Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

# Investor News

**Not intended for U.S. and UK Media**

## Bayer Receives Positive CHMP Opinion for regorafenib for the Second-Line Systemic Treatment of Liver Cancer

- Positive opinion based on data from the Phase III RESORCE study, in which regorafenib demonstrated significant improvement in overall survival in hepatocellular carcinoma (HCC) patients previously treated with Nexavar® (sorafenib)
- Approval could provide first treatment advance in nearly a decade
- Final decision from the European Commission anticipated within the next two months

---

**Leverkusen, Germany, June 23, 2017** – Bayer announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has recommended regorafenib for the treatment of adult patients with hepatocellular carcinoma (HCC) who have been previously treated with Nexavar® (sorafenib). Regorafenib is the first and only treatment that has demonstrated a significant improvement in overall survival in second-line HCC patients who previously had no other options. The final decision of the European Commission on the marketing authorization is expected in the coming months. The anti-cancer medication from Bayer is already approved under the brand name Stivarga® in more than 90 countries worldwide for the treatment of metastatic colorectal cancer (CRC), including countries of the EU, and in more than 80 countries globally for the treatment of metastatic gastrointestinal stromal tumors (GIST), including countries of the EU. The product recently gained approval in the U.S. for second-line treatment of HCC and additional regulatory filings for Stivarga in HCC are under review in countries around the world, including China.

“Liver cancer is one of the leading cancer-related causes of death in Europe. Nexavar, as the first and only approved systemic treatment for HCC, has been a major advance in this field, but effective second-line treatment options are urgently needed for patients,” said Robert LaCaze, Executive Vice President and Head of the Oncology Strategic Business Unit at Bayer. “The positive opinion for regorafenib in Europe is great news for patients as it supports our efforts to make this treatment available to as many patients as possible in

the second-line HCC setting and offers a treatment plan with two therapies that both have shown to improve overall survival."

Liver cancer is often more difficult to treat than other cancers with an annual mortality rate of 48,000 in in the EU. Globally, it is the second leading cause of cancer-related deaths.

The positive opinion is based on data from the international, multicenter, placebo-controlled Phase III RESORCE [REgorafenib after SORafenib in patients with hepatoCEllular carcinoma; NCT 01774344] trial, which investigated patients with HCC whose disease had progressed during treatment with Nexavar. In the trial, regorafenib plus best supportive care (BSC) was shown to provide a statistically significant and clinically meaningful improvement in overall survival (OS) versus placebo plus BSC (HR 0.63; 95% CI 0.50-0.79; $p<0.0001$), which translates to a 37% reduction in the risk of death over the trial period. The median OS was 10.6 vs. 7.8 months for regorafenib and the placebo groups, respectively. Adverse events observed in the trial were generally consistent with the known safety profile of regorafenib. The most common treatment-emergent adverse events (regorafenib vs. placebo group) were hand–foot skin reaction (53% vs. 8%), diarrhea (41% vs. 15%), fatigue (40% vs. 32%) and hypertension (31% vs. 6%).

**About Hepatocellular Carcinoma**

Hepatocellular carcinoma, or HCC, is the most common form of liver cancer representing 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 (52,000 in the European Union, 501,000 in the Western Pacific region 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 48,000 in the European Union, 477,000 in the Western Pacific region and 24,000 in the United States.

**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, China 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, China and Japan, for the treatment of metastatic gastrointestinal stromal tumors (GIST). It was recently approved in the U.S. for second-line treatment of HCC. Additional regulatory filings for Stivarga in HCC are under review in countries around the world, including China.

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 cancer treatments. The oncology franchise at Bayer currently 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 2016, the Group employed around 115,200 people and had sales of EUR 46.8 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.7 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.

Bayer AG, Investor Relations contacts:

Oliver Maier (+49-214-30-81013)
Dr. Jürgen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)
Constance Spitzer (+49-214-30-33021)
Prof. Dr. Olaf Weber (+49-214-30-33567)

**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.