



---

### **Results Reported for Exploratory Phase II Trial of Nexavar in Combination with Chemotherapeutic Agent Paclitaxel for Treatment of Advanced Breast Cancer**

Preliminary results require further analysis and interpretation

---

**Leverkusen, September 30, 2009** – Bayer HealthCare AG and Onyx Pharmaceuticals, Inc. today announced results from a randomized, placebo-controlled Phase II trial sponsored by Northwestern University. The study, which evaluated Nexavar<sup>®</sup> (sorafenib) tablets in combination with the chemotherapeutic agent paclitaxel in patients with locally advanced or metastatic HER-2 negative breast cancer, demonstrated a positive trend towards improvement of progression-free survival in the treatment group (*p-value=0.09*). The safety and tolerability profile of the combination was consistent with previous experience with each agent and no new toxicities were observed. A complete data analysis from this study is expected to be presented at an upcoming scientific meeting. Patients are continuing to be followed for a secondary endpoint of overall survival.

The trial was led by principle investigator William Gradishar, M.D., professor of medicine, Robert H. Lurie Comprehensive Cancer Center of Northwestern University. "These encouraging data warrant further investigation to determine the potential of the Nexavar and paclitaxel treatment combination in patients with advanced breast cancer, an often underserved patient population," said Dr. Gradishar.

"The preliminary results in this study demonstrate a clinical signal in favor of this treatment combination. These data require further analysis and interpretation before we determine the appropriate path forward," said Dimitris Voliotis, vice president, Global Clinical Development Oncology, Bayer HealthCare. "This trial is the second of four from our comprehensive clinical program in breast cancer, which is intended to explore Nexavar's utility in a number of disease settings."

Bayer and Onyx recently reported statistically significant results in a randomized Phase II trial demonstrating that Nexavar in combination with the oral chemotherapeutic agent, capecitabine, significantly extended progression free survival by 74% in patients with locally advanced or metastatic HER-2 negative breast cancer. Treatment with Nexavar plus capecitabine was tolerable and resulted in no new side effects. Common grade 3 or 4 treatment-related adverse events included hand-foot skin reaction, diarrhea, dyspnea, neutropenia and mucositis.

### **Breast Cancer Trial Design and Results**

The randomized, double-blind, placebo-controlled Phase II study evaluated Nexavar in combination with the chemotherapeutic agent, paclitaxel, in 237 patients. These patients had locally recurrent or metastatic HER-2 negative breast cancer and had not received prior chemotherapy in this setting. The study included an assessment of the primary endpoint of 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 paclitaxel, given at 90 mg/m<sup>2</sup> weekly for three weeks followed by one week of rest.

### **About the Nexavar Clinical Program in Breast Cancer**

The study is part of a clinical development program known as TIES (Trials to Investigate the Effects of Sorafenib in Breast Cancer), where Nexavar is being evaluated in collaboration with investigators and cooperative groups in four large randomized Phase II trials for patients with advanced breast cancer and in a variety of treatment settings. In addition to the study evaluating Nexavar in combination with paclitaxel, Bayer and Onyx recently reported results in a Phase II trial demonstrating that Nexavar in combination with the oral chemotherapeutic agent, capecitabine, significantly extended progression free survival. One of two remaining trials is evaluating Nexavar plus gemcitabine or capecitabine in the first- or second-line setting following progression on bevacizumab, and the second trial is evaluating 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 United States (1 in 4 cancer diagnoses is breast cancer). Approximately, 75% of women diagnosed have HER-2 negative breast cancer and 25% have HER-2 positive breast cancer. There are approximately 200,000 new cases of breast cancer in the U.S. and 430,000 in Europe each year. More than 40,000 women in the U.S. 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 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](http://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](http://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](http://www.bayerscheringpharma.de).

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)

Ilia Kürten (+49-214-30-35426)

Ute Menke (+49-214-30-33021)

Judith Nestmann (+49-214-30-66836)

Dr. Olaf Weber (+49-214-30-33567)

**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](http://www.bayer.com). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.