



## Investor News

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### **BAY 43-9006 Shown to Delay Disease Progression in Phase III Study in Advanced Kidney Cancer Patients**

Study met surrogate endpoint

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**West Haven, CT and Emeryville, CA** – Bayer Pharmaceuticals Corporation (NYSE: BAY) and Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) today announced that an independent data monitoring committee (DMC) has reviewed the safety and efficacy data from the companies' pivotal Phase III trial in patients with advanced kidney cancer. Based on its analysis, the DMC has concluded that the trial met its surrogate endpoint -- resulting in statistically significant longer progression-free survival in those patients administered BAY 43-9006 versus those patients administered placebo. As a result of this favorable outcome, Bayer and Onyx plan to prepare a New Drug Application for possible accelerated approval in the United States.

As previously agreed with the U.S. Food and Drug Administration (FDA), the two companies will continue the Phase III study as originally planned to its primary endpoint of overall survival. Bayer and Onyx also intend to submit data from the Phase III study for the upcoming American Society of Clinical Oncology meeting, May 13-17, in Orlando, Florida.

#### **Phase III Summary**

The multi-national, placebo-controlled Phase III study recently finished enrolling over 800 patients with advanced kidney cancer. The primary endpoint of the study is overall survival, with disease progression, overall response rate, and safety also being assessed. The pivotal trial was initiated in the fourth quarter of 2003 after a Special Protocol Assessment (SPA) was completed by the FDA.

#### **About BAY 43-9006**

BAY 43-9006, a novel investigational drug candidate, has demonstrated both anti-

proliferative and anti-angiogenic properties – two important anticancer activities. In preclinical models, BAY 43-9006 inhibited tumor cell proliferation by targeting the RAF/MEK/ERK signaling pathway at the level of RAF kinase. BAY 43-9006 also exerted an antiangiogenic effect by targeting the receptor tyrosine kinases VEGFR-2 and PDGFR and their associated signaling cascades. In addition, BAY 43-9006 also inhibited other tyrosine kinases, including FLT-3 and c-KIT.

**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 BAY 43-9006 with Bayer Pharmaceuticals Corporation. For more information about Onyx's pipeline and activities, visit the company's web site at: [www.onyx-pharm.com](http://www.onyx-pharm.com).

**About Bayer HealthCare AG**

Bayer HealthCare AG, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the health care and medical products industry. In 2004, the Bayer HealthCare subgroup generated sales amounting to some 8.5 billion Euro.

The company combines the global activities of the divisions Animal Health, Biological Products, Consumer Care, Diabetes 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. The products enhance well-being and quality of life by diagnosing, preventing and treating 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 our public reports filed with the Frankfurt Stock Exchange and with the U.S. Securities and Exchange Commission (including our Form 20-F). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.