



## Investor News

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First organ-specific diagnostic agent approved in the U.S. in more than a decade:

### **Primovist<sup>®</sup> approved in the U.S. for the Detection and Characterization of Liver Lesions**

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**Leverkusen, July 8, 2008** –The U.S. Food and Drug Administration (FDA) has approved Bayer Schering Pharma's magnetic resonance imaging (MRI) contrast agent Primovist<sup>®</sup> (gadoxetate disodium) for the detection and characterization of liver lesions in adults with known or suspected focal liver disease. The product will be marketed in the United States under the name EOVI<sup>®</sup>; it is currently marketed as Primovist outside the U.S. and as EOB Primovist in Japan. It is the first organ-specific MRI contrast agent to be approved in the U.S. for over a decade. Bayer plans to make EOVI available to customers in the U.S. in the summer of 2008.

"Primovist not only offers the unique benefit of being able to simultaneously detect, locate and distinguish various types of liver lesions, but also helps to guide and follow-up on treatment decisions, as it enables radiologists to identify even tiny pathological liver lesions," said Dr. Gunnar Riemann, Member of the Board of Management of Bayer Schering Pharma AG, responsible for the company's Business Units. "Bayer is now in the unique position of offering Primovist for diagnosing patients with liver cancer and Nexavar for treating hepatocellular carcinoma – the most common form of liver cancer."

Using Primovist for the early detection, localization and definition of the exact lesion type (characterization) of malignant and benign focal liver lesions enhances diagnostic accuracy and increases diagnostic confidence. The contrast agent combines liver-specific imaging capabilities within a rapidly eliminated and well-tolerated compound. It is administered by intravenous injection. Primovist has a dual route of excretion: approximately 50 percent is eliminated through the liver, 50 percent through the kidney.

Primovist's mode of action has several distinctive features compared to existing contrast agents. It improves the detection of liver lesions during the liver-cell specific imaging phase and thus enables an early diagnosis of liver diseases such as hepatocellular carcinoma (HCC). Furthermore, the precise image contrast achieved with Primovist allows a clear delineation of structures, such as tumors and intrahepatic vessels. By combining early dynamic and hepatocyte-phase imaging, Primovist-enhanced MRI helps to characterize and clearly localize liver tumors and can act as a guide for surgical planning.

Liver cancer is the sixth most common cancer in the world and the third leading cause of cancer-related deaths globally. More than 15,000 cases of liver cancer are diagnosed every year in the United States and the incidence is increasing. Earlier staging of primary tumors with metastases in the liver, such as colon cancer, may improve treatment decisions and hence the survival rate. Approximately 510,000 new cases of colon cancer are diagnosed every year globally, more than 200,000 patients per year die at a late stage of colon cancer.

Primovist was first approved in Europe in 2004 followed by Japan in 2007; it is registered in more than 40 countries.

### **About Primovist**

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 are therefore more readily detected and localized. Primovist also provides useful diagnostic information immediately after contrast administration (dynamic imaging) and thus is also supporting lesion characterization (i.e. distinction between different types of liver lesions).

### **About Bayer**

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](http://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, General Medicine, Specialty Medicine 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](http://www.bayerscheringpharma.de).

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