Bayer

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Investor News

Sorafenib (BAY 43-9006) Accepted into FDA Pilot 1 Program

Leverkusen / May 4, 2005 – May 4, 2005 – Bayer Pharmaceuticals Corporation (NYSE: BAY) and Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) today announced that sorafenib (formerly BAY 43-9006) has been accepted into the U.S. Food and Drug Administration's (FDA) Pilot 1 Program for continuous marketing applications. The Pilot 1 Program was designed for therapies that have been granted Fast Track status by the FDA and that have the potential to provide important therapeutic benefit over available therapy. Sorafenib was granted Fast Track status for metastatic renal cell carcinoma (RCC), or kidney cancer, in March 2004.

"Participating in the Pilot 1 Program offers Bayer and Onyx the opportunity to continue the productive dialogue that was established with the FDA at the beginning of this clinical program," said Wolfgang Plischke, Head of Bayer HealthCare's Pharmaceuticals Division. "We are preparing our New Drug Application (NDA) for submission in this indication and receiving Pilot 1 status facilitates the review process. Pending completion of the NDA filing, we hope to make this treatment available to patients in the first half of 2006 if approved by FDA."

As one of the Prescription Drug User Fee Act (PDUFA) goals, the Pilot 1 Program is intended to expedite the continuous marketing application (CMA) concept (known generally as a "Rolling NDA"). As part of the program, eligible applicants submit portions ("Reviewable Units") of an application before submitting the complete NDA. The FDA agrees to complete review of these sections within a specified period of time and to provide early feedback to the applicant. Under the Pilot 1 Program designation, the FDA is committed to completing the review of each of these sections on a six-month timeline.

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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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.