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Nexavar shown to significantly extend survival for patients with advanced liver cancer

Trial to be stopped early based on positive outcome

BAYER HEALTHCARE



IMAGE: NEXAVAR(R) (SORAFENIB) TABLETS [view more >](#)

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West Haven, CT and Emeryville, CA - February 12, 2007 - Bayer Pharmaceuticals Corporation (NYSE: BAY) and Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) today announced that an independent data monitoring committee (DMC) has reviewed the safety and efficacy data from the companies' pivotal Phase 3 trial in patients with advanced hepatocellular carcinoma (HCC), or primary liver cancer. Based on this planned interim analysis, the DMC has concluded that the trial met its primary endpoint resulting in superior overall survival (OS) in those patients receiving Nexavar® (sorafenib) tablets versus those patients receiving placebo. The DMC also noted that there was no demonstrated difference in serious adverse event rates between the two treatment arms (Nexavar and placebo). Based on these conclusions, the DMC recommended that the trial be stopped early.

As a result of this recommendation, Bayer and Onyx will stop the trial and allow all patients enrolled in this trial access to Nexavar. Given that there are limited approved systemic therapies for this disease, the companies will continue discussions with health authorities worldwide, including the U.S. Food and Drug Administration (FDA) and European health authorities regarding the next steps in filing for approval for the treatment of HCC. Following these discussions, the companies will proceed to file as rapidly as possible. The two companies also reported that they plan to submit the results from the trial to the American Society of Clinical Oncology (ASCO), for presentation at its annual meeting, June 1-5, 2007.

"The observed superiority in overall survival for Nexavar-treated patients over patients receiving placebo demonstrates the efficacy of Nexavar in advanced primary liver cancer," said Dr. Jordi Bruix, co-principal investigator and Head of the Barcelona Clinic Liver Cancer Group, Liver Unit, Hospital Clinic Barcelona,

Spain.

Dr. Josep M. Llovet, co-principal investigator and Associate Professor of Medicine/Director, HCC Research Program, Division of Liver Diseases, Mount Sinai School of Medicine, New York, and Professor of Research at Barcelona Clinic Liver Cancer Group, Liver Unit, Hospital Clinic Barcelona added, "These results point to new potential treatment options for those patients suffering from this devastating disease."

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About the SHARP Trial

This analysis was conducted using data from the Sorafenib HCC Assessment Randomized Protocol (SHARP) Trial, an international Phase 3 double-blind, randomized, placebo-controlled trial designed to evaluate Nexavar in patients with advanced HCC, or primary liver cancer, who had no prior systemic therapy. Six hundred and two patients were randomized and enrolled at sites in the Americas, Europe, and Australia/New Zealand. The primary objectives of the study are to compare OS and time to symptom progression (TTSP) in patients administered Nexavar versus those patients administered placebo.

About Hepatocellular Carcinoma

Hepatocellular carcinoma, also known as primary liver cancer, 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.

About Nexavar

Nexavar is an oral multi-kinase inhibitor that targets both the tumor cell and tumor vasculature. In preclinical models, Nexavar targeted 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 nearly 50 countries, including the United States and in the European Union, for the treatment of patients with advanced kidney cancer. In addition, Nexavar is being evaluated by the companies, international study groups, government agencies or individual investigators as a single agent or combination treatment in a wide range of cancers, including adjuvant RCC, advanced liver cancer, metastatic melanoma, non-small cell lung cancer and breast cancer.

Important Safety Considerations for U.S. Patients Taking Nexavar

Based on the currently approved package insert for the treatment of patients with advanced kidney cancer, hypertension may occur early in the course of therapy and blood pressure should be monitored weekly during the first six weeks of therapy and treated as needed. Incidence of bleeding regardless of causality was 15% for Nexavar vs. 8% for placebo and the incidence of treatment-emergent cardiac ischemia/infarction was 2.9% for Nexavar vs. 0.4% for placebo. Most common treatment-emergent adverse events with Nexavar were diarrhea, rash/desquamation, fatigue, hand-foot skin reaction, alopecia, and nausea. Grade 3/4 adverse events were 38% for Nexavar vs. 28% for placebo. Women of child-bearing

potential should be advised to avoid becoming pregnant and advised against breast-feeding. In cases of any severe or persistent side effects, temporary treatment interruption, dose modification or permanent discontinuation should be considered.

For U.S. Nexavar prescribing information, visit www.nexavar.com or call 1.866.NEXAVAR (1.866.639.2827).

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 Pharmaceuticals Corporation. Nexavar has been approved for the treatment of advanced kidney cancer. For more information about Onyx's pipeline and activities, visit the company's web site at: www.onyx-pharm.com.

About Bayer Pharmaceuticals Corporation

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 division comprises the following business units: Women's Healthcare, Diagnostic Imaging, Specialized Therapeutics, Hematology/Cardiology, Primary Care, and Oncology. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. The products enhance well-being and quality of life by diagnosing, preventing and treating diseases.

Forward Looking Statements

This news release contains forward-looking statements based on current assumptions and forecasts made by Bayer Group management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports filed with the Frankfurt Stock Exchange and with the U.S. Securities and Exchange Commission (including its Form 20-F). Bayer assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

This news release also contains "forward-looking statements" of Onyx within the meaning of the federal securities laws. These forward-looking statements include without limitation, statements regarding the timing, progress and results of the clinical development, regulatory processes, and commercialization efforts of Nexavar. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated. Reference should be made to Onyx's Annual Report on Form 10-K for the year ended December 31, 2005, filed with the Securities and Exchange Commission under the heading "Risk Factors" and Onyx's Quarterly Reports on Form 10-Q for a more detailed description of such factors. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date of this release. Onyx undertakes no obligation to update publicly any forward-looking statements to reflect new information, events, or circumstances after the date of this release except as required by law.

Nexavar® (sorafenib) tablets is a registered trademark of Bayer Pharmaceuticals Corporation.

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