# NEXAVAR SIGNIFICANTLY IMPROVES OVERALL SURVIVAL BY 47 PERCENT IN ASIA-PACIFIC LIVER CANCER STUDY

Trial Results Confirm Efficacy for Population Most Affected by Disease

Wayne, NJ and Emeryville, CA - May 16, 2008

Bayer HealthCare Pharmaceuticals, Inc. and Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) today announced that Nexavar® (sorafenib) tablets significantly improved overall survival by 47.3 percent (HR=0.68; p-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 were 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 3, randomized trial evaluated efficacy and safety of Nexavar versus placebo in 226 Asian patients 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 viral infections, which now impact approximately 275 million people in the region," said Ann-Lii Cheng, MD, PhD, 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 SHARP trial, despite these patients in the Asia-Pacific trial having poorer health status and more metastases."

Additional results from the trial are as follows:

- 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.
- Disease control rate (complete response + partial response + stable disease ≥ 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."

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. 1,2

In addition, chronic hepatitis B (HBV) and C (HCV) viral infections are the leading causes of primary liver cancer worldwide. In the Asia-Pacific region, more than eight percent of the general population is infected with HBV and between two and four percent is infected with HCV. <sup>3,4</sup>

# **Nexavar's Differentiated Mechanism**

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. 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.

### Important Safety Considerations For Patients Taking Nexavar

Based on the currently approved U.S. package insert for the treatment of patients with unresectable hepatocellular carcinoma, hypertension may occur early in the course of therapy and blood pressure should be monitored weekly during the first six weeks of therapy and treated as needed. Bleeding with a fatal outcome from any site was reported in 2.4% for Nexavar and 4% in placebo. The incidence of treatment-emergent cardiac ischemia/infarction was 2.7% for Nexavar vs. 1.3% for placebo. Most common adverse events reported with Nexavar in patients with unresectable HCC were diarrhea, fatigue, abdominal pain, weight loss, anorexia, nausea and hand-foot skin reaction. Grade 3/4 adverse events were 45% for Nexavar vs. 32% for placebo. Women of child-bearing potential should be advised to avoid becoming pregnant and advised against breast-feeding. In cases of any severe or persistent side effects, temporary treatment interruption, dose modification or permanent discontinuation should be considered.

For information about Nexavar including U.S. Nexavar prescribing information, visit <a href="http://www.nexavar.com/">http://www.nexavar.com/</a> or call 1.866.NEXAVAR (1.866.639.2827).

#### About Bayer HealthCare Pharmaceuticals Inc.

Bayer HealthCare Pharmaceuticals Inc. is the U.S.-based pharmaceuticals unit of Bayer HealthCare LLC, a division of Bayer AG. One of the world's leading, innovative companies in the healthcare and medical products industry, Bayer HealthCare combines the global activities of the Animal Health, Consumer Care, Diabetes Care, and Pharmaceuticals divisions. In the U.S., Bayer HealthCare Pharmaceuticals comprises the following business units: Women's Healthcare, Diagnostic Imaging, Specialized Therapeutics, Hematology/Cardiology and Oncology. The company's aim is to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases.

#### 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 <a href="https://www.onyx-pharm.com">www.onyx-pharm.com</a>.

## Forward-Looking Statements

This news release contains forward-looking statements based on current assumptions and forecasts made by Bayer Group 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 our annual and interim reports filed with the Frankfurt Stock Exchange. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

This news release also contains "forward-looking statements" of Onyx within the meaning of the federal securities laws. These forward-looking statements include without limitation, statements regarding the timing, progress and results of the clinical development, safety, regulatory processes, and commercialization efforts of Nexavar. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated. Reference should be made to Onyx's Annual Report on Form 10-K for the year ended December 31, 2007, filed with the Securities and Exchange Commission under the heading "Risk Factors" and Onyx's Quarterly Reports on Form 10-Q for a more detailed description of such factors. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date of this release. Onyx undertakes no obligation to update publicly any forward-looking statements to reflect new information, events, or circumstances after the date of this release except as required by law.

Nexavar® (sorafenib) tablets is a registered trademark of Bayer HealthCare Pharmaceuticals, Inc.

<sup>&</sup>lt;sup>1</sup> Ferlay J, et al., GLOBOCAN 2002. Cancer Incidence, Mortality and Prevalence Worldwide. IARC CancerBase No.5, Version 2.0. IARCPress, Lyon, 2004. Available at: http://www-dep.iarc.fr/. Accessed May 2008.

<sup>2</sup> 2005 Cancer Register System (CRS) annual report. http://crs.cph.ntu.edu.tw/crs.c/annual.html. Accessed May

<sup>&</sup>lt;sup>2</sup> 2005 Cancer Register System (CRS) annual report, http://crs.cph.ntu.edu.tw/crs\_c/annual.html. Accessed May 12, 2008.

<sup>&</sup>lt;sup>3</sup> World Health Organization, Fact Sheet N°164, October 2000. http://www.who.int/mediacentre/factsheets/fs164/en/. Accessed May 2008.

<sup>&</sup>lt;sup>4</sup> Stanford University School of Medicine, Asian Liver Center, "FAQ About Hepatitis B," February 2008. http://liver.stanford.edu/Education/faq.html. Accessed May 2008.