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Investor News

Bayer and Onyx Announce European Marketing Submission for Sorafenib

European Trial to Provide Access to Sorafenib for Individuals with Advanced Renal Cell Carcinoma

West Haven, CT and Emeryville, CA / September 12, 2005 – Bayer Pharmaceuticals Corporation (NYSE: BAY) and Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) today announced that a Marketing Authorization Applications (MAA) has been submitted by Bayer to the European Medicines Agency (EMEA) in London for the approval to market sorafenib within the European Union (EU) for the treatment of advanced Renal Cell Carcinoma (RCC), or kidney cancer. The application has been submitted under the EMEA's centralized procedure for product approval, which provides review and approval for all countries within the European Union.

The companies also announced a single-arm Phase III trial in the European Union for patients with advanced kidney cancer that have been previously treated. The study, to be managed by Bayer and known as the European Advanced Renal Cell Carcinoma Sorafenib (EU ARCCS) study, will take place at sites in 11 EU countries including Germany, France, UK, Spain, Italy, the Netherlands, and Poland. The study is scheduled to begin this fall. More information is available under www.clinicaltrials.bayerhealthcare.com.

"The filing of our Marketing Authorization Application is an important step towards making sorafenib available to doctors and patients in the EU," said Wolfgang Plischke, President of Bayer HealthCare's Global Pharmaceutical Division. "In the meantime, the initiation of the EU ARCCS trial will provide advanced RCC patients with access to this innovative anti-cancer drug candidate."

Bayer and Onyx have also completed the submission of a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for sorafenib for patients with advanced renal cell carcinoma (RCC), or kidney cancer in July 2005.

"With an experienced sales and marketing team in place, both companies are working aggressively to prepare for sorafenib's commercial launch in the U.S.," said Wolfgang Plischke, President of Bayer HealthCare's Global Pharmaceutical Division.

The European and the U.S. submission are based on an ongoing Phase III trial in patients with advanced kidney cancer. Results from the study – the largest randomized, placebo-controlled trial ever conducted in advanced renal cell cancer were presented in May at the 41st Annual Meeting of the American Society of Clinical Oncology (ASCO).

Sorafenib is being co-developed by Bayer and Onyx. The co-development collaboration calls for Onyx to fund 50 percent of the development and marketing costs for sorafenib worldwide, except in Japan. In return, Onyx has a 50/50 profit share in the United States, where the companies plan to co-promote the product if approved. In all other countries (except Japan) Bayer has exclusive marketing rights and Onyx's profit share is less than 50 percent. In Japan, Bayer will fund product development and Onyx will receive a royalty.

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.