



Investor News

Sorafenib (BAY 43-9006) Doubles Progression-Free Survival in Phase III Kidney Cancer Trial

Independent Assessment Shows Median Progression-Free Survival of 24 Weeks

Leverkusen / May 14, 2005 – Bayer Pharmaceuticals Corporation (NYSE: BAY) and Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) today announced that sorafenib (formerly BAY 43-9006) demonstrated efficacy and was well tolerated in an ongoing Phase III trial in patients with advanced renal cell carcinoma (RCC), or kidney cancer. Results from the study – the largest randomized controlled trial ever conducted in advanced renal cell cancer – were presented in an oral session during the 41st annual meeting of the American Society of Clinical Oncology (ASCO) meeting in Orlando, FL.

Dr. Bernard Escudier, Head of Immunotherapy and Innovative Therapy Unit at the Gustave-Roussy Institute, Paris, France, and co-principal investigator of the study, reported that disease progression was significantly delayed in those patients who received sorafenib. As assessed by independent radiologic review, a measure of disease progression called progression-free survival (PFS) was doubled to a median value of 24 weeks (167 days) in patients receiving sorafenib as compared to 12 weeks (84 days) for patients receiving placebo (p-value < 0.000001). Bayer and Onyx are currently preparing a New Drug Application (NDA) for possible approval in this indication by the US Food and Drug Administration (FDA) in the United States. Discussions are also underway with regulatory agencies about registration in other territories.

“We now have randomized data documenting that sorafenib substantially delays tumor growth in patients with advanced RCC,” said Dr. Escudier. “At the same time, the side effects observed were readily managed in the clinical setting. This randomized data is

important since advanced renal cancer is a disease with differences among patient populations that can make comparisons to historical controls unreliable. These results underscore the clinical significance of disease control as an important measure of therapeutic benefit.” Dr. Escudier is co-principle investigator of the Phase III study along with Ronald Bukowski, M.D., Director of the Experimental Therapeutics Program of The Cleveland Clinic Taussig Cancer Center, Cleveland, OH.

There were 768 patients evaluated for safety. Drug-related adverse events (all grades) were similar to what has been observed in previous clinical trials and included rash, diarrhea, hand foot syndrome, hair loss, itching and nausea, hypertension, and fatigue.

“We are encouraged by the Phase III clinical results with sorafenib and look forward to further studies, including studies in combination with other agents,” said Arthur Higgins, chairman of Bayer HealthCare's executive committee. “We are working diligently to complete our NDA filing and hope to launch sorafenib in the first half of 2006 if approved by the FDA.”

Phase III Summary

More than 900 patients with advanced kidney cancer, who had previously failed one prior systemic therapy, have been randomized in the ongoing multi-national, placebo-controlled Phase III study. Approximately 120 sites accrued patients enabling the companies to finish enrolling the study approximately fifteen months from the time the first patient was treated. Participating patients were randomized one-to-one to receive either 400 mg sorafenib or placebo twice a day. The primary endpoint of the study is overall survival, with PFS, overall response rate, quality of life, and safety also being assessed. Tumors were evaluated using RECIST criteria. The pivotal trial was initiated in the fourth quarter of 2003 after a Special Protocol Assessment (SPA) was completed by the FDA. Per the SPA, the formal PFS analysis can be used as the basis for an NDA filing. In March 2004 sorafenib was granted Fast Track status by the FDA, and in April 2005 was accepted into the Pilot 1 Program. Previously, the companies announced that patients enrolled in the Phase III kidney cancer trial who were receiving placebo could “cross over” to drug treatment based on the clinical and statistical significance of the PFS data. The study is ongoing and patients will continue to be treated and followed for survival.

About Sorafenib

Sorafenib, a novel investigational drug candidate, is the first oral multi-kinase inhibitor that targets serine/threonine and receptor tyrosine kinases in both the tumor

cell and tumor vasculature. In preclinical models, sorafenib targeted members of two classes of kinases known to be involved in both tumor cell proliferation (tumor growth) and tumor angiogenesis (tumor blood supply) - two important cancer growth activities. These kinases included RAF kinase, VEGFR-2, VEGFR-3, PDGFR- β , KIT, FLT-3 and RET.

About Onyx Pharmaceuticals, Inc.

Onyx Pharmaceuticals, Inc. is engaged in the development of novel cancer therapies that target the molecular basis of cancer. With its collaborators, the company is developing small molecule drugs, including sorafenib with Bayer Pharmaceuticals Corporation. 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 Pharmaceuticals Corporation (www.bayerpharma.com) is part of the worldwide operations of Bayer HealthCare AG, a subgroup of Bayer AG.

Bayer HealthCare, with sales of approximately 8.5 billion Euro in 2004, is one of the world's leading, innovative companies in the health care and medical products industry. The company combines the global activities of the divisions Animal Health, Biological Products, Consumer Care, Diagnostics and Pharmaceuticals. Bayer HealthCare employed 35,300 people worldwide in 2004.

Our aim is to discover and manufacture innovative products that will improve human and animal health worldwide. Our products enhance well-being and quality of life by diagnosing, preventing and treating disease.

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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)

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

Ilia Kürten (+49-214-30-35426)

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

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 sorafenib. 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, 2004, as amended, filed with the Securities and Exchange Commission under the heading "Additional Business Risks" 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.