Bayer to Reveal Latest Data on Regorafenib at ASCO GI 2017


Berlin, January 18, 2017 – Bayer announced today that the company will present seven abstracts on regorafenib in advanced liver and colorectal cancers at the 2017 American Society of Clinical Oncology Gastrointestinal (ASCO GI) Cancer Symposium taking place on January 19-21 in San Francisco. These data include additional analyses from the Phase III RESORCE trial in patients with unresectable hepatocellular carcinoma (uHCC) who progressed after treatment with Nexavar® (sorafenib) tablets. Additional posters include data on regorafenib in patients with metastatic colorectal cancer (mCRC) from several studies including the RECORA study of the therapy in the real-world setting. These post marketing and real-world setting presentations of regorafenib in mCRC and the additional analyses from the RESORCE trial in HCC reinforce the clinical potential of regorafenib across multiple tumor types.

Regorafenib is approved under the brand name Stivarga® in many countries, including the U.S., to treat metastatic colorectal cancer and unresectable and/or metastatic gastrointestinal stromal tumors. The compound has been submitted to regulatory authorities in the U.S., Japan and the EU for the treatment of second-line HCC and submissions in additional countries are in progress.

Bayer’s regorafenib data at the ASCO GI 2017 Cancer Symposium include:

- Survival by pattern of tumor progression during prior sorafenib (SOR) treatment in patients with hepatocellular carcinoma (HCC) in the phase 3 RESORCE trial comparing second-line treatment with regorafenib (REG) or placebo
  - Abstract 229, Poster Session B: Cancers of the Pancreas, Small Bowel, and Hepatobiliary Tract
- Friday, January 20, 12:30 PM-2:00 PM PT and 5:30 PM-7:00 PM PT

- **Outcomes with sorafenib (SOR) followed by regorafenib (REG) or placebo (PBO) for hepatocellular carcinoma (HCC): Results of the international, randomized phase 3 RESORCE trial**
  - Abstract 344, Poster Session B: Cancers of the Pancreas, Small Bowel, and Hepatobiliary Tract
  - Friday, January 20, 12:30 PM-2:00 PM PT and 5:30 PM-7:00 PM PT

- **Exposure–response (ER) relationship of regorafenib (REG) in patients with hepatocellular carcinoma (HCC)**
  - Abstract 374, Poster Session B: Cancers of the Pancreas, Small Bowel, and Hepatobiliary Tract
  - Friday, January 20, 12:30 PM-2:00 PM PT and 5:30 PM-7:00 PM PT

- **Population pharmacokinetics (popPK) to evaluate the effect of intrinsic and extrinsic factors on regorafenib (REG) exposure in REG studies including patients with hepatocellular carcinoma (HCC)**
  - Abstract 320, Poster Session B: Cancers of the Pancreas, Small Bowel, and Hepatobiliary Tract
  - Friday, January 20, 12:30 PM-2:00 PM PT and 5:30 PM-7:00 PM PT

- **Clinical efficacy and safety of regorafenib in the treatment of metastatic colorectal cancer (mCRC) in daily practice in Germany: Interim results of the prospective multicentre non-interventional RECORA study**
  - Abstract 769, Poster Session C: Cancers of the Colon, Rectum, and Anus
  - Saturday, January 21: 7:00 AM-7:55 AM PT and 12:30 PM-2:00 PM PT

- **Safety and effectiveness of regorafenib (REG) in patients with metastatic colorectal cancer (mCRC) in routine clinical practice: An interim analysis (IA) from the prospective, observational CORRELATE study**
  - Abstract 700, Poster Session C: Cancers of the Colon, Rectum, and Anus
  - Saturday, January 21: 7:00 AM-7:55 AM PT and 12:30 PM-2:00 PM PT

- **Safety and efficacy of regorafenib post-marketing surveillance (PMS) in Japanese patients with metastatic colorectal cancer (mCRC)**
  - Abstract 721, Poster Session C: Cancers of the Colon, Rectum, and Anus
  - Saturday, January 21: 7:00 AM-7:55 AM PT and 12:30 PM-2:00 PM PT
About Regorafenib (Stivarga®)
Regorafenib is an oral multi-kinase inhibitor that potently blocks multiple protein kinases involved in tumor angiogenesis (VEGFR1, -2, -3, TIE2), oncogenesis (KIT, RET, RAF-1, BRAF), metastasis (VEGFR3, PDGFR, FGFR) and tumor immunity (CSF1R).

Regorafenib is approved under the brand name Stivarga® in more than 90 countries worldwide, including the U.S., countries of the EU and Japan for the treatment of metastatic colorectal cancer (mCRC). The product is also approved in over 80 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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ko (2017-0013E)

Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer 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.