



Investor News

Phase III Asia-Pacific Study:

Nexavar Significantly Extends Overall Survival in Liver Cancer by 47 percent

Trial Results Confirm Efficacy for Population Most Affected by the Disease

Leverkusen, May 16, 2008 – Bayer HealthCare and Onyx Pharmaceuticals, Inc. today announced that Nexavar[®] (sorafenib) tablets significantly improved overall survival by 47.3 percent ($HR=0.68$; $p\text{-value}=0.014$) in patients in the Asia-Pacific region with advanced hepatocellular carcinoma (HCC), or primary liver cancer, versus those receiving placebo. Nexavar also significantly improved time to progression in these patients by 74 percent ($HR=0.57$; $P=0.001$). These data will be presented at the 44th annual meeting of the American Society of Clinical Oncology (ASCO) and further confirm Nexavar's efficacy in liver cancer.

The international, Phase III, randomized trial evaluated the efficacy and safety of Nexavar versus placebo in 226 patients from the Asia-Pacific region with advanced HCC who had not received prior systemic therapy. The study was designed to compare overall survival, time to progression, time to symptomatic progression, response as defined by RECIST criteria and safety in patients receiving Nexavar versus placebo. Median overall survival was 6.5 months in patients treated with Nexavar versus 4.2 months for those taking placebo. The survival benefit was seen across multiple patient subsets analyzed, including age, extrahepatic spread and/or macroscopic vascular invasion.

"Liver cancer in the Asia-Pacific region continues to grow because of a high incidence of chronic hepatitis B infections, which now impacts approximately 275 million people in the region," said Ann-Lii Cheng, MD, Ph. D., Department of Internal Medicine and Department of Oncology, National Taiwan University Hospital, Taipei, Taiwan and principal investigator of the trial. "Nexavar demonstrated a clear survival benefit in Asia-Pacific patients and had comparable results to last year's international SHARP trial,

despite these patients in the Asia-Pacific trial having poorer health status and more metastases."

Additional results from the trial showed that median time to progression was 2.8 months in Nexavar-treated patients versus 1.4 months for those taking placebo. Median time to symptomatic progression was 3.5 months in patients treated with Nexavar versus 3.4 months for those taking placebo. The disease control rate (complete response + partial response + stable disease \geq 12 weeks) was 35 percent in Nexavar-treated patients versus 16 percent for those taking placebo.

Data from the study indicate that Nexavar was safe and well-tolerated in patients from the Asia-Pacific region. Adverse events were low to moderate in severity and treatment was well tolerated. The most common serious adverse events observed in the study were hand-foot-skin reaction, diarrhea, alopecia, fatigue, and rash/desquamation.

"These data provide further evidence that Nexavar is efficacious in liver cancer across multiple geographical regions and independent of disease characteristics and etiologies of underlying liver disease," said Susan Kelley, MD, Vice President, Therapeutic Area Oncology, Bayer HealthCare Pharmaceuticals. "Nexavar has quickly become the systemic standard of care for liver cancer, and is the only systemic therapy that has been shown to improve overall survival in Asian patients with liver cancer."

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.

In addition, chronic hepatitis B and C infections are the leading cause of primary liver cancer worldwide. In the Asia-Pacific region, more than eight percent of the general

population is infected with hepatitis B and between two and four percent is infected with hepatitis C.

About Nexavar®

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 currently approved in more than 40 countries for liver cancer and in more than 70 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 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 cancers, including metastatic melanoma, lung cancer, breast cancer and as an adjuvant therapy for kidney cancer.

About Onyx Pharmaceuticals, Inc.

Onyx Pharmaceuticals, Inc. is a biopharmaceutical company committed to improving the lives of people with cancer. The company, in collaboration with Bayer HealthCare Pharmaceuticals, Inc., is developing and marketing Nexavar® (sorafenib) tablets, a small molecule drug. For more information about Onyx, visit the company's website at www.onyx-pharm.com.

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, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma AG. 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.

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.

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Forward-Looking Statements Bayer AG

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