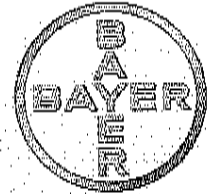


Bayer



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## Investor News

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### **Bayer and Onyx Initiate Phase III Metastatic Melanoma Trial Administering Sorafenib (BAY 43-9006) in Combination with Chemotherapy**

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**Leverkusen / May 13, 2005** – Bayer Pharmaceuticals Corporation (NYSE: BAY) and Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) today announced the opening of a randomized, double-blind Phase III trial administering sorafenib (formerly BAY 43-9006) in combination with the chemotherapeutic agents carboplatin and paclitaxel in patients with advanced metastatic melanoma.

This multicenter study will evaluate the safety and efficacy of sorafenib, a novel investigational anticancer agent, when co-administered with carboplatin and paclitaxel. The trial, which is expected to enroll over 200 patients, has progression-free survival as its primary endpoint. Participating patients must have failed only one previous systemic chemotherapeutic treatment with either dacarbazine (DTIC) or temozolomide. Patients will be randomized to receive 400 mg of oral sorafenib twice daily or matching placebo, in addition to a standard dosing schedule of carboplatin (AUC 6) and paclitaxel (225 mg/m<sup>2</sup>). The study will include sites in the United States, Canada, Europe, and Australia. Bayer and Onyx also announced that the U.S. Food and Drug Administration (FDA) completed a Special Protocol Assessment (SPA) for the Phase III trial. An SPA is a written agreement on the design and size of clinical trials that are intended to form the basis of a new drug application.

“Metastatic melanoma can be a deadly disease, and there are few treatment options for these patients,” said Scott Freeman, M.D., Vice President of Clinical Development at Onyx. “We are pleased to be evaluating sorafenib in patients with metastatic melanoma. In addition to this Phase III study, there is an ongoing, randomized Phase II study that combines sorafenib and the chemotherapeutic agent dacarbazine, or DTIC.”

### **Melanoma**

Cancer of the skin (nonmelanoma and melanoma skin cancers combined) is the most common type of cancer, accounting for more than 50 percent of all cancers.

Melanoma accounts for about 4 percent of skin cancer cases but causes about 79 percent of skin cancer deaths. In 2002, about 160,000 people worldwide were diagnosed with melanoma, and more than 40,000 died from the disease.<sup>1</sup> Once the disease becomes metastatic, it is rapidly fatal due to the lack of an effective therapy.

For more information on melanoma, visit the Melanoma International Foundation (MIF) web site at: [www.melanomainternational.org](http://www.melanomainternational.org).

### **About Sorafenib**

Sorafenib, a novel investigational drug candidate, is the first oral multi-kinase inhibitor that targets serine/threonine and receptor tyrosine kinases in both the tumor cell and tumor vasculature. In preclinical models, sorafenib targeted members of two classes of kinases known to be involved in both tumor cell proliferation (tumor growth) and tumor angiogenesis (tumor blood supply) - two important cancer growth activities. These kinases included RAF kinase, VEGFR-2, VEGFR-3, PDGFR- $\beta$ , KIT, FLT-3 and RET.

Sorafenib has shown anticancer activity in a number of tumor types. It is being evaluated both as a single therapy agent and in combination with other oncology agents in a number of ongoing clinical trials. For more information on sorafenib clinical trials, visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **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 sorafenib with Bayer Pharmaceuticals Corporation. For more information about Onyx, visit the company's web site at: [www.onyx-pharm.com](http://www.onyx-pharm.com).

### **About Bayer Pharmaceuticals Corporation**

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

Bayer HealthCare, with sales of approximately 8.5 billion Euro in 2004, is one of the world's leading, innovative companies in the health care and medical products.

industry. The company combines the global activities of the divisions Animal Health, Biological Products, Consumer Care, Diagnostics and Pharmaceuticals. Bayer HealthCare employed 35,300 people worldwide in 2004.

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

Leverkusen, May 13, 2005

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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 our 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 sorafenib. 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, 2004, as amended, filed with the Securities and Exchange Commission under the heading "Additional Business Risks" 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.