

Investor News

Phase 3 Study: Nexavar[®] Significantly Extends Overall Survival by 44% in Liver Cancer Patients

First Agent Ever to Demonstrate Significant Survival Benefit in Liver Cancer

Leverkusen / June 4, 2007 – Bayer HealthCare, a subsidiary of Bayer AG (NYSE: BAY), and Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) today announced that Nexavar[®] (sorafenib) tablets significantly extended overall survival in patients with hepatocellular carcinoma (HCC), or primary liver cancer versus those taking placebo by 44%. Results were presented at the 43rd annual meeting of the American Society of Clinical Oncology (ASCO). The data showed a reduced risk to die for patients treated with Nexavar versus placebo with a hazard ratio of 0.69. Results are statistical significant (p=0.0006).

The international, Phase 3, placebo-controlled Sorafenib **HCC Assessment Randomized Protocol (SHARP)** trial randomized and evaluated 602 liver cancer patients who had no prior systemic therapy at sites in the Americas, Europe, and Australia/New Zealand. The primary objective of the study was to compare overall survival in patients administered Nexavar versus those administered placebo. Median overall survival was 10.7 months in Nexavar-treated patients compared to 7.9 months in those taking placebo.

“Because there are no therapies that significantly improve survival for the thousands of patients with liver cancer, these findings demonstrate the compelling study results of Nexavar as the new reference standard of care for the first-line treatment of HCC,” said Dr. Josep M. Llovet, co-principal investigator and Professor of Research, Barcelona Clinic Liver Cancer (BCLC) Group, IDIBAPS, Liver Unit, Hospital Clinic Barcelona; Director of Research, HCC Program, Associate Professor of Medicine, Mount Sinai School of Medicine, New York.

Bayer and Onyx halted the SHARP trial in February 2007 when an independent data monitoring committee determined in a pre-scheduled analysis that the overall survival endpoint had been met. There were no significant differences in serious adverse events 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. Based on the strength of the data, the companies are now in the process of preparing applications to the U.S. Food and Drug Administration (FDA) and European health authorities for this new indication for Nexavar in treatment of patients with liver cancer.

“Although much progress has been made in cancer research, the number of lives lost to liver cancer is increasing,” said Dr. Jordi Bruix, co-principal investigator and Head of the Barcelona Clinic Liver Cancer (BCLC); Senior Consultant, Liver Unit, Hospital Clinic of Barcelona. “For that reason, these results represent an unprecedented achievement and Nexavar could become the first widely-approved new therapy for this difficult to treat cancer.”

Hepatocellular carcinoma is the most common form of liver cancer and is responsible for about 90 percent of the primary malignant liver tumors in adults. It is the fifth most common cancer in the world and the third leading cause of cancer-related deaths globally. Over 600,000 new cases of HCC are diagnosed globally each year (19,000 in the United States and 32,000 in the European Union), and in 2002 approximately 600,000 people (about 13,000 Americans and 57,000 Europeans) died of HCC. Although overall cancer incidence and mortality are decreasing in the United States, both the incidence and mortality of liver cancer are increasing.

Nexavar’s Differentiated Mechanism

Nexavar targets both the tumor cell and tumor vasculature and is the only oral multi-kinase inhibitor that does not require patients to interrupt their treatment schedule.

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 the Raf/MEK/ERK-pathway has a role in HCC; therefore blocking signaling through Raf-1 may offer therapeutic benefits in HCC.

Nexavar is currently approved in more than 50 countries, including the United States and in 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.

In addition, Nexavar is being evaluated in clinical trials by the companies, international study groups, government agencies and/or individual investigators as a single agent or combination treatment in a wide range of other cancers, including adjuvant therapy for kidney cancer, metastatic melanoma, breast cancer and non-small cell lung cancer (NSCLC). The Phase 3 ESCAPE (Evaluation of sorafenib, carboplatin, and paclitaxel efficacy in NSCLC) trial recently completed enrollment of more than 900 previously untreated patients with NSCLC of all histologies.

“HCC is the second tumor type in which Nexavar has demonstrated a clinical benefit. We intend to move swiftly with our partner Onyx to file these data for health authority review,” said Susan Kelley, MD, Vice President, Therapeutic Area Oncology, Bayer HealthCare Pharmaceuticals. “Our strategy of leveraging the unique attributes of Nexavar, the only approved orally administered anti-angiogenic that targets the Raf pathway, has led to a robust ongoing clinical program that could bring the potent cancer fighting properties of this oral multi-kinase inhibitor to an even broader number of patients in the coming years.”

Bayer HealthCare

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 and as Bayer HealthCare Pharmaceuticals in the US and Canada. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide.

Bayer Schering Pharma

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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.

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Forward-looking statements

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