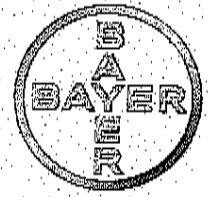


Bayer



Bayer AG  
Investor Relations  
51368 Leverkusen  
Germany  
[www.investor.bayer.com](http://www.investor.bayer.com)

## Investor News

---

### **Bayer and Onyx Complete Filing of New Drug Application for Sorafenib for Individuals with Advanced Renal Cell Carcinoma**

---

**Leverkusen / July 11, 2005** – Bayer Pharmaceuticals Corporation (NYSE: BAY) and Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) today announced that the companies have completed the submission of a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for sorafenib (BAY 43-9006) for patients with advanced renal cell carcinoma (RCC), or kidney cancer.

“New treatment options are clearly needed for people with advanced kidney cancer,” said Wolfgang Plischke, President of Bayer HealthCare’s Global Pharmaceutical Division. “We were encouraged by our Phase III results, as we are now with the completion of the NDA filing. Pending the FDA’s acceptance and favorable review of our filing, we expect to launch sorafenib in the first half of 2006.”

Sorafenib was accepted by the FDA into the Pilot 1 Program for continuous marketing applications. The Pilot 1 Program was designed for therapies that have been granted Fast Track status and have the potential to provide important therapeutic benefit over available therapies. Under the Pilot 1 Program designation, the FDA is committed to reviewing each “reviewable unit” of the submission within a six month timeframe.

The sorafenib submission is based on an ongoing Phase III trial in patients with advanced kidney cancer. Results from the study – the largest randomized, placebo-controlled trial ever conducted in advanced renal cell cancer – were presented in May at the 41<sup>st</sup> Annual Meeting of the American Society of Clinical Oncology (ASCO).

Sorafenib is currently available to patients throughout the United States through a treatment protocol known as the Advanced Renal Cell Carcinoma Sorafenib (ARCCS) study. To be eligible, individuals with advanced kidney cancer may not have been previously treated with sorafenib. Physicians who are interested in becoming investigators should call 1-866-639-2827. Interested patients should discuss this with

their doctor or call the number above. A similar trial will start in Europe shortly, and Bayer and Onyx are in discussions with regulators about similar programs in other territories.

**Phase III Results Presented at ASCO: Progression-free Survival Doubled**

At ASCO, investigators reported that sorafenib doubled progression-free survival (PFS) when compared to those patients who received placebo. As assessed by independent radiologic review, PFS was doubled to a median value of 24 weeks in patients receiving sorafenib as compared to 12 weeks for patients receiving placebo (p-value < 0.000001). More than 900 patients with advanced kidney cancer, who had previously failed one prior systemic therapy, have been randomized in this ongoing multi-national Phase III study.

The pivotal trial was initiated in the fourth quarter of 2003 after a Special Protocol Assessment (SPA) was completed by the FDA. Previously, the companies announced that patients enrolled in the Phase III kidney cancer trial who were receiving placebo could "cross over" to drug treatment based on the clinical and statistical significance of the PFS data. The study is ongoing, and patients will continue to be treated and followed for survival.

Thus far, 769 patients have been evaluated for safety. Drug-related adverse events (all grades) were similar to what has been observed in previous clinical trials and included: rash, diarrhea, hand foot syndrome, hair loss, itching, nausea, hypertension, and fatigue.

**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.

**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's pipeline and activities, 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 subgroup 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.

Our 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, July 11, 2005

### **Bayer AG, Investor Relations contacts:**

Dr. Alexander Rosar (+49-214-30-81013)

Dr. Juergen Beunink (+49-214-30-65742)

Peter Dahlhoff (+49-214-30-33022)

Ute Krippendorf (+49-214-30-33021)

Ilia Kürten (+49-214-30-35426)

Judith Nestmann (+49-214-30-66836)

### **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 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.