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Investor News

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Bayer's Regorafenib Submitted for U.S. Marketing Authorization for the Treatment of Gastrointestinal Stromal Tumors (GIST)

Leverkusen, Germany, August 30, 2012 – Bayer HealthCare has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its oral multi-kinase inhibitor regorafenib for the treatment of metastatic and/or unresectable gastrointestinal stromal tumors (GIST) in patients whose disease has progressed despite prior treatment with other kinase inhibitors.

"The submission of regorafenib for the treatment of GIST brings us one step closer to meeting a significant medical need for patients with this aggressive disease," said Kemal Malik, MD, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "We are committed to developing new oncology therapies for patients, especially for whom available therapies no longer work and new options are needed."

The submission is supported by data from the Phase III GRID (GIST – Regorafenib In Progressive Disease) trial. 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.

Earlier this year, Bayer submitted a Marketing Authorization Application to the European Medicines Agency (EMA) and a New Drug Application to the FDA for regorafenib for the treatment of patients with metastatic colorectal cancer (mCRC). The FDA has granted priority review status to the application for regorafenib in 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 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 individually and collectively impact upon tumor growth, formation of a stromal microenvironment and disease 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 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 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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