U.S. FDA Approves Bayer's Gadavistâ„¢ (Gadobutrol) Injection for MRI of the Central Nervous System

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WAYNE, N.J., March 14, 2011 /PRNewswire/ -- Bayer HealthCare Pharmaceuticals Inc. announced today that the U.S. Food and Drug Administration has approved Gadavist™ (gadobutrol) Injection, a macrocyclic gadolinium-based contrast agent (GBCA), for intravenous use in diagnostic magnetic resonance imaging (MRI) in adults and children (2 years of age and older) to detect and visualize areas with disrupted blood brain barrier (BBB) and/or abnormal vascularity of the central nervous system (CNS).

Gadavist is formulated at a higher concentration (1 mmol/mL) compared to certain other GBCAs. Compared to 0.5 molar gadolinium-based contrast agents, the higher concentration of Gadavist results in half the volume of administration and a more compact contrast bolus. It is important to closely examine the dosing table in the full prescribing information to determine the volume of Gadavist to be administered.

"The approval of Gadavist enriches our strong portfolio of MRI contrast media and provides a new option for U.S. healthcare providers in contrast-enhanced imaging of the CNS," said John Rotondo, Vice President, Commercial Operations, Bayer HealthCare Pharmaceuticals. "Our MR contrast agents are some of the most widely used today, and Bayer is proud to be a world leader in diagnostic imaging."IMPORTANT SAFETY INFORMATIONWARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle and internal organs.
The risk for NSF appears highest among patients with: Chronic, severe kidney disease (GFR < 30 mL/min/1.73m(squared)), or Acute kidney i
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