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Investor News

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Sorafenib Recommended for Approval in the European Union for the Treatment of Differentiated Thyroid Cancer

Final decision from European Commission expected by mid-2014

Leverkusen, April 25, 2014 – Bayer HealthCare Pharmaceuticals Inc. and Onyx Pharmaceuticals, Inc., an Amgen subsidiary, announced today that the European Committee for Medicinal Products for Human Use (CHMP) recommended the oral multi-kinase inhibitor sorafenib (Nexavar®) for approval for the treatment of patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma, refractory to radioactive iodine. In November 2013, sorafenib was granted an orphan drug designation for the treatment of follicular and papillary thyroid cancer by the European Commission. The decision of the European Commission on the approval is expected by mid-2014. The U.S. Food and Drug Administration approved sorafenib for this indication in November 2013.

“The recommendation by the CHMP for sorafenib in differentiated thyroid cancer is an important milestone because it brings patients one step closer to a new treatment option for this difficult-to-treat form of thyroid cancer,” said Dr. Joerg Moeller, member of the Bayer HealthCare Executive Committee and Head of Global Development. “Nexavar is already approved for patients with hepatocellular carcinoma and advanced renal cell carcinoma in countries around the globe, and the CHMP’s positive decision in this third indication addresses another serious unmet medical need.”

“European patients with RAI-refractory differentiated thyroid cancer currently have no approved active systemic treatments and are eager for new options that delay the spread of their disease,” said Martin Schlumberger, M.D., of Institut Gustave-Roussy in Villejuif, France and co-lead investigator of the DECISION trial. “In the DECISION trial, sorafenib provided valuable benefit to patients in need of treatment; therefore we are pleased that it may soon be approved for this patient population in Europe.”

The CHMP recommendation is based on data from the Phase III DECISION (stu**D**y of soraf**E**nib in lo**C**ally advanced or metastat**I**c patient**S** with radioactive **I**odine refractory thyr**O**id ca**N**cer) trial. In the study, sorafenib significantly extended progression-free survival (PFS), the primary endpoint of the study, compared to placebo (HR=0.59 [95% CI, 0.46-0.76]; p<0.001), which represents a 41 percent reduction in the risk of disease progression or death for patients who received sorafenib compared to placebo-treated patients. The median PFS was 10.8 months in patients treated with sorafenib, compared to 5.8 months in patients receiving placebo.

The safety and tolerability profile of sorafenib in patients in the trial was generally consistent with the known profile of sorafenib. The most common treatment-emergent adverse events in the sorafenib arm were hand-foot skin reaction, diarrhea, alopecia, weight loss, fatigue, hypertension and rash. Results from the trial were presented at the Annual Meeting of the American Society of Clinical Oncology (ASCO) in June 2013 and published online on April 23, 2014 in *The Lancet*.

About Thyroid Cancer

Thyroid cancer is the most common endocrine malignancy.[1]There are more than 298,000 new cases of thyroid cancer annually and nearly 40,000 people die from thyroid cancer worldwide each year.[2]

Papillary, follicular (including Hürthle cell) and poorly differentiated types of thyroid cancer are classified as “differentiated thyroid cancer” and account for approximately 94 percent of all thyroid cancers.[3] While the majority of differentiated thyroid cancers are treatable, RAI-refractory locally advanced or metastatic disease is more difficult to treat and is associated with a lower patient survival rate.[3,4]

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 http://www.healthcare.bayer.com.

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