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### **FDA Accepts New Drug Application for Gadovist® 1.0 Injection in Magnetic Resonance Imaging**

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**Leverkusen, August 4, 2010** – Bayer Schering Pharma AG, Berlin, Germany, announced today that the Food and Drug Administration (FDA) has accepted for filing a New Drug Application to the U.S. for gadobutrol injection, a gadolinium-based contrast agent for magnetic resonance imaging (MRI).

Gadovist® 1.0 (gadobutrol injection) is a macrocyclic, non-ionic gadolinium-based contrast agent formulated at a 1.0 molar concentration. The submission for gadobutrol injection in contrast enhanced MRI of the CNS (central nervous system) is supported by two adequate and well-controlled Phase III studies. The first Phase III study compared the efficacy of combined gadobutrol-enhanced images plus unenhanced images to unenhanced images alone. The second Phase III study used a crossover design with an active control, gadoteridol, to also compare the efficacy of the combined gadobutrol-enhanced plus unenhanced images to unenhanced images alone, as well as to confirm noninferiority of combined gadobutrol imaging versus combined gadoteridol imaging.

“If approved by the FDA, Gadovist 1.0 would complement our portfolio of contrast agents in the United States,” says Prof. Hans Maier, Head of the Diagnostic Imaging business unit at Bayer Schering Pharma in Berlin. “This submission to the FDA is an important milestone for us.”

Magnetic resonance imaging is a non-invasive medical test that helps healthcare professionals diagnose medical conditions and make treatment decisions. Contrast agents are often used during an MRI to help make disease easier to see.

### **About Bayer HealthCare**

The Bayer Group is a global enterprise with core competencies in the fields of healthcare, 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](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).

### **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**

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