

Investor News

Nexavar[®] First FDA-Approved Drug Therapy for Liver Cancer

Only Systemic Therapy Proven to Significantly Improve Overall Survival in Patients with Liver Cancer

Leverkusen, November 19, 2007 – Bayer HealthCare AG and Onyx Pharmaceuticals, Inc. today announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental New Drug Application for Nexavar[®] (sorafenib) tablets for the treatment of patients with unresectable hepatocellular carcinoma (HCC), or liver cancer. Nexavar, an oral anti-cancer drug, is the first approved systemic drug therapy for liver cancer and the only drug therapy shown to significantly improve overall survival in patients with the disease. In Europe, Nexavar was approved for the treatment of HCC in October of this year. In 2005, Nexavar became the first new treatment in more than a decade for advanced kidney cancer and is currently approved in more than 60 countries for this indication.

“The approval of Nexavar in HCC marks the second time in two years that this novel kinase inhibitor has been granted FDA approval on a Priority Review basis, making it rapidly available to patients who previously had limited treatment options,” said Arthur J. Higgins, chairman of the Executive Committee of Bayer HealthCare. “This milestone will likely establish Nexavar as the standard systemic therapy for the treatment of liver cancer and is a turning point in improving treatment outcomes in patients facing the devastating impact of this disease.”

“Liver cancer is one of the cancers in which the number of related deaths continues to increase,” said Hollings C. Renton, chairman, president and chief executive officer of Onyx Pharmaceuticals, Inc. “This second approval for Nexavar demonstrates our commitment to expediting the clinical development of this innovative therapy to treat today’s unmet needs in cancer. We are grateful to the patients, families and investigators who make this important research possible.”

HCC, the most common form of liver cancer, is responsible for about 90 percent of the primary malignant liver tumors in adults. Liver cancer is the sixth most common cancer in the world and the third leading cause of cancer-related deaths globally. More than 600,000 cases of liver cancer are diagnosed worldwide each year (about 19,000 in the U.S., 54,000 in Europe and 390,000 in China, Korea and Japan) and incidence is increasing.

“The American Liver Foundation (ALF) is always pleased when new therapies prove effective for those affected by liver disease. Researchers worldwide, including those supported by ALF, have spent decades studying liver cancer,” said James L. Boyer, M.D., chairman, board of directors, American Liver Foundation. “This new treatment provides a valuable option for liver cancer patients and will enable ALF to further promote the treatment of liver disease through our education and advocacy efforts.”

Phase 3 Data Summary

The FDA approval was based on positive data from the international, Phase 3, placebo-controlled **Sorafenib HCC Assessment Randomized Protocol (SHARP)** trial which demonstrated that Nexavar improved overall survival by 44 percent in patients with HCC (HR=0.69; p=0.0006) versus placebo. Median overall survival was 10.7 months in Nexavar-treated patients compared to 7.9 months in those taking placebo. No indication of imbalances was observed in serious adverse event rates between the Nexavar and placebo-treated groups with the most commonly observed adverse events in patients receiving Nexavar being diarrhea and hand-foot skin reaction.

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. Preclinical models have also demonstrated that Raf/MEK/ERK has a role in HCC. Therefore, blocking signaling through Raf-1 may offer therapeutic benefits in HCC.

Nexavar is currently approved in more than 60 countries, including the United States and the European Union, for the treatment of patients with advanced kidney cancer. In Europe, Nexavar is approved 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 adjuvant therapy for kidney cancers, breast cancer, non-small cell lung cancer (NSCLC), and metastatic melanoma.

About Onyx Pharmaceuticals, Inc.

Onyx Pharmaceuticals, Inc. is a biopharmaceutical company developing innovative therapies that target the molecular mechanisms that cause cancer. The company is developing Nexavar, a small molecule drug, with Bayer HealthCare. For more information about Onyx's pipeline and activities, visit the company's web site at: www.onyxpharm.com.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of healthcare, 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, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma AG. 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, Hematology/Cardiology, Oncology, Primary Care, Specialized Therapeutics 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.

Bayer AG, Investor Relations contacts:

Dr. Alexander Rosar (+49-214-30-81013)

Dr. Juergen Beunink (+49-214-30-65742)

Peter Dahlhoff (+49-214-30-33022)

Ilia Kürten (+49-214-30-35426)

Ute Menke (+49-214-30-33021)

Judith Nestmann (+49-214-30-66836)

Dr. Olaf Weber (+49-214-30-33567)

Forward-Looking Statements

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