



News Release

Phase III Trial Started to Evaluate Combination Therapy of Nexavar[®] and Tarceva[®] in Patients with Liver Cancer

Berlin, May 28, 2009 – Bayer HealthCare AG, Onyx Pharmaceuticals, Inc., OSI Pharmaceuticals, Inc. and Roche today announced the initiation of a Phase III trial examining Nexavar[®] (sorafenib) tablets in combination with Tarceva[®] (erlotinib) tablets as a potential new treatment option for patients with advanced hepatocellular carcinoma (HCC), or primary liver cancer.

The SEARCH (Sorafenib and erlotinib, a randomized trial protocol for the treatment of patients with hepatocellular carcinoma) trial aims to further build on data from the Phase III SHARP trial, which demonstrated that Nexavar significantly extended overall survival in patients with unresectable liver cancer by 44 percent. Based on the strength of these data, Nexavar was approved for the treatment of patients with unresectable HCC in the U.S. and in Europe for the treatment of HCC. Nexavar is currently approved in more than 70 countries for the treatment of HCC, including China where more than half of all liver cancer cases worldwide occur each year.

“Nexavar is the only approved targeted therapy with efficacy and tolerability in liver cancer,” said Dimitris Voliotis, MD, vice president, Nexavar Clinical Development, Bayer HealthCare Pharmaceuticals. “We look forward to seeing the potential of combining Nexavar with another effective cancer treatment, Tarceva, in treating this disease and further extending the lives of patients.”

“This study will enable us to learn whether combining two oral targeted therapies, Nexavar and Tarceva, can improve survival in a disease that is difficult to treat since most patients are diagnosed at an advanced stage,” said Karsten Witt, M.D., Vice President, Clinical Development Oncology and Drug Safety, OSI Pharmaceuticals. “We are pleased to collaborate with Roche, Bayer and Onyx to explore Tarceva in HCC, a new disease area which if successful, has the potential to expand the use of Tarceva beyond its

current indications in second/third-line non-small cell lung cancer and first-line pancreatic cancer.”

About the Phase III Study

The international, multicenter, randomized, placebo-controlled, Phase III study is expected to enroll approximately 700 patients with advanced liver cancer. The study will examine whether Nexavar in combination with Tarceva prolongs survival as compared to Nexavar alone. The primary endpoint of the study is overall survival and the secondary endpoints are safety, time to radiographic progression, disease control rate and patient-reported outcome.

Patients will be randomized to receive either 400 mg of Nexavar twice daily and 150 mg of Tarceva once daily or 400 mg of Nexavar twice daily with matching placebo. The study will be conducted at more than 95 sites in North America, Europe and the Asia-Pacific region. For more information about the study, please visit www.clinicaltrials.gov.

About Hepatocellular Carcinoma

Hepatocellular carcinoma is the most common form of liver cancer and is responsible for about 90 percent of the primary malignant liver tumors in adults. Liver cancer is the sixth most common cancer in the world and the third leading cause of cancer-related deaths globally. More than 600,000 cases of liver cancer are diagnosed worldwide each year (more than 400,000 in China, South Korea, Japan and Taiwan, 54,000 in the European Union, and 15,000 in the United States) and the incidence is increasing. In 2002, approximately 600,000 people died of liver cancer including approximately 370,000 in China, South Korea and Japan, 57,000 in the European Union, and 13,000 in the United States.

About Nexavar[®]

Nexavar, an oral anti-cancer therapy, is currently approved in more than 70 countries for liver cancer and in more than 80 countries for the treatment of patients with advanced kidney cancer. In Europe, Nexavar is approved for the treatment of hepatocellular carcinoma and for the treatment of patients with advanced renal cell carcinoma (RCC) who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy.

Nexavar targets both the tumor cell and tumor vasculature. In preclinical studies, Nexavar has been shown to target members of two classes of kinases known to be involved in both cell proliferation (growth) and angiogenesis (blood supply) – two important processes that enable cancer growth. These kinases included Raf kinase, VEGFR-1, VEGFR-2, VEGFR-3, PDGFR-B, KIT, FLT-3 and RET.

Nexavar, which is co-developed by Bayer Healthcare and Onyx Pharmaceuticals, is being evaluated by the companies, international study groups, government agencies and individual investigators as a single agent or combination treatment in a wide range of other cancers, including breast cancer, lung cancer, ovarian cancer, colorectal cancer, and as an adjuvant therapy for kidney cancer and liver cancer.

A science podcast about Sorafenib can be found here: www.podcast.bayer.com.

About Tarceva[®]

Tarceva[®] is a once-a-day pill that targets the EGFR pathway. Tarceva is designed to inhibit the tyrosine kinase activity of the EGFR signaling pathway inside the cell, one of the critical growth factors in NSCLC and pancreatic cancers. Tarceva is indicated as a monotherapy for patients with locally advanced or metastatic NSCLC whose disease has progressed after one or more courses of chemotherapy. Results from two multicenter, placebo-controlled, randomized Phase III trials conducted in first-line patients with locally advanced or metastatic NSCLC showed no clinical benefit with the concurrent administration of Tarceva with platinum-based chemotherapy (carboplatin and paclitaxel or gemcitabine and cisplatin) and its use is not recommended in that setting.

In pancreatic cancer, Tarceva is indicated in combination with gemcitabine for the first-line treatment of patients with locally advanced pancreatic cancer, pancreatic cancer that cannot be surgically removed or pancreatic cancer that has spread to distant body organs.

About Onyx Pharmaceuticals, Inc.

Onyx Pharmaceuticals, Inc. is a biopharmaceutical company committed to improving the lives of people with cancer. The company, in collaboration with Bayer HealthCare Pharmaceuticals, Inc., is developing and marketing Nexavar[®] (sorafenib) tablets, a small molecule drug. For more information about Onyx, visit the company's website at www.onyx-pharm.com.

About OSI Pharmaceuticals

OSI Pharmaceuticals is committed to "shaping medicine and changing lives" by discovering, developing and commercializing high-quality, novel and differentiated targeted medicines designed to extend life and improve the quality of life for patients with cancer and diabetes/obesity. For additional information about OSI, please visit <http://www.osip.com>.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma AG. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Find more information at www.bayerhealthcare.com.

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Specialty Medicine and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life. Find more information at www.bayerscheringpharma.de.

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Forward-Looking Statements

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