



Investor News

Phase II Study in Advanced Breast Cancer:

Nexavar[®] in Combination with Chemotherapy Demonstrates 74 Percent Improvement in Progression-Free Survival

First presentation of results at joint ECCO-ESMO congress in Berlin, Germany

Leverkusen, September 23, 2009 – Bayer HealthCare AG and Onyx Pharmaceuticals, Inc. today announced the full results from their first collaborative group-sponsored randomized, double-blind, placebo controlled Phase II trial showing that Nexavar[®] (sorafenib tablets) in combination with the oral chemotherapeutic agent, capecitabine, significantly extended progression-free survival in patients with advanced breast cancer by 74 percent. The data were presented at the joint 15th European CanCer Organisation (ECCO) and 34th European Society for Medical Oncology (ESMO) Multidisciplinary Congress in Berlin, Germany.

Jose Baselga, M.D., chairman and Professor of Medicine at Vall d'Hebron Institute of Oncology in Barcelona, scientific chairman of SOLTI and the principal investigator of this study, reported that patients receiving Nexavar plus capecitabine had a 74 percent improvement in the time they lived without their disease progressing compared to those who received chemotherapy alone. The difference in median progression-free survival of Nexavar plus capecitabine versus capecitabine plus placebo was statistically significant, 6.4 months vs. to 4.1 months ($HR=0.576$, $p=0.0006$).

“These data represent a potentially significant advance in the treatment of breast cancer, which is the second leading cause of cancer-related death in women,” said Dimitris Voliotis, vice president, Global Clinical Development Oncology, Bayer HealthCare. “In addition to the positive signal generated in this trial, Bayer and Onyx are committed to the development of Nexavar in breast cancer in a variety of settings through a robust clinical program.”

The study evaluated Nexavar in combination with the oral chemotherapeutic, capecitabine, in patients with locally advanced or metastatic HER-2 negative breast cancer. Overall, treatment with Nexavar plus capecitabine showed an acceptable tolerability, without any new side effects. Common grade 3 or 4 treatment-related adverse events included hand-foot skin reaction, diarrhea, dyspnea, neutropenia and mucositis.

Breast Cancer Phase-II-Trial Design

The randomized, double-blind, placebo-controlled Phase II study evaluated Nexavar in combination with the oral chemotherapeutic agent, capecitabine, in 229 patients. All patients had locally advanced or metastatic HER-2 negative breast cancer and had received no more than one prior chemotherapy. The primary endpoint of the study was progression-free survival. Secondary endpoints included 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 1000 mg/m² of capecitabine twice daily for 14 days followed by a seven day rest from capecitabine.

“Bayer and Onyx have built a strong foundation with Nexavar in treating unresectable liver cancer and advanced kidney cancer – both disease areas with a previously unmet treatment need,” said Todd Yancey, M.D., vice president of clinical development at Onyx. “These new results signify an important step in understanding the potential role of Nexavar in breast cancer.”

About the Nexavar Clinical Program in Breast Cancer

In a clinical development program known as Trials to Investigate the Effects of Sorafenib in Breast Cancer (TIES), Nexavar is being evaluated in diverse treatment settings for patients with breast cancer in collaboration with investigators and cooperative groups. Among these clinical 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 second leading cause of cancer-

related death among women (approximately 465,000 deaths). It is the most commonly diagnosed cancer among women in the United States (1 in 4 cancer diagnoses is breast cancer). There are approximately 200,000 new cases of breast cancer in the United States and 430,000 in Europe each year. More than 40,000 women in the United States and more than 130,000 in Europe die of breast cancer each year.

About Nexavar®

Nexavar®, an oral anti-cancer therapy, is currently approved in more than 80 countries for liver cancer and in more than 90 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 SOLTI

Founded in 1995, SOLTI (Spanish Collaborative Group for the Study, Treatment and Other Experimental Strategies in Solid Tumors) is a collaborative group that leads cutting-edge clinical research in breast cancer to answer important questions that will lead to a reduction in the morbidity and mortality in breast cancer, and to carry out trials with new molecules and targeted therapeutics in oncology. SOLTI's network of high level oncology services spans Spain and Portugal promoting excellence in breast cancer care.

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.

Details on the study and the abstract # 3LBA can be found on the ECCO 15 - 34th ESMO website: <http://www.ecco-org.eu/Conferences-and-Events/ECCO-15/page.aspx/216>

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Forward-Looking Statements

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