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Investor News

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Phase III Trial of Sorafenib as Adjuvant Therapy for Liver Cancer Did Not Meet Primary Endpoint

Leverkusen, Germany, March 11, 2014 – Bayer HealthCare Pharmaceuticals Inc. and Onyx Pharmaceuticals, Inc., an Amgen subsidiary, today announced that a Phase III trial evaluating sorafenib (Nexavar®) tablets as an adjuvant treatment for patients with hepatocellular carcinoma (HCC, a form of liver cancer) who had no detectable disease after surgical resection or local ablation, did not meet its primary endpoint of improving recurrence-free survival. The safety findings were consistent with the known profile of sorafenib. Data from this study will be submitted for presentation at an upcoming scientific congress.

“We are disappointed that the trial did not meet its primary endpoint. However, we remain committed to exploring the full potential of sorafenib in all stages of liver cancer,” said Dr. Jörg Möller, member of the Bayer HealthCare Executive Committee and Head of Global Development. “The outcome announced today does not affect the currently approved indications. Nexavar remains the only approved systemic treatment for unresectable HCC with a proven overall survival benefit.”

About the STORM Trial

The Phase III, randomized, double-blind, placebo-controlled STORM (**S**orafenib as Adjuvant **T**reatment in the Prevention **o**f **R**ecurrence of Hepatocellular Carcino**m**a) trial is an international multicenter study that evaluated the clinical benefit of sorafenib versus placebo as an adjuvant treatment in patients with HCC following potential curative treatment (surgical resection or local ablation). The primary endpoint of the study was recurrence-free survival (i.e., the length of time that a patient survives without recurrence of HCC). Secondary endpoints included time to recurrence of HCC and overall survival. Safety and tolerability were also assessed. More than 1,100 patients were randomized to receive either 400 mg of sorafenib twice daily or matching placebo for four years or until disease recurrence, whichever comes first.

About Hepatocellular Carcinoma

Hepatocellular carcinoma (HCC) is the most common form of liver cancer and is responsible for approximately 70-85 percent of the total liver cancer burden worldwide.[1] Liver cancer is the sixth most common cancer in the world and the second leading cause of cancer-related deaths globally. More than 780,000 cases of liver cancer are diagnosed worldwide each year (more than 395,000 in China, 52,000 in the European Union, and 30,000 in the United States) and the incidence is increasing. In 2012, approximately 746,000 people died of liver cancer including approximately 383,000 in China, 48,000 in the European Union, and 24,000 in the United States.[2]

About Nexavar® (sorafenib)

Nexavar® (sorafenib), an oral anti-cancer therapy, is currently approved in more than 100 countries worldwide. In Europe, it is approved for the treatment of hepatocellular carcinoma (HCC) 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. Nexavar is also approved in the United States for the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid cancer (DTC) that is refractory to radioactive iodine treatment.

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 include 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.

Nexavar is co-developed by Onyx Pharmaceuticals, Inc., an Amgen subsidiary, and Bayer, except in Japan where Bayer manages all development. The companies co-promote Nexavar in the U.S. Outside of the U.S. Bayer has exclusive marketing rights, and Bayer and Onyx share profits globally, excluding Japan.

About Oncology at Bayer

Bayer is committed to delivering *science for a better life* by advancing a portfolio of innovative treatments. The oncology franchise at Bayer now includes three oncology products and several other compounds in various stages of clinical development.

Together, these products reflect the company's approach to research, which prioritizes targets and pathways with the potential to impact the way that cancer is treated.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 18.9 billion (2013), 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 56,000 employees (Dec. 31, 2013) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

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