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Investor News

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Phase III Trial of Sorafenib in Combination with Capecitabine Does Not Meet Primary Endpoint in Patients with Advanced Breast Cancer

Leverkusen, Germany, July 25, 2014 – Bayer HealthCare Pharmaceuticals and Onyx Pharmaceuticals, Inc., an Amgen subsidiary, today announced that an investigational Phase III trial of sorafenib (Nexavar®) tablets plus capecitabine in patients with advanced breast cancer did not meet its primary endpoint of improving progression-free survival (PFS).

The study, called RESILIENCE, evaluated the efficacy and safety of sorafenib in combination with capecitabine, an oral chemotherapeutic agent, compared to placebo plus capecitabine, in patients with HER2 negative breast cancer who are resistant to or have failed prior taxane, and are resistant to or have failed an anthracycline or for whom further anthracycline therapy is not indicated. Based on initial review of the data, the types of adverse events observed were generally comparable with those known for either sorafenib or capecitabine. Detailed efficacy and safety analyses from this study are expected to be presented at an upcoming scientific congress.

“We are disappointed that the trial did not show an improvement in progression-free survival in patients with advanced breast cancer,” said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “While the primary endpoint of this trial was not met, the results do not affect the currently approved indications for Nexavar. We would like to thank the patients and the study investigators for their contributions and participation in this study.”

Phase III Trial Design

The RESILIENCE (Phase III TRial Comparing CapecitabinE in Combination with SorafenIb or PLacebo for Treatment of Locally Advanced or MetastatIc HER2–Negative Breast CancEr) trial is a randomized, double-blind, placebo-controlled Phase III study

which enrolled 537 patients in more than 20 countries, including the United States, Europe, Japan and Australia. The study evaluated sorafenib in combination with capecitabine in patients with locally advanced or metastatic HER2 negative breast cancer who are resistant to or have failed prior taxane, and are resistant to or have failed an anthracycline or for whom further anthracycline therapy is not indicated.

The primary endpoint of the study was progression-free survival. Secondary endpoints included overall survival, time to progression, overall response rate, disease control rate, duration of response, patient reported quality of life and safety. Patients were randomized to receive 600 mg of oral sorafenib or matching placebo daily on a continuous schedule, in addition to 1000mg/m^2 of capecitabine twice daily for 14 days of a 21 day cycle.

About Nexavar® (sorafenib)

Nexavar® (sorafenib), an oral anti-cancer therapy, is currently approved in more than 100 countries worldwide. In Europe, Nexavar is approved for the treatment of hepatocellular carcinoma (HCC); 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; and for progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma, refractory to radioactive iodine.

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., excluding Japan, Bayer has exclusive marketing rights, and Bayer and Onyx share profits globally.

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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