET, PDGFR, and FGFR which control tumor growth, infrastructure and progression. Regorafenib is currently being investigated in clinical trials for its potential to treat patients with various tumor types.

Regorafenib is an investigational agent and is not approved by the United States Food and Drug Administration (FDA), the European Medicines Agency (EMA) or other health authorities.

In 2011, Bayer entered into an agreement with Onyx Pharmaceuticals, Inc. under which Onyx will receive a royalty on any future global net sales of regorafenib in oncology.

About Bayer Yakuhin

Bayer Yakuhin Ltd., headquartered in Osaka, is a healthcare company which combines business activities of Pharmaceuticals, Radiology & Interventional and Animal Health (companion and food animal products). Pharmaceuticals business is focused on the following areas: Cardiovascular & Neurology, Oncology & Hematology, Women's Health & Dermatology and Ophthalmology. 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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