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Investor News

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Phase III data at ESMO 18th World Congress on Gastrointestinal Cancer (WCGC):

Bayer's Regorafenib Significantly Improves Overall Survival in Patients with Unresectable Liver Cancer

- Initial results from Phase III trial RESORCE to be presented as Late-Breaking Abstract in oral abstract session at WCGC
- Median overall survival was 10.6 months for patients treated with regorafenib plus best supportive care versus 7.8 months in the group treated with placebo plus best supportive care

Leverkusen, Germany, June 28, 2016 – Bayer today announced results from the Phase III RESORCE trial investigating its oncology compound regorafenib in patients with unresectable hepatocellular carcinoma (HCC) who progressed during treatment with sorafenib (Nexavar®) tablets. In this trial, treatment with regorafenib plus best supportive care significantly improved overall survival (OS) compared to the control group receiving placebo plus best supportive care.

The results showed that the Hazard Ratio (HR) for OS in patients who received regorafenib compared with the control group was 0.62 (95% CI 0.50-0.78; p<0.001), which translates to a 38% reduction in the risk of death over the trial period. Median overall survival was 10.6 months for those who received regorafenib versus 7.8 months for those in the control group. The safety and tolerability were generally consistent with the known profile of regorafenib. These data will be presented at the ESMO 18th World Congress on Gastrointestinal Cancer (WCGC) in an oral abstract session on June 30 at 5.40pm CEST. The congress is taking place on June 29-July 2 in Barcelona, Spain.

"The incidence of liver cancer continues to increase globally. There is only one approved systemic treatment option for patients with this disease, and there are currently no proven or approved second-line treatment options for patients with advanced HCC," said Dr. Jordi Bruix, BCLC Group, Liver Unit, Hospital Clinic, University of Barcelona, IDIBAPS,

CIBEREHD, Spain. Dr. Bruix is the Principal Investigator of the RESORCE study as well as the Phase III study SHARP which investigated sorafenib in HCC.

“The regorafenib data seen in RESORCE may translate into additional hope for patients by providing doctors, nurses and other healthcare providers with a much needed second proven option for the treatment of liver cancer. The appropriate and timely start of systemic therapy may be important in improving patients’ treatment outcomes by potentially providing patients with the opportunity of receiving both proven systemic treatment options,” Dr. Bruix continued.

In addition to the primary endpoint of the study, all secondary endpoints, which were assessed by the modified Response Evaluation Criteria in Solid Tumors (mRECIST) and RECIST 1.1 criteria, were also met. Median progression-free survival was 3.1 versus 1.5 months, respectively (HR= 0.46 (95% CI 0.37–0.56; p<0.001). Median time to progression was 3.2 vs. 1.5 months (HR 0.44; 95% CI 0.36–0.55; p<0.001). Disease control rate (composed of complete and partial responses and stable disease) was 65.2% vs 36.1% (p<0.001). Overall response rate (complete and partial responses) was 10.6% vs 4.1% (p=0.005), respectively. All numerical values of the secondary endpoints are based on mRECIST.

The safety and tolerability were generally consistent with the known profile of regorafenib. The most common adverse events (grade 3 or higher) were hypertension (15.2% in the regorafenib group vs. 4.7% in the placebo group), hand-foot skin reaction (12.6% vs. 0.5%), fatigue (9.1% vs. 4.7%), and diarrhea (3.2% vs. 0%).

Bayer plans to submit data from the RESORCE study as the basis for marketing authorization of regorafenib in the treatment of unresectable HCC in 2016.

About the RESORCE trial

The Phase III data being presented at WCGC are from the RESORCE [REgorafenib after SORafenib in patients with hepatoCEllular carcinoma] clinical trial, which enrolled 573 patients who were randomized in a 2:1 ratio to receive either regorafenib plus best supportive care (BSC) or placebo plus BSC.

Patients received 160 mg regorafenib once daily or placebo, for 3 weeks on/1week off, with 28 days constituting one full treatment cycle. The primary endpoint of the study was overall survival, and secondary endpoints were time to progression, progression-free

survival, objective tumor response rate and disease control rate. Safety and tolerability were also continuously monitored.

About Hepatocellular Carcinoma

Hepatocellular carcinoma (HCC) is the most common form of liver cancer and represents approximately 70-85 percent of liver cancer worldwide. Liver cancer is the sixth most common cancer in the world and the second leading cause of cancer-related deaths globally. More than 780,000 cases of liver cancer are diagnosed worldwide each year (more than 395,000 in China, 52,000 in the European Union, and 30,000 in the United States) and the incidence rate is increasing. In 2012, approximately 746,000 people died of liver cancer including approximately 383,000 in China, 48,000 in the European Union, and 24,000 in the United States.

About Regorafenib (Stivarga®)

Regorafenib is an oral multi-kinase inhibitor that blocks various kinases within the mechanisms involved in tumor growth and progression – angiogenesis, oncogenesis and the tumor microenvironment. In preclinical studies, regorafenib has been shown to inhibit 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 control tumor growth, formation of a stromal microenvironment and disease progression.

Regorafenib is approved under the brand name Stivarga® in 90 countries worldwide, including the U.S., countries of the EU and Japan for the treatment of metastatic colorectal cancer. The product is also approved in over 70 countries, including the U.S., countries of the EU and Japan, 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 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.

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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