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Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

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Nexavar® (sorafenib) Granted Priority Review for Differentiated Thyroid Cancer in the U.S.

Currently no approved therapies specifically for differentiated thyroid cancer refractory to radioactive iodine

Leverkusen, August 27, 2013 – Bayer HealthCare and Onyx Pharmaceuticals today announced that the U.S. Food and Drug Administration (FDA) has granted priority review designation to the Supplemental New Drug Application (sNDA) for Nexavar® (sorafenib) tablets, for the treatment of locally advanced or metastatic radioactive iodine (RAI)-refractory differentiated thyroid cancer.

"We welcome this priority review as it supports our ongoing effort to make more treatment options available for cancer patients who until now have only limited or no treatment options," said Kemal Malik, MD, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

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 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 for 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, 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 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).

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 with treatment options such as resection and/or radioactive iodine (RAI), RAI-refractory differentiated thyroid cancer 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 55,300 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

Bayer AG, Investor Relations contacts:

Dr. Alexander Rosar (+49-214-30-81013)
Dr. Juergen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)

Dr. Olaf Weber (+49-214-30-33567)
Fabian Klingen (+49-214-30-35426)

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