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Investor News

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Bayer's Stivarga® Approved for the Treatment of Patients with Gastrointestinal Stromal Tumors in Japan

Leverkusen, Germany, August 20, 2013 – Bayer HealthCare has received approval from the Ministry of Health, Labor and Welfare (MHLW) in Japan for the marketing of Stivarga® (regorafenib) for the treatment of patients with gastrointestinal stromal tumor (GIST) who have progressed after prior systemic cancer therapy. This marks the second indication approved for Stivarga in Japan.

"The approval of Stivarga in Japan is an important development as it means that patients with GIST have a new option to slow the progression of this rare but aggressive disease," said Kemal Malik, MD, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "We are pleased that Stivarga can make a difference to patients diagnosed with advanced GIST."

The approval of Stivarga is based on the positive results from the pivotal Phase III GRID (GIST – Regorafenib In Progressive Disease) trial that demonstrated a statistically significant improvement in progression-free survival (PFS) compared to placebo in patients with GIST whose disease had progressed after treatment with imatinib mesylate and sunitinib malate.

Results from the GRID 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 "*The Lancet*".

Stivarga is approved in several countries, including the USA and Japan, for the treatment of patients with metastatic colorectal cancer (mCRC). Stivarga was recommended for approval by the European Committee for Medicinal Products for Human Use (CHMP) for

the treatment of adults with mCRC on June 27, 2013. The decision of the European Commission on the marketing authorization is expected later in 2013.

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 harbor 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 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 tumor microenvironment. In preclinical studies, Stivarga 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, KIT, RET, PDGFR, and FGFR, which individually and collectively impact upon tumor growth, formation of a stromal microenvironment and disease progression.

Stivarga is a compound developed by Bayer and jointly promoted by Bayer and Onyx in the USA. In 2011, Bayer entered into an agreement with Onyx, under which Onyx receives a royalty on all global net sales of Stivarga in oncology.

About Oncology at Bayer
Bayer is committed to delivering *science for a better life* by advancing a portfolio of innovative treatments. The oncology franchise at Bayer now includes three oncology products and several other compounds in various stages of clinical development. Together, these products reflect the company’s approach to research, which prioritizes targets and pathways with the potential to impact the way that cancer is treated.

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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