



MR contrast agents for diagnosis of breast cancer

Bayer starts Phase III study to evaluate efficacy and safety of Gadovist® in magnetic resonance mammography

Leverkusen, March 10, 2010 – Bayer has started an international clinical Phase III study to develop its contrast agent Gadovist® (gadobutrol®) for use in magnetic resonance imaging (MRI) of the breast. The trial will evaluate the efficacy and safety of Gadovist in contrast-enhanced breast MRI (magnetic resonance mammography, MRM). Gadovist is already approved for the most frequently used contrast-enhanced MRI examinations including imaging of the central nervous system, the liver, the kidney and for imaging of blood vessels in adults and for the use in children aged 2 years and older.

“As a pioneer in contrast-media research, Bayer is continuously working to provide physicians with high-quality contrast media for use in various indications of contrast enhanced MRI,” said Thomas Balzer, Head of Global Clinical Development Diagnostic Imaging at Bayer Schering Pharma. “Due to its high T1-shortening – an important characteristic in the field of radiology – Gadovist offers a potentially excellent image quality in MRI and thus could be very valuable in MRM.”

About the Phase III Trial Design

The objective of this multi-center, open-label, non-randomized Phase III study with corresponding blinded image evaluations is to determine the efficacy and safety of a single intravenous injection of 0.1 mmol/kg body weight of Gadobutrol 1.0 Molar (Gadovist®) in patients with newly diagnosed breast cancer referred for contrast-enhanced breast MRI. The extent of malignant disease will be determined and compared between various imaging approaches, including unenhanced breast MRI, gadobutrol-enhanced MRI, and X-ray mammography. The active enrollment phase III will cover one year with the estimated completion date around beginning 2011.

About Breast Cancer

With about 1.3 million new cases every year, breast cancer is the most common form of cancer among women today. Diagnostic imaging plays an important role in the detection and management of this devastating disease. MRI is considered to be the most sensitive method for detection of breast cancer and also the best method to exclude additional cancer lesions. Therefore, it is used as an adjunct to X-ray mammography for e.g., screening in high-risk patients, pre-operative tumor staging, monitoring response to neo-adjuvant chemotherapy, and evaluation of breast implants. The MRI procedure consists of unenhanced and contrast-enhanced MRI scans to differentiate into benign and malignant lesions using morphological (shape and margin) and dynamic (contrast enhancement, signal intensity time curves) criteria. The performance of MRI strongly depends on the efficacy and safety of the applied contrast agent.

About Gadovist®

Gadovist® is a modern, highly efficient contrast agent, approved for the contrast-enhanced MRI of various parts of the body, including the brain, the spinal chord, the liver, the kidney and the blood-vessel system. With its 1.0 mol/L concentration of gadobutrol, a stable macrocyclic gadolinium compound, Gadovist contains twice as much gadolinium per unit of volume as other extracellular contrast media available on the market. Moreover, Gadovist has a high T1-relaxivity in plasma. Due to its combination of high concentration and high relaxivity, Gadovist exhibits the highest T1-shortening per ml of all gadolinium contrast media. This results in potentially excellent image quality and offers practical advantages in the case of smaller injection volumes. Gadovist received market authorization for the first time in 1998 and is now approved in over 50 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, Bayer Schering Pharma, Consumer Care and Medical Care divisions. Bayer HealthCare's aim is to discover, manufacture and market 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, 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.

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)

Ilia Kürten (+49-214-30-35426)

Judith Nestmann (+49-214-30-66836)

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

Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.