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Investor News

Bayer and Onyx Provide Update on Phase III Trial of Nexavar® in Patients with Non-Small Cell Lung Cancer

Leverkusen, February 18, 2008 – Bayer HealthCare Pharmaceuticals and Onyx Pharmaceuticals, Inc. today announced that a Phase III trial evaluating Nexavar® (sorafenib) tablets in patients with non-small cell lung cancer (NSCLC) was stopped early following a planned interim analysis, when the independent Data Monitoring Committee (DMC) concluded that the study would not meet its primary endpoint of improved overall survival. The Phase III ESCAPE (**E**valuation of **S**orafenib, **C**arboplatin **A**nd **P**aclitaxel **E**fficacy in NSCLC) trial evaluated Nexavar when administered in combination with the chemotherapeutic agents carboplatin and paclitaxel in patients with NSCLC. Safety events were generally consistent with those previously reported. However, higher mortality was observed in the subset of patients with squamous cell carcinoma of the lung treated with sorafenib and carboplatin and paclitaxel versus those treated with carboplatin and paclitaxel alone.

Bayer and Onyx are providing information regarding this DMC recommendation to health authorities and those clinical investigators involved in studies of Nexavar. In addition, the companies will further review the findings of this analysis and DMC recommendation to determine what, if any, impact they have on other ongoing Nexavar lung cancer trials. Data from this study will be presented at an upcoming scientific meeting.

“While we are disappointed in this outcome, Bayer and Onyx remain committed to our comprehensive pan-tumor clinical trial program for Nexavar. Nexavar has proven significant clinical benefit for patients with liver cancer and advanced kidney cancer and we will continue to investigate its potential across a wide variety of tumors,” said Susan Kelley, MD, vice president, Therapeutic Area Oncology, Bayer HealthCare Pharmaceuticals.

ESCAPE Trial Design

This multicenter, randomized, double-blind, placebo-controlled Phase III study enrolled more than 900 patients with non-small cell lung cancer at more than 140 clinical sites in North America, South America, Europe and the Asia Pacific region. The primary endpoint was overall survival, and secondary endpoints included progression-free survival, tumor response, patient quality of life and safety. Participating patients had not received any prior systemic anti-cancer treatment for their lung cancer and enrollment was open to patients with all histologies (or cell types) of NSCLC, including those with squamous cell carcinoma or adenocarcinomas.

Patients were randomized to receive 400 mg of oral Nexavar twice daily or placebo, in addition to two chemotherapeutic agents – carboplatin and paclitaxel – for up to six cycles. Subsequently, patients continued in a maintenance phase where Nexavar or placebo was administered as a single agent until study drug was discontinued due to progression of tumor or side effects.

Comprehensive NSCLC Program

Bayer and Onyx have a comprehensive program of clinical trials studying Nexavar for the treatment of NSCLC in a variety of patient populations and in combination with other anti-cancer regimens. These include a second ongoing Phase III study, known as NExUS (**N**SCLC research **Ex**perience **U**tilizing **S**orafenib), in previously untreated patients, administering Nexavar in combination with two chemotherapeutics commonly used in Europe, gemcitabine and cisplatin. In addition, a Phase II trial sponsored by a cooperative study group in the United States in patients who have failed two or more therapeutic regimens has also completed enrollment. There are also multiple Phase II studies in patients who have experienced disease progression despite treatment with one prior therapeutic regimen.

Nexavar's Differentiated Mechanism

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 currently approved in more than 30 countries for liver cancer and in more than 60 countries for the treatment of patients with advanced kidney cancer, including the United States and the European Union. 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 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 other cancers, including metastatic melanoma, breast cancer and as an adjuvant therapy for kidney cancer and liver 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.

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