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Investor News

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Bayer Submits Nexavar® (Sorafenib) for Marketing Authorization in Thyroid Cancer in Japan

- Regulatory submission based on positive data from Phase III DECISION trial, in which sorafenib significantly extended progression–free survival
- Sorafenib has been granted orphan drug status for the treatment of patients with thyroid cancer in Japan

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Leverkusen, Germany, September 30, 2013 – Bayer HealthCare has submitted an additional application for marketing authorization to the Ministry of Health, Labour and Welfare (MHLW) in Japan for Nexavar® (Sorafenib) tablets, for the treatment of locally advanced or metastatic thyroid cancer. The MHLW granted sorafenib orphan drug status for this indication in September.

“The regulatory filing in Japan for sorafenib for the treatment of thyroid cancer brings us another step closer to addressing a significant medical need for patients whose disease has advanced and who have limited or no treatment options,” said Kemal Malik, M.D., Member of the Bayer HealthCare Executive Committee and Head of Global Development. “Nexavar is already approved for the treatment of hepatocellular carcinoma and advanced renal cell carcinoma. We are committed to fully exploring sorafenib’s utility across tumor types, especially in hard-to-treat cancers where there are limited treatment options.”

In June 2013, Bayer submitted Nexavar for regulatory review to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of locally advanced or metastatic differentiated thyroid cancer refractory to radioactive iodine (RAI). Nexavar received priority review designation from the FDA in August of this year for this indication. The FDA grants priority review to medicines that, if approved, would significantly improve the efficacy or safety of treatment for serious conditions. Under the

Prescription Drug User Fee Act (PDUFA), the FDA aims to complete priority review within six months, rather than the standard ten-month review cycle.

The regulatory submission 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, an international, multicenter, placebo-controlled trial. In the trial, sorafenib significantly extended progression-free survival (PFS), the primary endpoint of the study, compared to placebo (HR=0.587 [95% CI, 0.454-0.758]; p<0.0001), 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 the trial were 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, rash/desquamation, fatigue, weight loss and hypertension. Results from the trial were presented at the Annual Meeting of the American Society of Clinical Oncology (ASCO) in June 2013.

DECISION Trial Design

The 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 was an international, multicenter, placebo-controlled study. A total of 417 patients with locally advanced or metastatic, RAI-refractory, differentiated thyroid cancer (papillary, follicular, Hürthle cell and poorly differentiated) who had received no prior chemotherapy, tyrosine kinase inhibitors, monoclonal antibodies that target VEGF or VEGF receptor, or other targeted agents for thyroid cancer were randomized to receive 400 mg of oral sorafenib twice daily (207 patients) or matching placebo (210 patients). Ninety-six percent of randomized patients had metastatic disease.

About Thyroid Cancer

Thyroid cancer has become the fastest-increasing cancer in the world in recent years and is the sixth most common cancer in women. There are more than 213,000 new cases of thyroid cancer annually and approximately 35,000 people die from thyroid cancer worldwide each year.

Papillary, follicular, 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. 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.

About Nexavar® (sorafenib) Tablets

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 (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.

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 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 18.6 billion (2012), 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 54,900 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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