

Bayer



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

## Investor News

---

### **FDA Grants Orphan Drug Designation to BAY 43-9006 for the Treatment of Renal Cell Carcinoma**

---

**Leverkusen / October 27, 2004** – Bayer Pharmaceuticals Corporation (NYSE: BAY) and Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) announced today that BAY 43-9006 has been granted orphan drug status for the treatment of renal cell carcinoma by the U.S. Food and Drug Administration (FDA). The compound is being evaluated for the treatment of metastatic renal cell carcinoma, an advanced form of kidney cancer. A similar designation has been granted in the European Union by the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA). Currently in Phase III clinical testing, BAY 43-9006 is a novel RAF kinase and VEGFR inhibitor that is intended to prevent tumor growth by combining two anticancer activities: inhibition of tumor cell proliferation and tumor angiogenesis. BAY 43-9006 is being co-developed by Bayer and Onyx.

The FDA orphan drug designation provides incentives to companies that develop drugs for diseases affecting less than 200,000 people in the United States.

“The orphan drug designation in the U.S. signifies another important step for Bayer and Onyx in the development of BAY 43-9006,” said Susan Kelley, M.D., vice president, Oncology, Bayer Pharmaceuticals Corporation. BAY 43-9006 recently received the FDA’s fast track designation and both the fast track and orphan drug designation provide mechanisms for more frequent communications with the FDA, helping to streamline development as well as the review and approval process.

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.

Renal cell carcinoma is the most common form of kidney cancer. Nearly 190,000 people worldwide (about 32,000 Americans) are diagnosed with renal cell carcinoma each year, and more than 91,000 of them (about 12,000 Americans) die from the disease annually.

### **About Orphan Drug Designation**

In the U.S., orphan drug designation provides a drug U.S. market exclusivity for a particular indication for a seven-year period if the sponsor complies with certain FDA specifications. Additional incentives for the sponsor include tax credits related to clinical trial expenses and a possible exemption from the FDA-user fee. The designation does not shorten the duration of the regulatory review and approval process. If a product with orphan-drug designation in a particular indication is the first product of its type to receive FDA approval for that indication, the product is entitled to orphan product exclusivity. This means the FDA may not approve any applications from other companies to market a drug with same active ingredient in the US for that disease for seven years, except in limited circumstances. The FDA may permit additional companies to market the same drug for the designated condition if such companies can demonstrate better safety, efficacy, or a major contribution to patient care. The FDA may also approve more than one product for the same orphan indication or disease as long as the products are different drugs.

Leverkusen, October 27, 2004

### Bayer AG, Investor Relations contacts:

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

Bayer HealthCare AG, a subgroup of Bayer AG with sales of approximately 8.9 billion Euro in 2003, 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. 34,600 people are employed by Bayer HealthCare worldwide.

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.

#### **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.