



News Release

Not intended for U.S. and UK Media

Bayer's Stivarga[®] (regorafenib) Approved in the EU for the Treatment of Metastatic Colorectal Cancer

Berlin, August 30, 2013 – Bayer HealthCare announced today that the European Commission has approved Stivarga[®] (regorafenib) tablets for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have previously been treated with, or are not considered candidates for, available therapies. These include fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy.

“Following the approval of Stivarga for mCRC in several countries worldwide, including the US and Japan, we are pleased to offer patients in Europe a new treatment option”, said Kemal Malik, MD, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “At Bayer, we are committed to developing treatments that can improve the lives of patients, and from these data anticipate that Stivarga can positively impact those suffering from mCRC.”

“Colorectal cancer is one of the most prevalent cancer types for which there is a real unmet need for new treatment options. Currently people with early CRC can have surgery to remove the cancer, preceded or followed by radiotherapy and/or chemotherapy to prevent it coming back. Yet for many people their disease progresses to other parts of the body, dramatically reducing their chance of being cured,” said Prof. Eric Van Cutsem, Lead CORRECT investigator, University Hospital Gasthuisberg Leuven, Belgium.

“The multi-targeted action of Stivarga provides a new option in targeting mCRC. In the CORRECT trial, Stivarga significantly improved both overall and progression-free survival

in this difficult-to-treat population. These data show that Stivarga can provide new treatment option for patients with mCRC,” van Cutsem concluded.

The approval of Stivarga was based on data from the pivotal Phase III CORRECT (Colorectal cancer treated with regorafenib or placebo after failure of standard therapy) trial. Full results from the CORRECT study were presented at the 48th Annual Meeting of the American Society of Clinical Oncology in June 2012 and published online on November 22, 2012 in *The Lancet*.

Stivarga is approved for the treatment of patients with mCRC and gastrointestinal stromal tumors (GIST) in several countries, including the U.S and Japan.

About Colorectal Cancer

CRC is the third most common cancer worldwide, with over one million cases occurring every year. 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 Stivarga®

Stivarga® (regorafenib) 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 VEGFR 1-3, KIT, RET, PDGFR, and FGFR, which individually and collectively impact upon tumor growth, formation of a stromal microenvironment and disease progression.

Stivarga is a Bayer 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 regorafenib 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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