News Release

Intended for U.S. Media Only

Bayer's Stivarga® (regorafenib) Tablets Approved by U.S. FDA for Treatment of Metastatic Colorectal Cancer

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Wayne, NJ, and South San Francisco, CA, September 27, 2012 – Bayer HealthCare and Onyx Pharmaceuticals, Inc. (NASDAQ: ONXX) announced today that the U.S. Food and Drug Administration (FDA) approved Bayer's Stivarga® (regorafenib) tablets for the treatment of patients with metastatic colorectal cancer (mCRC) who have been previously treated with currently available therapies (including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy).[1] The approval of Stivarga is based on results from the pivotal Phase III study (CORRECT) that demonstrated improvement in overall survival (OS) and progression-free survival (PFS) compared to placebo in patients with mCRC whose disease had progressed after approved standard therapies.[2,3]

Stivarga is a Bayer compound developed by Bayer. 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 Stivarga in oncology. Bayer and Onyx will jointly promote Stivarga in the United States.

To view the Multimedia News Release, go to: http://www.multivu.com/mnr/57608-bayer-regorafenib-for-treatment-of-metastatic-colorectal-cancer.

"The approval of regorafenib adds to the treatments we have for metastatic colorectal cancer, which is important for those patients who have no further options," said Heinz-Josef Lenz, MD, FACP, CORRECT investigator and associate director for clinical research and co-leader of the Gastrointestinal Cancers Program at the USC Norris Comprehensive Cancer Center. "The drug has been shown to prolong survival and slow the progression of cancer in patients whose disease has progressed after treatment with currently available therapies. It provides patients another avenue to fight this cancer."

In the CORRECT (Colorectal cancer treated with regorafenib or placebo after failure of standard therapy) trial, Stivarga plus best supportive care (BSC) significantly improved OS [HR=0.77 (95% CI, 0.64-0.94), two-sided p=0.0102] and PFS [HR=0.49 (95% CI, 0.42-0.58), two-sided p<0.0001] compared to placebo plus BSC. Median OS was 6.4 months with Stivarga versus 5.0 months with placebo; median PFS was 2.0 months with Stivarga versus 1.7 months with placebo. No difference in overall response rate was observed. Five patients (1%) in the regorafenib arm and one patient (0.4%) in the placebo arm experienced partial responses.

The most frequently observed adverse drug reactions (≥30%) in patients receiving Stivarga were asthenia/fatigue, decreased appetite and food intake, hand-foot-skin reaction (HFSR)/palmar-plantar erythrodysesthesia (PPE), diarrhea, mucositis, weight loss, infection, hypertension and dysphonia. The most serious adverse drug reactions in patients receiving Stivarga included hepatotoxicity, hemorrhage, and gastrointestinal perforation. Full results from the study were presented at the 2012 Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (ASCO) (January 2012), and updated results at the 48th ASCO Annual Meeting (June 2012).[2,3]

“The approval of Stivarga reflects Bayer’s commitment to confronting the challenges of difficult-to-treat cancers,” said Pamela A. Cyrus, MD, Vice President and Head of U.S. Medical Affairs, Bayer HealthCare Pharmaceuticals. “Patients with metastatic colorectal cancer whose disease has returned after treatment will now have a new option that has been shown to prolong survival and keep the cancer from progressing.”

About Colorectal Cancer

Colorectal cancer is the third most commonly diagnosed cancer and the third leading cause of cancer death in the United States, in both men and women. It is estimated that more than 143,000 people will be diagnosed with CRC in 2012, and nearly 52,000 people will die from the disease.[4] Approximately 50% of colon cancer patients will be diagnosed with metastases (most commonly to the liver) either at the time of diagnosis or due to recurrent disease.[5]

In mCRC, KRAS status is an important biomarker and can be a predictor of treatment response.[6] Approximately 40% of colorectal cancers are characterized by mutations in the KRAS gene.[7]

About the CORRECT Study

CORRECT was an international, multicenter, randomized, double-blind, placebo-controlled Phase III study that enrolled 760 patients with mCRC whose disease had progressed during or within

three months following last administration of approved standard therapies. Patients were randomized to receive regorafenib plus BSC or placebo plus BSC. Treatment cycles consisted of 160 mg of regorafenib (or matching placebo) once daily for three weeks on / one week off plus BSC.[1]

About Stivarga (regorafenib)

Stivarga is indicated for the treatment of patients with mCRC who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy.[1]

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.[1]

Stivarga was developed and reviewed under the fast track program and received priority review designation from the FDA. These designations are granted by the FDA to expedite the development and review of drugs to treat serious diseases and fill an unmet medical need (fast track), and given to drugs that provide a treatment where no adequate therapy exists (priority review).

For full prescribing information, including BOXED WARNINGS, visit www.stivarga-us.com. Bayer offers patient assistance through the Bayer REACH® (Resources for Expert Assistance and Care Helpline) program. Patients may contact the REACH Program at 1-866-639-2827 for additional information.

Important Safety Information for Stivarga (regorafenib)

WARNING: HEPATOTOXICITY: Severe and sometimes fatal hepatotoxicity has been observed in clinical trials. Monitor hepatic function prior to and during treatment. Interrupt and then reduce or discontinue Stivarga for hepatotoxicity as manifested by elevated liver function tests or hepatocellular necrosis, depending upon severity and persistence.

