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Investor News

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

EMA filing follows EU approval of Stivarga® (regorafenib) for use in metastatic colorectal cancer

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Leverkusen, Germany, September 5, 2013 – Bayer HealthCare has submitted an application for marketing authorization to the European Medicines Agency (EMA) for the oral multi-kinase inhibitor, regorafenib, for the treatment of patients with gastrointestinal stromal tumors (GIST) who have been previously treated with two tyrosine kinase inhibitors. The EMA filing follows the EU approval of regorafenib (Stivarga®) for use in metastatic colorectal cancer in August 2013.

"The submission of regorafenib to EMA is an exciting advance because it means patients with GIST will have a potential new treatment option to help manage an aggressive disease", said Kemal Malik, M.D., Member of the Bayer HealthCare Executive Committee and Head of Global Development. "We look forward to offering patients and physicians a new path forward."

"GIST is a disease that only affects a limited number of people, about 15 per million per year. However, of those who are affected over half develop recurrent metastatic disease, for which there are currently very few treatment options once resistance to first line treatments are observed", said Prof. Jean-Yves Blay, M.D., Ph.D, University Claude Bernard Lyon, Centre Léon Bérard, Department of Medicine, French Sarcoma Group (GSF-GETO), European Organisation for Research and Treatment of Cancer (EORTC). "The results from the GRID study suggest a significant progression free survival benefit for patients with GIST who have been treated with regorafenib."

Stivarga is approved in the USA, Europe and Japan, for the treatment of patients with metastatic colorectal cancer (mCRC). Stivarga has also been approved in the USA and Japan for the treatment of GIST.

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 1.5 cases per 100,000 people in Europe. At the point of diagnosis, an estimated 10-25 percent of GIST cases have disease that has metastasized.

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 regorafenib (Stivarga®)
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 that have regulatory approval or are undergoing regulatory review and several

other compounds in earlier 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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