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Investor News

Not intended for U.S. and UK Media

New Phase III Study for Stivarga® (Regorafenib):

Bayer collaborates with U.S. National Surgical Adjuvant Breast and Bowel Project (NSABP) to Investigate Stivarga® (Regorafenib) as Additional Adjuvant Therapy in Colon Cancer

- Study will include patients with Stage IIIB and IIIC colon cancer who have undergone complete surgical resection of primary tumor and received standard adjuvant chemotherapy
- Indication-seeking trial will be conducted by NSABP with the support from Bayer

Leverkusen, Germany, June 1, 2016 – Bayer and the U.S. National Surgical Adjuvant Breast and Bowel Project (NSABP), a leading clinical trials cooperative group, are collaborating on a new Phase III study to investigate Stivarga® (regorafenib) as an additional adjuvant therapy in colon cancer. The ARGO trial will investigate regorafenib as a single agent for the adjuvant treatment of Stage IIIB and IIIC colon cancer following completion of standard adjuvant chemotherapy. In this stage, the tumor has started to invade the wall of the colon, but not yet spread to other distant organs.

“In 2016, more than 134,000 adults in the United States will be diagnosed with colorectal cancer. Two-thirds of these cases, or more than 95,000, will be cancers of the colon,” said Norman Wolmark, MD, Chairman of the Foundation. “Despite receiving adjuvant chemotherapy, patients with stage IIIB and IIIC colon cancer have about a 40% risk of developing metastatic disease, meaning that the disease has spread from the colon to distant organs. Given the anti-metastatic effects of regorafenib demonstrated pre-clinically and the treatment benefits in the metastatic setting of colorectal cancer, we are keen to explore if it could also help patients at earlier stages of the disease.”

The Phase III study ARGO, a randomized, double-blind, placebo-controlled study, will be conducted by NSABP, with Bayer offering consultation as well as financial support. If

positive, Bayer may use the results for submission of marketing authorization of Stivarga in this earlier stage of the disease.

“We are excited to be collaborating with NSABP to further explore the potential of regorafenib in an earlier line of treatment for patients with colon cancer, one of the most common forms of cancer worldwide,” said Dr. Joerg Moeller, member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Development. “We believe that by partnering with those on the front line of patient care, we will be in a position to deliver additional therapeutic options to treating physicians and their patients.”

Regorafenib is approved under the trade name Stivarga® in 90 countries worldwide, including the United States, Europe, and Japan for the treatment of metastatic CRC. The approval of regorafenib 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 published in January 2013 in *The Lancet*.

About the ARGO Study

The Phase III study ARGO (A Phase III Randomized Placebo-Controlled Study Evaluating ReGOrafenib Following Completion of Standard Chemotherapy for Patients with Stage III Colon Cancer) will investigate whether providing oral regorafenib monotherapy in the adjuvant setting after standard chemotherapy increases disease-free survival (DFS) in patients with Stage IIIB/IIIC colorectal cancer. The secondary study endpoints include overall survival (OS) and safety. The trial will enroll approximately 1,100 patients from the U.S. who will be randomized in a 1:1 ratio to receive either 120 mg regorafenib or placebo for a planned duration of two years.

About Colon Cancer

The colon is part of the body’s digestive system, which is called the gastrointestinal system. Most colon cancers begin as a growth or a polyp on the inner lining of the colon, a part of the large intestine. Some types of polyps can develop into cancer over the course of several years. The cancer occurs when cells in the body begin to grow out of control.

Colon cancer is often grouped with rectal cancer because the two diseases share many common features. However, treatment approaches may differ for colon and rectal cancers, especially in the earlier stages.

Worldwide, colon and rectal cancers make up the third most common cancer in men and women combined. In 2012, there were an estimated 1.3 million new cases, and that number is expected to increase to 1.6 million by 2020.

About Regorafenib (Stivarga®)

Regorafenib is an oral multi-kinase inhibitor that targets various kinases involved in 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 (the growth of new blood vessels). In addition to VEGFR 1-3 it also inhibits various oncogenic and tumor microenvironment kinases including TIE-2, RAF-1, BRAF, BRAFV600, KIT, RET, PDGFR, and FGFR, which individually and collectively impact upon tumor growth, formation of a stromal microenvironment and disease progression.

Regorafenib is approved under the brand name Stivarga® in 90 countries for the treatment of mCRC and in more than 70 countries for the treatment of metastatic gastrointestinal stromal tumors (GIST). In the EU, Stivarga is indicated for the treatment of adult patients with mCRC who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy, as well as for the treatment of adult patients with unresectable or metastatic GIST who progressed on or are intolerant to prior treatment with imatinib and sunitinib.

Regorafenib is a compound developed by Bayer. In 2011, Bayer entered into an agreement with Onyx, now an Amgen subsidiary, under which Onyx receives a royalty on all global net sales of regorafenib in oncology.

About the National Surgical Adjuvant Breast and Bowel Project

The National Surgical Adjuvant Breast and Bowel Project (NSABP) is a clinical trials cooperative group supported since its inception by the National Cancer Institute (NCI). Since its beginning the NSABP has enrolled more than 110,000 women and men in clinical trials in breast and colorectal cancer. Headquartered in Pittsburgh, Pennsylvania, the NSABP has research sites at nearly 1000 major medical centers, university hospitals, large oncology practice groups, and health maintenance organizations in the United States, Canada, Puerto Rico, Australia, and Ireland. In addition to federally sponsored studies, the NSABP also conducts research supported by other resources.

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 marketed 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.

Bayer: Science For A Better Life

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2015, the Group employed around 117,000 people and had sales of EUR 46.3 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.3 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to www.bayer.com.

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