Obtain liver function tests (ALT, AST, and bilirubin) before initiation of Stivarga and monitor at least every 2 weeks during the first 2 months of treatment. Thereafter, monitor monthly or more frequently as clinically indicated. Monitor liver function tests weekly in patients experiencing elevated liver function tests until improvement to less than 3 times the upper limit of normal (ULN) or baseline values.

In clinical trials, Stivarga was associated with an increased incidence of hemorrhage, including fatal hemorrhage. Permanently discontinue Stivarga in patients with severe or life-threatening hemorrhage and monitor INR levels more frequently in patients receiving warfarin.

Hand-foot skin reaction (HFSR) (also known as palmar-plantar erythrodysesthesia [PPE]) and rash are the most frequently observed dermatological reactions with Stivarga. Temporarily hold and then reduce or permanently discontinue Stivarga depending on the severity and persistence of dermatologic toxicity.

An increased incidence of hypertension has been observed with Stivarga. Do not initiate Stivarga until blood pressure is adequately controlled. Monitor blood pressure weekly for the first 6 weeks of treatment and then every cycle, or more frequently, as clinically indicated. Temporarily or permanently withhold Stivarga for severe or uncontrolled hypertension.

Stivarga has been associated with an increased incidence of myocardial ischemia and infarction. Withhold Stivarga in patients who develop new or acute cardiac ischemia or infarction, and resume only after resolution of acute cardiac ischemic events.

Reversible posterior leukoencephalopathy syndrome (RPLS) has been reported with Stivarga. Confirm the diagnosis of RPLS with MRI and discontinue Stivarga in patients who develop RPLS.

Gastrointestinal perforation and fistula have been reported in patients treated with Stivarga. Permanently discontinue Stivarga in patients who develop gastrointestinal perforation or fistula.

Treatment with Stivarga should be stopped at least 2 weeks prior to scheduled surgery. The decision to resume regorafenib after surgery should be based on clinical judgment of adequate wound healing. Stivarga should be discontinued in patients with wound dehiscence.

Stivarga can cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

The most frequently observed adverse drug reactions (≥30%) in Stivarga-treated patients vs placebo-treated patients, respectively, were: asthenia/fatigue (64% vs 46%), decreased appetite and food intake (47% vs 28%), HFSR/PPE (45% vs 7%), diarrhea (43% vs 17%), mucositis (33% vs 5%), weight loss (32% vs 10%), infection (31% vs 17%), hypertension (30% vs 8%), and dysphonia (30% vs 6%).

About Oncology at Bayer

Bayer is committed to delivering *science for a better life* by advancing a portfolio of innovative treatments. Bayer's oncology franchise now includes two oncology products and several other compounds in various stages of clinical development. Together, these products reflect the company's approach to research, which prioritizes novel targets and pathways with the potential to transform the way that cancer is treated across tumor types and stages of disease.

About Bayer HealthCare Pharmaceuticals Inc.

Bayer HealthCare Pharmaceuticals Inc. is the U.S.-based pharmaceuticals business of Bayer HealthCare LLC, a subsidiary of Bayer AG. Bayer HealthCare is one of the world's leading, innovative companies in the healthcare and medical products industry, and combines the activities of the Animal Health, Consumer Care, Medical Care, and Pharmaceuticals divisions. As a specialty pharmaceutical company, Bayer HealthCare provides products for General Medicine, Hematology, Neurology, Oncology and Women's Healthcare. The company's aim is to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases.

About Onyx Pharmaceuticals, Inc.

Based in South San Francisco, California, Onyx Pharmaceuticals, Inc. is a global biopharmaceutical company engaged in the development and commercialization of innovative therapies for improving the lives of people with cancer. The company is focused on developing novel medicines that target key molecular pathways. For more information about Onyx, visit the company's website at www.onyx.com.

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Forward-Looking Statement
This news release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

This news release contains "forward-looking statements" of Onyx within the meaning of the federal securities laws. These forward-looking statements include, without limitation, statements regarding results of clinical development, regulatory processes, safety and commercial potential of Stivarga (regorafenib). These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks and uncertainties related to: competition; failures or delays in clinical trials or the regulatory process; Onyx or Bayer, as the case may be, may be unsuccessful in launching, maintaining adequate supply of or obtaining reimbursement for Stivarga; market acceptance and the rate of adoption of Stivarga; pharmaceutical pricing and reimbursement pressures; serious adverse side effects, if they are associated with Stivarga; and government regulation. Reference should be made to Onyx's Annual Report on Form 10-K for the year ended December 31, 2011 filed with the Securities and Exchange Commission, as updated by Onyx's subsequent Quarterly Reports on Form 10-Q, under the heading "Risk Factors" for a more detailed description of these and other risks. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date of this release. Onyx undertakes no obligation to update publicly any forward-looking statements to reflect new information, events, or circumstances after the date of this release except as required by law.

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References:

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4. American Cancer Society. Colorectal Cancer. Available at: http://www.cancer.org/Cancer/ColonandRectumCancer/DetailedGuide/colorectal-cancer-key-statistics. Accessed on August 3, 2012.
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