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Investor News

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Phase III Trial Evaluating the Addition of Tarceva® (erlotinib) to Nexavar® (sorafenib) Did Not Provide Additional Benefit to Patients with Liver Cancer versus Nexavar Alone

Leverkusen, Germany, July 23, 2012 – Bayer HealthCare, Onyx Pharmaceuticals, Inc. and Astellas Pharma Inc. today announced that a Phase III trial evaluating the efficacy and safety of the addition of Tarceva® (erlotinib) tablets to Nexavar® (sorafenib) tablets for patients with hepatocellular carcinoma (HCC) did not further improve overall survival versus the standard therapy with Nexavar alone. The SEARCH (Sorafenib and Erlotinib, a rAndomized tRial protoCol for the treatment of patients with Hepatocellular carcinoma) trial compared Nexavar in combination with Tarceva to Nexavar alone. The safety and tolerability of the treatment combination were generally as expected based upon experience and use of the two products alone and did not show any new or unexpected toxicities or changes to the respective product safety profiles. Data from this study will be presented at an upcoming scientific meeting. Nexavar is jointly developed by Bayer and Onyx.

“The data from SEARCH showed that the addition of Tarceva to Nexavar did not provide additional benefit to patients with HCC,” said Dr. Dimitris Voliotis, Vice President, Global Clinical Development Oncology, Bayer HealthCare. “The results of this combination trial confirm the proven efficacy and safety profiles of Nexavar in HCC. Nexavar is approved for patients with inoperable liver cancer and advanced kidney cancer.”

About the Phase III Study

The SEARCH trial is an international multicenter placebo-controlled Phase III study that randomized 720 patients with advanced liver cancer. The study examined whether the addition of Tarceva to Nexavar prolongs survival as compared to Nexavar alone. The primary endpoint of the study was overall survival and the secondary endpoints were safety, time to radiographic progression, disease control rate and patient-reported outcome.

Patients were randomized to receive either 400 mg of Nexavar twice daily and 150 mg of Tarceva once daily or 400 mg of Nexavar twice daily with matching placebo.

About Hepatocellular Carcinoma

Hepatocellular carcinoma (HCC) is the most common form of liver cancer and is responsible for approximately 90 percent of the primary liver cancers in adults. Liver cancer is the seventh most common cancer in the world and the third leading cause of cancer-related deaths globally.

About Nexavar®

Nexavar®, an oral anti-cancer therapy for liver cancer and for the treatment of patients with advanced kidney cancer, is currently approved in more than 100 countries worldwide. In Europe, Nexavar is approved for the treatment of hepatocellular carcinoma and 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 preclinical studies, Nexavar has been shown to inhibit multiple kinases thought 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.

Nexavar is also being evaluated by Bayer and Onyx, international study groups, government agencies and individual investigators in a range of other cancers.

About Tarceva®

Tarceva® is approved for patients with advanced non-small cell lung cancer (NSCLC) whose cancer has not spread or grown after initial treatment with certain types of chemotherapy (maintenance treatment). Tarceva is also approved for patients with advanced NSCLC whose cancer has spread or grown after receiving at least one chemotherapy regimen (second-/thirdline treatment). Tarceva is approved for first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine.Tarceva is not meant to be used at the same time as certain types of chemotherapy for NSCLC. In the EU, Tarceva is approved for the first line treatment of locally advanced or metastatic NSCLC with EGFR (epidermal growth factor receptor) activating mutations.

About Onyx Pharmaceuticals, Inc.

Based in South San Francisco, California, Onyx Pharmaceuticals, Inc. is a global biopharmaceutical company engaged in the development and commercialization of innovative therapies for improving the lives of people with cancer. The company is focused on developing novel medicines that target key molecular pathways. For more information about Onyx, visit the company's website at www.onyx-pharm.com.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 17.2 billion (2011), 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, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2011) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

About Astellas

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas has approximately 17,000 employees worldwide. The organization is committed to becoming a global category leader in Urology, Immunology (including Transplantation) and Infectious Diseases, Oncology, Neuroscience and DM Complications and Kidney Diseases. For more information on Astellas Pharma Inc., please visit the company website at www.astellas.com/en.

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