



Investor News

Nexavar[®] Approved by European Commission for the Treatment of Advanced Kidney Cancer

West Haven, CT and Emeryville, CA – July 23, 2006 – Bayer Pharmaceuticals Corporation (NYSE: BAY) and Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) today announced that the European Commission has granted marketing authorization to Nexavar[®] (sorafenib) tablets for the treatment of patients with advanced renal cell carcinoma (RCC), or kidney cancer, who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy. Bayer will commercialize Nexavar in Europe.

“Today’s approval of Nexavar, which has shown to double progression-free survival, is a significant advance in the fight against kidney cancer,” said Dr. Gunnar Riemann, Head of Bayer HealthCare’s Pharmaceuticals Division. “For more than a decade, Europeans with kidney cancer have not had a new approved treatment. We are pleased to play a part in addressing this unmet medical need.”

The decision by the European Commission to grant marketing authorization to Nexavar followed a positive opinion issued by the European Medicines Agency’s Committee on Medicinal Products for Human Use (CHMP) in April this year. Nexavar was approved by the U.S. Food and Drug Administration (FDA) in December 2005 and has since been approved in Switzerland, Mexico, Chile, Brazil, and Korea. Regulatory filings have been completed in several countries, including Australia, Canada, Turkey, and Japan.

“Nexavar delays the progression of kidney cancer and is generally well tolerated,” said Dr. Escudier, head of Immunotherapy and Innovative Therapy Unit at the Gustave-Roussy Institute in Paris, France, and co-principal investigator of the pivotal study that led to the approval of Nexavar by the European Commission.

Every year, more than 200,000 people around the world are diagnosed with kidney cancer and more than 102,000 die from the disease.¹ In Europe, there are more than 46,000 new cases of kidney cancer annually.^{2,3} At the time of diagnosis, the cancer has already metastasized (spread to distant body locations) in about one-third of people with kidney cancer.⁴

About the Phase III Pivotal Study

Nexavar EMEA approval was based on Phase III data from the largest randomized, placebo-controlled trial ever conducted in patients with advanced renal cell carcinoma. In the Phase III study, Nexavar doubled progression-free survival (PFS) in previously treated patients when compared to placebo. Progression-free survival measures the time that a patient lives without evident tumor growth. In this study, PFS was doubled to a median value of six months in patients receiving Nexavar as compared to three months for patients receiving placebo (p -value < 0.000001). All subgroups examined, including patients who had not received conventional treatment with biologics, such as interleukin-2 or interferon-alpha, appeared to benefit as well.

In April 2005, Bayer and Onyx discussed the clinical and statistical significance of this analysis with the principal investigators, an independent data monitoring committee (DMC), and with regulatory authorities and decided that it would not be ethical to continue the study with a placebo-control arm. The companies immediately recommended that all patients in the trial be offered access to Nexavar. In parallel, an interim analysis of overall survival (OS) was conducted. The median overall survival for placebo was 14.7 months, while the median OS survival for Nexavar had not been reached (p =0.018, hazard ratio 0.72).

In June 2006, a further interim analysis of OS was presented, based on 367 deaths and after 48 percent of the placebo patients (N =217) had crossed over to Nexavar. Median OS for this analysis was 19.3 months for Nexavar patients versus 15.9 months for placebo patients (p =0.015, hazard ratio 0.77). Although these data did not reach the pre-specified result required for statistical significance and to stop the OS analysis early, they suggest a favorable survival trend for patients who received Nexavar. The final analysis of OS is planned when 540 events are observed.

About Nexavar

Nexavar is an oral multi-kinase inhibitor that targets both the tumor cell and tumor vasculature. In preclinical models, Nexavar targeted 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- β , KIT, and FLT-3.

Nexavar is being studied in a variety of cancers; to date, more than 8,000 clinical trial patients have received the drug. Nexavar is currently in Phase III clinical trials for the treatment of advanced hepatocellular carcinoma (HCC), or liver cancer, and metastatic melanoma, or skin cancer. Enrollment in both these trials has been completed. A Phase III clinical trial in non-small cell lung cancer (NSCLC) for first-line patients was initiated in February 2006. In addition to company-sponsored trials, there are a variety of Nexavar studies being sponsored by government agencies, cooperative groups and individual investigators.

