



## News Release

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### **Nexavar<sup>®</sup> Approved in Japan for the Treatment of Advanced Liver Cancer**

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**Berlin, May 20, 2009** – Bayer received approval in Japan for Nexavar<sup>®</sup> (sorafenib) tablets for the treatment of unresectable hepatocellular carcinoma (HCC) from the Ministry of Health, Labour and Welfare (MHLW). Nexavar, an oral anti-cancer drug, jointly developed by Bayer HealthCare AG and Onyx Pharmaceuticals, Inc., is the only drug therapy shown to significantly improve overall survival in patients with the disease. The product is already marketed in Japan as a therapy for unresectable or metastatic renal cell carcinoma (RCC).

“Liver cancer is one of the leading causes of cancer-related deaths in Japan, and the incidence is continuing to rise,” said Gunnar Riemann, member of the Executive Committee of Bayer HealthCare. “We expect that this approval will provide patients a new option for improved treatment and we are pleased that with our MRI liver contrast agent Primovist we contribute to early diagnosis of HCC. We will make further efforts to contribute to patients and medical experts both in fields of diagnosis and treatment of HCC in Japan and worldwide.”

In Japan, approximately 40,000 people are diagnosed with liver cancer each year and approximately 36,000 people die from the disease, making primary liver cancer the third leading cause of cancer-related death in Japan. Hepatitis B viral infection (HBV) as well as hepatitis C viral infection (HCV) are leading risk factors for developing liver cancer worldwide, with HCV being the primary risk factor in Japan. An estimated 80 to 90 percent of Japanese patients diagnosed with liver cancer have HCV.

The MHLW’s decision is based on positive data from the international, Phase III, double-blind placebo-controlled Sorafenib HCC Assessment Randomized Protocol (SHARP) trial that evaluated more than 600 patients who received no prior systemic therapy. The study found that Nexavar extended overall survival by 44 percent in patients with HCC versus

placebo. Based on these data, Nexavar was approved to date in more than 70 countries for liver cancer, including the U.S. and Europe.

### **About Hepatocellular Carcinoma**

Hepatocellular carcinoma is the most common form of liver cancer and is responsible for about 90 percent of the primary malignant liver tumors in adults. Liver cancer is the sixth most common cancer in the world and the third leading cause of cancer-related deaths globally. More than 600,000 cases of liver cancer are diagnosed worldwide each year (more than 400,000 in China, South Korea, Japan and Taiwan, 54,000 in the European Union, and 15,000 in the United States) and the incidence is increasing. In 2002, approximately 600,000 people died of liver cancer including approximately 370,000 in China, South Korea and Japan, 57,000 in the European Union, and 13,000 in the United States.

### **Nexavar's Differentiated Mechanism**

Nexavar<sup>®</sup>, an oral anti-cancer therapy, is currently approved in more than 70 countries for liver cancer and in more than 80 countries for the treatment of patients with advanced kidney cancer. In Europe, Nexavar is approved for the treatment of hepatocellular carcinoma and for the treatment of patients with advanced renal cell carcinoma (RCC) who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy.

Nexavar targets both the tumor cell and tumor vasculature. In preclinical studies, Nexavar has been shown to target members of two classes of kinases known to be involved in both cell proliferation (growth) and angiogenesis (blood supply) – two important processes that enable cancer growth. These kinases included Raf kinase, VEGFR-1, VEGFR-2, VEGFR-3, PDGFR-B, KIT, FLT-3 and RET.

Nexavar is also being evaluated by the companies, international study groups, government agencies and individual investigators as a single agent or combination treatment in a wide range of other cancers, including non-small cell lung cancer, breast cancer, ovarian cancer and as an adjuvant therapy for kidney cancer and liver cancer.

### **Bayer / Onyx Collaboration**

Nexavar is being co-developed by Bayer and Onyx Pharmaceuticals, Inc. Under the collaboration, each company funds half of the development and marketing costs for

Nexavar worldwide, except in Japan. In the U.S., Bayer and Onyx co-promote Nexavar and share equally in any resulting profits. In all other countries (except Japan), Bayer has exclusive marketing rights, though the two companies also share profits. In Japan, Bayer funds all product development and marketing costs, and Onyx receives a royalty on sales.

### **About Bayer HealthCare**

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Bayer Schering Pharma, Consumer Care and Medical Care divisions. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Find more information at [www.bayerhealthcare.com](http://www.bayerhealthcare.com).

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Specialty Medicine and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life. Find more information at [www.bayerscheringpharma.de](http://www.bayerscheringpharma.de).

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### **Forward-Looking Statements**

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