

Wednesday - July 22, 2009

Nexavar® in Combination with Chemotherapy Shown To Extend Progression-Free Survival in Patients with Advanced Breast Cancer

Statistically Significant Results Reported from a Phase II Study Combining Two Oral Cancer Therapies

Berlin, July 22, 2009 – Bayer HealthCare AG and Onyx Pharmaceuticals, Inc. today announced that their first cooperative group-sponsored randomized Phase II trial in advanced metastatic breast cancer met its primary endpoint of progression-free survival. The study evaluated Nexavar® (sorafenib) tablets in combination with the oral chemotherapeutic, capecitabine, in patients with locally advanced or metastatic HER-2 negative breast cancer. Study findings demonstrated that the median progression-free survival was extended in patients treated with Nexavar and capecitabine compared to patients receiving capecitabine and placebo. These results were statistically significant (p-value = 0.0006). In this trial, the safety and tolerability of the combination was as expected and did not show any new or unexpected toxicities. A complete data analysis from this study is expected to be presented at an upcoming scientific meeting.

“Based on these encouraging data, Bayer and Onyx are evaluating various strategies for Nexavar in breast cancer. Nexavar is already benefiting patients worldwide with liver cancer and kidney cancer,” said Kemal Malik, member of the Bayer HealthCare Executive Committee and Chief Medical Officer. “Despite significant treatment advances, breast cancer continues to be the leading cause of cancer death in women. We hope to establish Nexavar as an important new treatment option for patients with this devastating disease.”

“This outcome represents a positive signal of the benefit of this combination for patients with advanced breast cancer and is the first statistical demonstration of efficacy for a multi-tyrosine kinase inhibitor in this disease,” said Jose Baselga, M.D., chairman and professor of medicine at Vall d'Hebron Institute of Oncology in Barcelona and the principle investigator of this study. “One goal of this study was to evaluate the success of an all oral regimen, which may represent a unique treatment option for patients with breast cancer.”

Breast Cancer Trial Design and Results

The randomized, double-blind, placebo-controlled Phase II study evaluated Nexavar in combination with the oral chemotherapeutic agent, capecitabine, in 229 patients. These patients had locally advanced or metastatic HER-2 negative breast cancer and had received no more than one prior chemotherapy in this setting. The primary endpoint of the study was progression-free survival. There were several secondary endpoints including overall survival, time to progression, and safety. Patients were randomized to receive 400 mg of oral Nexavar or matching placebo twice daily, in addition to 1000mg/m² of capecitabine twice daily for 14 days followed by a seven day rest from capecitabine.

About the Nexavar Clinical Program in Breast Cancer

Nexavar is being evaluated in collaboration with investigators and cooperative groups in a variety of treatment settings for patients with breast cancer. Among these trials are three ongoing randomized Phase II studies, including a trial to evaluate Nexavar plus paclitaxel in the first-line setting, a trial to evaluate Nexavar plus gemcitabine or capecitabine in the first- or second-line setting following progression on bevacizumab and a trial to evaluate Nexavar plus docetaxel and/or letrozole in the first-line setting.

About Breast Cancer

Breast cancer was the most commonly diagnosed cancer among women worldwide in 2007-2008 (approximately 1.3 million cases), and the leading cause of death among women with cancer (approximately 465,000 deaths). It is the most commonly diagnosed cancer among women in the western world (1 in 4 cancer diagnoses is breast cancer). There are approximately 200,000 new cases of breast cancer in the United States and 350,000 in Europe each year. More than 40,000 women in the United States and approximately 130,000 women in Europe die of breast cancer each year.

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 is also 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 cancers, including lung, ovarian and colorectal cancer and as an adjuvant therapy for liver and kidney cancer.

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 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, Bayer Schering Pharma, Consumer Care and Medical Care divisions. 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.

Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup 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 which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