Important Safety Considerations for U.S. Patients Taking Nexavar

Based on the current, approved package insert for the treatment of patients with advanced kidney cancer, 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. Incidence of bleeding regardless of causality was 15 percent for Nexavar vs. 8 percent for placebo and the incidence of treatment-emergent cardiac ischemia/infarction was 2.9 percent for Nexavar vs. 0.4 percent for placebo. Most common treatment-emergent adverse events with Nexavar were diarrhea, rash/desquamation, fatigue, hand-foot skin reaction, alopecia and nausea. Grade 3/4 adverse events were 38 percent for Nexavar vs. 28 percent 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 U.S. Nexavar prescribing information, visit www.nexavar.com or call 1.866.NEXAVAR (1.866.639.2827).

Bayer/Onyx Co-Development

Nexavar is being co-developed by Bayer and Onyx. The co-development collaboration calls for Onyx to fund 50 percent of the development and marketing costs for Nexavar worldwide, except in Japan. In return, Onyx has a 50/50 profit share in the United States, where the companies co-promote the product. In all other countries (except Japan) Bayer has exclusive marketing rights and Onyx's profit share

is slightly less than 50 percent. In Japan, Bayer will fund product development and Onyx will receive a royalty.

About Onyx Pharmaceuticals, Inc.

Onyx Pharmaceuticals, Inc. is engaged in the development of novel cancer therapies that target the molecular basis of cancer. With its collaborators, the company is developing small molecule drugs including Nexavar with Bayer Pharmaceuticals Corporation. For more information about Onyx's pipeline and activities, visit the company's web site at: www.onyx-pharm.com.

About Bayer Pharmaceuticals Corporation

Bayer Pharmaceuticals Corporation (www.bayerpharma.com) is part of the worldwide operations of Bayer HealthCare AG, a subsidiary of Bayer AG.

Bayer HealthCare AG, with sales of approximately 9.4 billion Euros in 2005, is one of the world's leading, innovative companies in the healthcare and medical products industry. The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care, Diagnostics and Pharmaceuticals divisions. Bayer Pharmaceuticals Corporation is part of the new Global Pharmaceutical Division, established January 1, 2006, which consists of the former Biological Products and Pharmaceutical Division and now comprises three business units: Hematology/Cardiology; Oncology and Primary Care. Bayer HealthCare AG employed 33,800 people worldwide in 2005.

Bayer HealthCare AG's aim is to discover and manufacture innovative products that will improve human and animal health worldwide. The products enhance well-being and quality of life by diagnosing, preventing and treating disease.

Nexavar[®] (sorafenib) tablets is a registered trademark of Bayer Pharmaceuticals Corporation.

¹ J. Ferlay, F. Bray, P. Pisani and D.M. Parkin. GLOBOCAN 2002: Cancer Incidence, Mortality and Prevalence Worldwide IARC CancerBase No. 5, version 2.0, IARC Press, Lyon, 2004. Available at: <http://www-dep.iarc.fr>. Accessed April 24, 2006.

² WHO, World Health Organisation. International Statistical Classification of Diseases and related health problems. Tenth revision, Vols 1-3. 1992-1994. Third edition. Geneva: WHO, 1994. (Information available at: http://www.startoncology.net/capitoli/interno_capitoli/default.jsp?menu=professional&ID=105&language=eng)

³ Ferlay J, Bray F, Sankila R, Parkin DM. EUCAN: Cancer Incidence, Mortality and Prevalence in the European Union 1995, version 2.0. IARC CancerBase No. 4. Lyon, IARC Press, 1999. (Information available at: http://www.startoncology.net/capitoli/interno_capitoli/default.jsp?menu=professional&ID=105&language=eng)

⁴ American Foundation for Urologic Disease.

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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 Bayer's public reports filed with the Frankfurt Stock Exchange and with the U.S. Securities and Exchange Commission (including its Form 20-F). Bayer 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, 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, 2005, 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 Pharmaceuticals Corporation.