



Nexavar in Combination with Chemotherapy Shown to Extend Progression-Free Survival in Patients with Advanced Breast Cancer
*Statistically Significant Results Reported from a Phase 2 Study
Combining Two Oral Cancer Therapies*

Wayne, NJ and Emeryville, CA – July 22, 2009 – Bayer HealthCare Pharmaceuticals and Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) today announced that their first cooperative group-sponsored randomized Phase 2 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 ($p = .0006$). 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, Onyx and Bayer are evaluating various strategies for Nexavar in breast cancer. Nexavar is already benefiting patients worldwide with liver cancer and kidney cancer,” said Todd Yancey, M.D., vice president of clinical development at Onyx. “Despite significant treatment advances, breast cancer continues to be the leading cause of cancer death in women¹. 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 potential 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 principal 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

The randomized, double-blind, placebo-controlled Phase 2 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 1000 mg/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 2 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 United States (1 in 4 cancer diagnoses is breast cancer). There are approximately 200,000 new cases of breast cancer in the U.S. and 350,000 in Europe each year. More than 40,000 women in the U.S. die of breast cancer each year.ⁱⁱ

Nexavar's Differentiated Mechanism

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. 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.

Important Safety Considerations For Patients Taking Nexavar

Based on the currently approved U.S. package insert for the treatment of patients with unresectable hepatocellular carcinoma and advanced kidney cancer, hypertension may occur early in the course of therapy and blood pressure should be monitored weekly during the first six weeks of therapy and treated as needed. In HCC patients, bleeding with a fatal outcome from any site was reported in 2.4% for Nexavar and 4% in placebo. The incidence of treatment-emergent cardiac ischemia/infarction was 2.7% for Nexavar vs. 1.3% for placebo. In RCC patients, incidence of bleeding regardless of causality was 15% for Nexavar vs. 8% for placebo and the incidence of treatment-emergent cardiac ischemia/infarction was 2.9% for Nexavar vs. 0.4% for placebo. Most common adverse events $\geq 20\%$ related to Nexavar for both HCC and RCC were fatigue, weight loss, rash/desquamation, hand-foot skin reaction, alopecia, diarrhea, nausea, and abdominal pain. Grade 3/4 adverse events in HCC and RCC patients, respectively, were 45% for Nexavar vs. 32% for placebo and 38% for Nexavar and 28% for placebo. Women of child-bearing potential should be advised to avoid becoming pregnant and advised against breast-feeding. In cases of any severe or persistent side effects, temporary treatment interruption, dose modification or permanent discontinuation should be considered.

For information about Nexavar including U.S. Nexavar prescribing information, visit www.nexavar.com or call 1.866.NEXAVAR (1.866.639.2827).

About Bayer HealthCare Pharmaceuticals Inc.

Bayer HealthCare Pharmaceuticals Inc. is the U.S.-based pharmaceuticals business of Bayer HealthCare LLC, a subsidiary of Bayer AG. Bayer HealthCare is one of the world's leading, innovative companies in the healthcare and medical products industry, and combines the activities of the Animal Health, Consumer Care, Diabetes Care, and Pharmaceuticals divisions. Bayer HealthCare Pharmaceuticals comprises the following business units: Women's

Healthcare, Diagnostic Imaging, General Medicine, which includes Cardiology and Primary Care and Specialty Medicine, which includes Hematology, Oncology and Multiple Sclerosis. The company's aim is to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases.

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.

Forward Looking Statements

This news 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 Web site 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.

This news release also contains "forward-looking statements" of Onyx within the meaning of the federal securities laws. These forward-looking statements include without limitation, statements regarding timing, progress and results of the clinical development, safety, regulatory processes, commercialization efforts or commercial potential of Nexavar. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated. Reference should be made to Onyx's Annual Report on Form 10-K for the year ended December 31, 2008, filed with the Securities and Exchange Commission under the heading "Risk Factors" and Onyx's Quarterly Reports on Form 10-Q for a more detailed description of such factors. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date of this release. Onyx undertakes no obligation to update publicly any forward-looking statements to reflect new information, events, or circumstances after the date of this release except as required by law.

Nexavar[®] (sorafenib) tablets is a registered trademark of Bayer Healthcare Pharmaceuticals, Inc.

Contacts:

David Freundel Media contact Bayer HealthCare Pharmaceuticals (973) 305-5310	Lori Murray Media contact Onyx Pharmaceuticals, Inc. (510) 597-6394
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Julie Wood
Investor contact
Onyx Pharmaceuticals, Inc.
(510) 597-6505

ⁱ American Cancer Society, 2009 Cancer Statistics

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