Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

# Investor News

## Bayer and Onyx Announce Phase II Results of Treatment with BAY 43-9006 In Patients with Advanced Primary Liver Cancer

52 Percent of Patients Experienced Disease Stabilization or Tumor Shrinkage

**Leverkusen / September 29,2004** – Bayer Pharmaceuticals Corporation and Onyx Pharmaceuticals, Inc. today announced results from a Phase II clinical trial of BAY 43-9006 administered as a single agent in patients with advanced hepatocellular carcinoma (HCC), or liver cancer (hepatoma). The results showed that 52 percent of patients experienced disease stabilization or tumor shrinkage. The data were presented at the 16th American Association for Cancer Research-National Cancer Institute-European Organization for Research and Treatment of Cancer (AACR-NCI-EORTC) meeting in Geneva, Switzerland.

BAY 43-9006, a novel RAF kinase and VEGFR inhibitor under investigation for the treatment of different types of cancer, combines two anticancer activities: inhibition of tumor cell proliferation and angiogenesis (the growth of new blood vessels).

"In this Phase II study of advanced primary liver cancer, 43 percent of patients treated with BAY 43-9006 experienced stable disease for at least four months and an additional nine percent of patients experienced tumor shrinkage," said Dr. Ghassan K. Abou-Alfa, lead investigator and clinical assistant attending at the Memorial Sloan-Kettering Cancer Center, New York, U.S.A. "As we continue to evaluate BAY 43-9006, this clinical study offers a promising step in the fight against primary liver cancer, a disease that has very limited treatment options."

Of 137 patients enrolled in the study, investigators reported seven patients with partial responses (tumor shrinkage of 50 percent or greater), five with minor responses (tumor shrinkage of 25 to 50 percent) and 59 with stable disease for at least four

months as their best response. Median overall survival for all patients was 9.2 months and median time-to-tumor progression (TTP) was 4.2 months.

In the study, safety data generated showed that BAY 43-9006 was well tolerated and side effects were predictable and manageable. The most common grade 3/4 drug-related toxicities were fatigue (9.5 percent), diarrhea (8 percent), and hand–foot skin reaction (5 percent).

"More than 500,000 people worldwide succumb to hepatocellular carcinoma each year. The disease is increasing in incidence rates and remains one of the most difficult tumor types to treat. We are encouraged by the signs of activity of BAY 43-9006 in HCC patients enrolled in this study," said Susan Kelley, M.D., vice president, Oncology, Bayer Pharmaceuticals Corporation. "Based on these preliminary data, we will be advancing the BAY 43-9006 clinical development program in HCC and will be initiating a Phase III single-agent study as well as a Phase II combination study with the chemotherapy agent doxorubicin."

**Phase II Study Design**

The BAY 43-9006 Phase II multi-center study enrolled 137 patients with inoperable HCC who had received no prior systemic treatment, had Child-Pugh score A or B (a measure of the severity of liver failure in cirrhosis) and an Eastern Cooperative Oncology Group (ECOG) performance status less than or equal to one. Patients received oral BAY 43-9006 at 400 mg twice a day continuously in four-week cycles. The goal of the study was to assess time to response, duration of response/stable disease, time to progression, overall survival and safety. Tumor response was assessed every eight weeks using World Health Organization (WHO) criteria.

**About BAY 43-9006**

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

BAY 43-9006 has shown anticancer activity in a number of tumor types. It is being evaluated both as a single agent therapy and in combination with conventional

chemotherapeutics in a number of ongoing clinical trials. For more information on BAY 43-9006 clinical trials, visit www.clinicaltrials.gov.

**About Heptocellular Carcinoma**

Hepatocellular carcinoma, also known as primary liver cancer, is the most common form of liver cancer and is responsible for 80 percent of the primary malignant liver tumors in adults. It is the fifth most common cancer in the world. In 2000, approximately 564,000 HCC cases were reported worldwide, with 11,500 cases in the United States and 50,000 in Europe. [i] HCC is most prevalent in developing countries, particularly in East and South-east Asia, the Pacific Basin, and sub-Saharan Africa. Of the 564,000 cases worldwide approximately 271,500 were reported in Eastern Asia (with 221,000 in China and 33,000 in Japan alone).[i] HCC causes more than 500,000 deaths annually worldwide. The five-year relative survival rate is about seven percent.[ii]

**Additional BAY 43-9006 AACR-NCI-EORTC Data**

Additional BAY 43-9006 data being presented at this year's AACR-NCI-EORTC meeting include:

- Phase I study of BAY 43-9006, a novel RAF kinase and VEGRF inhibitor, in combination with taxotere in patients with advanced, solid tumors. A. Awada, MD. (Poster #381)
- Phase II antitumor activity of BAY 43-9006, a novel RAF kinase and VEGRF inhibitor, in patients with sarcoma enrolled in a randomized discontinuation study. I. Judson, MD. (Poster #382)

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.

Leverkusen, September 29, 2004

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 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.

[1] GLOBOCAN 2000: Cancer Incidence, Mortality and Prevalence Worldwide, Version 1.0. IARC CancerBase No. 5. Lyon, IARCPress, 2001. http://www-dep.iarc.fr/globocan/globocan.html

[11] World Health Organization, http://www.who.int/emc-documents/hepatitis/docs/whocdscsrlyo20022/disease/hepatocellular_carcinoma.html