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Investor News

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Nexavar in Combination with Chemotherapy Improves Progression-Free Survival in Patients with Advanced Breast Cancer in Phase II Study

Leverkusen, May 19, 2011 – Bayer HealthCare Pharmaceuticals and Onyx Pharmaceuticals, Inc. today announced results from a Phase IIb trial evaluating Nexavar® (sorafenib) tablets in patients with locally advanced or metastatic breast cancer previously treated with a bevacizumab containing regimen, which showed that Nexavar was associated with statistically significant improvements in progression-free survival (the primary endpoint of the study) and time-to-progression. The study evaluated Nexavar in combination with a chemotherapeutic agent, either, gemcitabine or capecitabine. The data will be presented during an oral session at the 2011 Annual Meeting of the American Society of Clinical Oncology (ASCO), June 3-7, in Chicago, IL.

Clifford Hudis, M.D., Chief of the Breast Cancer Medicine Service and attending physician at the Memorial Sloan-Kettering Cancer Center, as well as Professor of Medicine at Weill Cornell Medical College, reported that patients receiving Nexavar in addition to standard chemotherapy agents obtained a progression-free survival benefit with median 3.4 months to progression versus 2.7 (HR=0.65, one-sided p-value=0.01). Time-to-progression was similarly improved from a median of 3.6 months from 2.7 months (HR=0.64, one-sided p-value =0.009) in this pre-treated population.

“These results demonstrate the importance of evaluating anti-angiogenic compounds and should remain a high priority for the research community,” said Dr. Hudis.

“We continue to explore the utility of Nexavar as a potential treatment option for breast cancer patients in variety of settings through our clinical trial program, such as in the ongoing **RESILIENCE** (Phase III T**R**ial Comparing Capecitabin**E** in Combination with **S**orafen**I**b or P**L**acebo for Treatment of Locally Advanced or Metastat**I**c H**E**R2–**N**egative Breast **C**anc**E**r) trial,” said Dr. Dimitris Voliotis, Vice President, Global Clinical

Development Oncology, Bayer HealthCare. “As the second leading cause of cancer-related death in women, there is still an unmet need for treatments for these advanced patients. We remain committed to evaluating Nexavar in this patient population.”

The safety and tolerability profile of the combination was consistent with the previous experience with each agent. The most commonly reported Grade 3 adverse events were hand-foot skin reaction (39 percent), neutropenia (16 percent) and stomatitis (10 percent).

Phase IIb Trial Design

This Phase IIb, randomized, double-blind, placebo-controlled trial evaluated Nexavar in combination with chemotherapeutic agent, agents gemcitabine (1000 mg/m^2) or capecitabine (1000 mg/m^2) in 160 patients with locally advanced or metastatic HER-2 negative breast cancer who had progressed on bevacizumab. Patients were randomized to receive 400 mg of oral Nexavar or matching placebo twice daily, in addition to chemotherapeutic agents – gemcitabine or capecitabine. The primary endpoint was progression-free survival, and secondary endpoints included overall survival, time-to-progression and safety.

About the RESILIENCE Phase III Breast Cancer Trial

The RESILIENCE trial is a company-sponsored randomized, double-blind, placebo-controlled Phase III study planned to enroll approximately 500 patients in more than 20 countries, including the United States, Brazil, Japan and Australia. The study will evaluate Nexavar in combination with capecitabine in patients with locally advanced or metastatic HER-2 negative breast cancer who are resistant to or have failed prior taxane and an anthracycline (chemotherapies) or for whom further anthracycline is not indicated. The primary endpoint of the study is progression-free survival. Secondary endpoints include overall survival, time to progression, and safety.

About the Nexavar Clinical Program in Breast Cancer

This Phase IIb is part of a company-supported clinical development program known as **TIES** (**T**rials to **I**nvestigate the **E**ffects of **S**orafenib in Breast Cancer), where Nexavar is being evaluated in four investigator-/cooperative group-sponsored Phase II trials for patients with advanced breast cancer and in a variety of treatment settings. The remaining ongoing trial under this program 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 (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 100 countries for liver cancer where it remains the only approved systemic agent proven to extend survival and in 100 countries for the treatment of patients with advanced kidney cancer. In Europe, Nexavar is approved for the treatment of hepatocellular carcinoma (HCC) 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 inhibits processes involved in 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 range of cancers, including lung, thyroid, 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, is developing and marketing Nexavar® (sorafenib) tablets, a small molecule drug that is currently approved for the treatment of liver cancer and advanced kidney cancer. Additionally, Nexavar is being investigated in several ongoing trials in a variety of tumor types. Beyond Nexavar, Onyx has established a development pipeline of anticancer compounds at various stages of clinical testing, including carfilzomib, a

selective proteasome inhibitor, that is currently being evaluated in multiple clinical trials for the treatment of patients with relapsed or relapsed/refractory multiple myeloma and solid tumors. ONX 0801, an alpha-folate receptor targeted inhibitor of thymidylate synthase, and ONX 0912, an oral proteasome inhibitor, are currently in Phase I testing. For more information about Onyx, visit the company's website at www.onyx-pharm.com.

To learn more about breast cancer, please visit:
www.bayerpharma.com/breastcancer

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 subgroup of Bayer AG with annual sales of EUR 16.913 billion (2010), 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, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2010) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

Find more information at www.bayerpharma.com.

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