



Investor News

Bayer and Onyx Initiate Phase III Trial of Nexavar® in Non-small Cell Lung Cancer

Leverkusen, June 1, 2009 – Bayer HealthCare AG and Onyx Pharmaceuticals, Inc. today announced that the companies have begun enrolling patients in an international Phase III trial to evaluate Nexavar® (sorafenib) tablets in patients with non-squamous non-small cell lung cancer (NSCLC) who have failed two or three previous treatments.

“Nexavar has proven efficacy in kidney cancer and liver cancer and we are committed to researching Nexavar in a variety of other solid tumors,” said Dimitris Voliotis, MD, vice president, Nexavar Clinical Development, Bayer HealthCare. “Based on strong findings in the Phase II trials, Bayer and Onyx moved to the next phase of development and initiated this Phase III trial evaluating Nexavar in NSCLC.”

About the Phase III Study

The MISSION (Monotherapy administration of Sorafenib in patients with non-small cell lung cancer) trial is an international multicenter study that will enroll approximately 850 patients with advanced relapsed or refractory non-squamous cell NSCLC who have failed two or three previous treatments. Patients will be randomized to receive either Nexavar as single agent or placebo. In both treatment arms, best supportive care will be provided. The primary endpoint of this trial is overall survival, and secondary endpoints include progression-free survival and overall response rate. The safety and tolerability of the two treatment groups will also be compared.

The study will be conducted at more than 120 sites in North America, South America, Europe, Africa and the Asia-Pacific region, including Japan. For information about this study, please visit www.clinicaltrials.gov.

“As the leading cause of cancer deaths worldwide, lung cancer is a complex disease that requires new therapeutic options for patients,” said Laura Brege, executive vice president

and chief operating officer at Onyx Pharmaceuticals. “We are committed to studying Nexavar to understand how it may play a role in the treatment paradigm of this difficult-to-treat disease.”

About Non-Small Cell Lung Cancer (NSCLC)

NSCLC accounts for 85-90 percent of diagnosed lung cancers and is a disease in which malignant (cancer) cells form in the tissues of the lung. It is characterized by several types of lung cancers, each of which grow and spread in different ways, including: squamous cell carcinoma, adenocarcinoma, and large cell carcinoma.

Every year 1.4 million people worldwide will be diagnosed with lung cancer and 1.2 million will die from the disease. Nearly 60 percent of people in the U.S. diagnosed with lung cancer die within one year of their diagnosis and 75 percent die within 2 years. These survival rates have not improved in the past 10 years.

About Nexavar[®]

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. 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 other cancers, including breast cancer, lung cancer, ovarian cancer, colorectal cancer, and as an adjuvant therapy for kidney cancer and liver cancer.

A science podcast about Sorafenib can be found here: www.podcast.bayer.com.

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.

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