Bayer



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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-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 ≥ 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

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

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Bayer and Onyx Announce Nexavar® Data Presentations at 44th American Society of Clinical Oncology (ASCO) Annual Meeting

Leverkusen, May 16, 2008 – Bayer HealthCare and Onyx Pharmaceuticals, Inc. today announced more than 40 data presentations at the 2008 American Society of Clinical Oncology (ASCO) annual meeting demonstrating the potential for Nexavar® (sorafenib) tablets in multiple tumor types as a single agent or in combination with other agents.

“Along with international study groups and investigators, Bayer and Onyx are committed to a comprehensive clinical trial program evaluating Nexavar for additional types of cancer,” Susan Kelley, MD, vice president, Therapeutic Area Oncology, Bayer HealthCare Pharmaceuticals. “With its proven track record in liver and kidney cancer, dual-targeted mechanism and proven tolerability, we continue to identify important new areas where Nexavar may provide clinical benefit for people affected by cancer.”

“Data at ASCO will expand upon and support the proven efficacy and tolerability of Nexavar in liver cancer and advanced kidney cancer and provide new insight into the potential of Nexavar in additional types of cancer,” said Henry Fuchs, M.D., Executive Vice President and Chief Medical Officer of Onyx Pharmaceuticals. “Highlights include studies demonstrating that Nexavar extends life for Asian patients with liver cancer; provides an effective, well-tolerated option for elderly patients with advanced kidney cancer and may provide benefit and warrants further study in heavily pretreated patients with non-small cell lung cancer.”

Nexavar data highlights include:

Hepatocellular Carcinoma

- *Randomized Phase III trial of sorafenib versus placebo in Asian patients with advanced hepatocellular carcinoma*
    - Ann Lii-Cheng, MD, PhD, department of internal medicine, National Taiwan University Hospital, Taipei, Taiwan

- Abstract #4509, oral presentation, Monday, June 02, 2008, 4:30 – 4:45 p.m., E-Hall D2

- *Efficacy and safety of sorafenib in patients with advanced hepatocellular carcinoma and vascular invasion or extrahepatic spread: a subanalysis from the SHARP trial*
  - Morris Sherman, MD, PhD, associate professor of medicine, University of Toronto, Toronto, Canada
  - Poster 37G, abstract #4584, poster, Monday, June 2, 2008, 8 a.m. – 12 p.m., S Hall A1

- *Is sorafenib safe and effective in patients with hepatocellular carcinoma (HCC) in Child-Pugh B (CPB) Cirrhosis?*
  - Ghassan Abou-Alfa, MD, internal medicine, Memorial Sloan Kettering Cancer Center, New York, NY
  - Poster 6, abstract #4518, poster discussion, Tuesday, June 3, 2008, 11 – 11:15 a.m., S406

- *Efficacy and safety of sorafenib in patients with advanced hepatocellular carcinoma according to ECOG performance status: a subanalysis from the SHARP trial*
  - Jean-Luc Raoul, MD, PhD, Centre Eugene Marquis, Rennes, France
  - Poster 38B, Abstract #4587, Monday, June 2, 2008, 8:00 a.m. - 12:00 p.m., S Hall A1

Renal Cell Carcinoma

- *Safety and efficacy of sorafenib in elderly patients ≥65 years: a subset analysis from the ARCCs expanded access program in North America*
  - Ronald Bukowski, MD, director of experimental therapeutics, Cleveland Clinic CICF Taussig Cancer Center, Cleveland, OH
  - Poster 17, Abstract #5045, Sunday, June 1, 2008, 8:00 - 12:00 p.m., W375e Lobby / 11:00 AM - 12:00 p.m., W375a

- *Comparison of kidney cancer symptoms and quality of life (QoL) in renal cell cancer (RCC) patients receiving sorafenib vs. interferon-α (IFN)*
  - Cezary Szczylik, MD, Central Clinical Hospital, Military Institute of Health, Warsaw, Poland

- Poster 44E, Abstract #9603, Saturday, May 31, 2008, 2:00 - 6:00 p.m., S Hall A1

- *Updated results of a Phase 1 trial of sorafenib and bevacizumab in patients with metastatic renal cell carcinoma (RCC)*
  - Jeffrey Sosman, MD, professor of medicine (hematology/oncology), Vanderbilt-Ingram Cancer Center, Nashville, TN
  - Abstract #5011, oral presentation, Saturday, May 31, 2008, 2:15 – 2:30 p.m., W375e

Lung Cancer

- *A randomized discontinuation Phase II study of sorafenib vs placebo in patients with non-small cell lung cancer who have failed at least two prior chemotherapy regimens*
  - Joan Schiller, MD, professor and chief of the Hematology/Oncology Division at University of Texas Southwestern and Andrea L. Simmons Distinguished Chair in Cancer Research, Dallas, TX
  - Abstract #8014, Monday, June 2, 4 – 4:15 p.m., W375e

- *A Phase II trial of BAY 43-9006 in patients with platinum treated extensive stage small cell lung cancer (E-SCLC): A SWOG (SO435) Phase II trial*
  - Barbara Gitlitz, MD, associate professor of clinical, director, Lung, Head and Neck Program, USC/Norris Comprehensive Cancer Center, Los Angeles, CA
  - Poster 20, abstract #8039, poster discussion, Monday, June 2, 2008, 12 – 1 p.m., W375d

Solid Tumors

- *A drug interaction study of sorafenib and rapamycin in patients with advanced malignancies*
  - Tara Gangadhar, MD, fellow, University of Chicago, Chicago, IL
  - Poster 10A, abstract #2545, poster discussion, Sunday, June 1, 2008, 2 – 6 p.m., S Hall A1

- *A phase II study: Combination of sorafenib with docetaxel and cisplatin in the treatment of metastatic or advanced unresectable gastric and gastroesophageal junction (GEJ) adenocarcinoma (ECOG 5203).*

- Weijing Sun, MD, assistant professor of medicine, University of Pennsylvania Philadelphia, PA), director of Upper GI and Pancreatic-biliary-hepatic Cancer Group and the associate director of the GI Cancer Program
- Poster 23, abstract #4535, poster discussion, Tuesday, June 3, 2008, 11:30 – 11:45 a.m., S406 – Vista Room

- *Activity of sorafenib (SOR) in patients (pts) with imatinib (IM) and sunitinib (SU)-resistant (RES) gastrointestinal stromal tumors (GIST): A phase II trial of the University of Chicago Phase II Consortium*
  - Lauren Wiebe, MD, fellow, University of Chicago, Chicago, IL
  - Abstract #10502, oral presentation, Saturday, May 31, 2008, 8:45 – 9 a.m. W375d

Thyroid Cancer

- *A Phase II study of sorafenib in metastatic thyroid carcinoma*
  - Marcia S. Brose, MD, PhD, assistant professor, director of cancer genetics laboratory, University of Pennsylvania Health System, Philadelphia, PA
  - Poster 18, abstract #6026, poster discussion, Sunday, June 1, 2008, 8 a.m. -12 p.m., E450b

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.

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