



News Release

Phase III Trial of Nexavar[®] in Chemotherapy-Naive Patients with Advanced Melanoma Does Not Meet Primary Endpoint

Study stopped based on interim analysis

Leverkusen, April 27, 2009 – Bayer HealthCare AG and Onyx Pharmaceuticals, Inc. today announced that a Phase III trial evaluating Nexavar[®] (sorafenib) tablets in patients with unresectable stage III or stage IV melanoma was stopped early following a planned interim analysis by an independent Data Monitoring Committee (DMC). The trial was sponsored by the National Cancer Institute and led by the Eastern Cooperative Oncology Group (ECOG) under a Clinical Trials Agreement between NCI and Bayer and Onyx. The DMC concluded that the study would not meet the primary endpoint of improved overall survival among patients receiving Nexavar in combination with the chemotherapeutic agents carboplatin and paclitaxel versus patients receiving placebo plus the chemotherapeutic agents. The treatment effect was comparable in each arm. The DMC also reported there were no unexpected serious side effects, though the final analysis of data will occur per protocol and statistical analysis plan.

Bayer and Onyx will further review the findings of this analysis and DMC recommendation to determine what, if any, impact these data might have on other ongoing Nexavar melanoma trials. Data from this study is expected to be presented at an upcoming scientific meeting.

“We’re disappointed with the results of the study and that the therapy did not bring benefit to patients with melanoma, a historically difficult tumor to treat,” said Dimitris Voliotis, Vice President in Global Clinical Oncology at Bayer HealthCare. “Onyx and Bayer remain committed to our broad clinical program to investigate the potential of Nexavar in a wide range of cancers, and we intend to build upon the success of Nexavar in our approved indications in hepatocellular carcinoma (liver cancer) and advanced renal cell carcinoma (kidney cancer).”

About the Phase III trial

The multicenter, randomized, double-blind, placebo-controlled Phase III study enrolled patients with unresectable stage III or stage IV melanoma at more than 200 clinical sites in the United States and Australia. The primary endpoint was overall survival, and secondary endpoints included progression-free survival and response rate.

Patients were randomized to receive 400mg oral Nexavar twice daily or placebo, in addition to two chemotherapeutic agents – carboplatin and paclitaxel. Following ten cycles of Nexavar plus chemotherapy, patients who achieved a response to the combination continued in a maintenance phase where Nexavar or placebo was administered as a single agent until disease progression.

About Melanoma

In 2007, more 108,000 people worldwide (about 59,000 in the U.S.) were diagnosed with melanoma and more than 40,000 of them (about 8,110 in the U.S.) died from the disease. In the United States, the percentage of people who develop melanoma has more than doubled in the past 20 years. Melanoma accounts for about four percent of skin cancer cases but causes about 79 percent of skin cancer deaths.

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 70 countries for the treatment of patients with 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 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, lung cancer, breast cancer and as an adjuvant therapy for kidney and liver 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, 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.

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

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