



Bayer and Onyx Initiate Phase III Trial of Nexavar® in Patients with Non-Responsive Thyroid Cancer

Leverkusen, October 23, 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 for the treatment of patients with radioactive iodine-refractory, locally advanced or metastatic differentiated thyroid cancer. This Phase III trial was started based on the results from Phase II clinical trials evaluating Nexavar in patients with advanced thyroid cancer.

“Patients with thyroid cancer, particularly those who failed to respond to surgical or radiotherapies have limited treatment options to help them manage their disease,” said Dimitris Voliotis, Vice President, Clinical Development, Bayer HealthCare. “Recognizing this unmet need, we are evaluating Nexavar in this special patient population.”

Phase III Trial Design

The DECISION (stuDy of sorafEnib in loCally advanced or metastatic patientS with radioactive Iodine-refractory thyrOid caNcer) trial is an international, multicenter, randomized, placebo-controlled study that will enroll approximately 400 patients with locally advanced or metastatic, radioactive iodine-refractory, differentiated thyroid cancer (papillary, follicular and Hurthle cell) who have received no prior systemic therapy.

Patients will be randomized to receive 400 mg of oral Nexavar twice daily or matching placebo. Patients will continue on treatment until disease progression, toxicity, non-compliance or withdrawal of consent. At the time of progression, patients receiving placebo will have an option to cross over to Nexavar at the discretion of the investigator, based on the patient’s clinical status. The primary endpoint of the study is progression-free survival as defined by RECIST criteria. Secondary endpoints include overall survival, time to progression and response rate. The safety and tolerability of the two treatment groups will also be compared.

The study will be conducted at sites in the United States, Europe, Asia, and Japan. For information about enrolling in the study, please visit www.clinicaltrials.gov.

Phase II Trial Results

Updated results from a single-institution, investigator-sponsored Phase II open-label study in 55 patients with metastatic, iodine-refractory, thyroid cancer treated with Nexavar 400 mg were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting, May 29-June 3, Orlando, FL, by Marcia Brose, M.D., Ph.D., an assistant professor of Hematology/Oncology and Otorhinolaryngology in the Abramson Cancer Center of the University of Pennsylvania, Philadelphia, PA, U.S.A. In 50 evaluable patients, 18 (36 percent) had a partial response per RECIST criteria. Updated survival results on the first 30 patients enrolled into the study demonstrated that across all histologies the median progression-free survival (PFS) was 63 weeks and the median overall survival was 140 weeks. The most common adverse events (AE) seen in the trial were palmar-plantar erythema, rash, fatigue, stomatitis/mucositis, weight loss, and musculoskeletal pain, and were predominantly grade 1 or 2. Dr. Brose and Martin J. Schlumberger, Institut Gustave-Roussy, Villejuif, France are the lead investigators on the Phase III trial.

“Based on the positive signal generated in the Phase II trial, the initiation of this Phase III trial represents progress in exploring the full potential of Nexavar in a variety of treatment settings and tumor types,” said Todd Yancey, Vice President of clinical development at Onyx. “Building on our successful foundation of treating unresectable liver cancer and kidney cancer, we are hopeful that this Phase III trial will lead to a new treatment option for patients with non-responsive thyroid cancer.”

About Thyroid Cancer

Thyroid cancer, one of the few cancers that has increased in incidence over the past several years, is the sixth most common cancer in women and about three times as many women as men get thyroid cancer. There are more than 140,000 new cases of thyroid cancer and more than 35,000 people die worldwide 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 breast, 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.

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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Forward-Looking Statements

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