



Investor News

Bayer and Onyx Announce Initiation of Phase III Clinical Trial of BAY 43-9006 in Patients with Advanced Primary Liver Cancer

Leverkusen / March 8, 2005 – Bayer Pharmaceuticals Corporation (NYSE: BAY) and Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) today announced the initiation of a randomized, double-blind, placebo-controlled Phase III clinical trial of BAY 43-9006 administered as a single agent in patients with advanced hepatocellular carcinoma (IICC), or liver cancer.

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). BAY 43-9006 is being evaluated in several clinical trials, including a Phase III randomized clinical trial for the treatment of renal cell carcinoma (RCC), or kidney cancer.

“BAY 43-9006 is the first RAF kinase inhibitor to be tested in a worldwide IICC Phase III study,” said Dr. Jordi Bruix, Head of the Barcelona Clinic Liver Cancer Group (BCLC), University of Barcelona, Spain. “Based on the results seen in the Phase II IICC studies, we are pleased to continue the clinical development of BAY 43-9006 in liver cancer, a difficult-to-treat patient population. IICC is a particularly aggressive type of cancer with a significant unmet treatment need. Because of this, it is vitally important to pursue research to develop potential new therapies for this disease.” Dr. Bruix is co-primary investigator along with Dr. Josep Llovet, Senior Scientist, Division of Liver Disease, Mount Sinai School of Medicine, New York.

The Phase III study is designed to measure differences in overall survival, time to symptom progression and time to tumor progression of BAY 43-9006 versus placebo in patients with advanced IICC. The trial will also evaluate the safety and pharmacokinetics of BAY 43-9006.

More than 500 patients with advanced IICC, who have not received previous systemic treatment for their disease, will be randomized to receive 400 mg of oral BAY 43-9006 twice daily or matching placebo. This study is expected to enroll patients in the Americas, Europe, and Australia/New Zealand.

“We are encouraged by the early Phase II findings in this patient population,” said Susan Kelley, M.D., vice president, Oncology, Bayer Pharmaceuticals Corporation. “We look forward to the results of the Phase III trial as we continue to study this compound for patients who greatly need new treatments.”

Phase II study results

Results of the Phase II study in advanced IICC, completed last year, were reported in a scientific congress in September 2004. 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).

Bayer and Onyx also reported today that the U.S. Food and Drug Administration (FDA) has completed a Special Protocol Assessment (SPA) for the Phase III IICC trial. An SPA is a written agreement on the design and size of clinical trials intended to form the basis for a new drug application.

The companies are also planning a Phase II trial for liver cancer patients to evaluate the use of BAY 43-9006 in combination with the chemotherapeutic agent doxorubicin.

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 also inhibits other tyrosine kinases such as c-KIT and FLT-3.

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

About Hepatocellular 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 2002, approximately 626,000 HCC cases were reported worldwide, with 15,000 cases in the United States and 53,600 in Europe. HCC is most prevalent in developing countries, particularly in East and South-east Asia, the Pacific Basin, and sub-Saharan Africa. Of the 626,000 cases worldwide, approximately 410,000 were reported in Eastern Asia (with 346,000 in China and 40,000 in Japan alone). HCC causes more than 600,000 deaths annually worldwide. The five-year relative survival rate is about seven percent.

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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 2003, the Bayer HealthCare subgroup generated sales amounting to some EUR 8.9 billion.

The company combines the global activities of the divisions Animal Health, Biological Products, Consumer Care, Diabetes Care, Diagnostics and Pharmaceuticals. 34,600 people are employed by Bayer HealthCare worldwide.

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.

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.

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.