Bayer



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Investor News

Bayer extends product portfolio for liver cancer patients in Japan

- Japanese authorities grant priority review status for Nexavar® in liver cancer
- Launch of liver-specific contrast agent Primovist® in Japan

Leverkusen, January 24, 2008 – Bayer is coming closer to its goal of extending its product portfolio for liver cancer patients in Japan to provide a comprehensive range of services from diagnosis to life-prolonging therapies. The Japanese health authority (MHLW) has granted Bayer priority review status (fast-track procedure) for marketing authorization of its anticancer drug product Nexavar® (sorafenib) for the treatment of hepatocellular carcinoma (HCC). In addition, the contrast agent Primovist® (gadoxetic acid disodium) for magnetic resonance imaging of the liver was recently granted regulatory approval in Japan. This product is scheduled to be launched on the Japanese market in the immediate future.

Liver cancer is the sixth most common cancer in the world and the third leading cause of cancer-related deaths globally. More than 600,000 cases of liver cancer are diagnosed worldwide each year and incidence is increasing. Japan has the second largest population of liver cancer patients in the world; most of them suffer from HCC which claims 36,000 lives every year. Thus, the medical need for an early and reliable diagnosis and for life-prolonging treatment is high.

Nexavar, an oral anti-cancer drug, is the first and only drug shown to significantly improve overall survival in patients with HCC. In Japan, Nexavar was filed in June 2006 for the treatment of renal cell carcinoma (RCC) and an additional application for HCC was submitted in September 2007.

“The fact that the Japanese authorities granted priority review status underlines the high medical need for innovative treatments options for patients with liver cancer. This devastating disease is one of the cancers in which the number of related deaths continues to increase,” said Paolo Pucci, President of Bayer HealthCare’s Global

Business Unit Oncology. “We at Bayer are highly committed to expediting the clinical development of this innovative therapy also across additional tumour types.”

Primovist is authorized for the detection and characterization of liver lesions by magnetic resonance imaging (MRI) including liver tumors such as hepatocellular carcinomas (HCC), liver metastases and other malignant and benign lesions.

“Primovist is a gadolinium-based contrast medium that offers the possibility to simultaneously detect, locate and distinguish various types of liver lesions, thus providing a powerful tool that increases the diagnostic confidence“, said Professor Hans Maier, Head of the Global Business Unit Diagnostic Imaging at Bayer Schering Pharma. “Primovist enables radiologists to identify even tiny pathological liver lesions; it thus helps to guide and follow-up on treatment decisions and has the potential to considerably optimize patient benefit.”

About Nexavar

Nexavar targets both the tumor cell and tumor vasculature. In preclinical studies, Nexavar has been shown to target members of two classes of kinases known 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. Preclinical models have also demonstrated that Raf/MEK/ERK has a role in HCC. Therefore, blocking signaling through Raf-1 may offer therapeutic benefits in HCC.

Nexavar is currently approved in more than 60 countries, including the United States and the European Union, for the treatment of patients with advanced kidney cancer. In Europe, Nexavar is approved 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 the U.S., Nexavar is approved for the treatment of patients with unresectable hepatocellular carcinoma (HCC). Nexavar is approved in more than 30 countries for the treatment of hepatocellular carcinoma.

Nexavar is also being evaluated by the companies, international study groups, government agencies or individual investigators as a single agent or combination treatment in a wide range of other cancers such as kidney cancer, non-small cell lung cancer (NSCLC), breast cancer and metastatic melanoma. Nexavar is being co-developed by Bayer and Onyx Pharmaceuticals, Inc.

About Primovist

Primovist enhances contrast of magnetic resonance images. Owing to its structural properties, Primovist is specifically taken up by liver cells (hepatocytes), thus enhancing healthy liver tissue (parenchymal enhancement). Lesions with no or minimal hepatocyte function (cysts, metastases, the majority of hepatocellular carcinomas) will remain unenhanced and will therefore be more readily detected and localized. Primovist furthermore provides useful diagnostic information at the time immediately after contrast administration (dynamic imaging) and thus also supports lesion characterization (i.e. distinction of malignant and benign types of liver lesions). Primovist is currently approved in 40 countries.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subsidiary of Bayer AG, 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, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma AG. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Find more information at www.bayerhealthcare.com.

About Bayer Schering Pharma

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, Hematology/Cardiology, Oncology, Primary Care, Specialized Therapeutics and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life. Find more information at www.bayerscheringpharma.de.

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Forward-Looking Statements

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