FDA Approves Gadavist for Central Nervous System Scans

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SILVER SPRING, Md., March 15, 2011 /PRNewswire-USNewswire/ --The U.S. Food and Drug Administration approved Gadavist (gadobutrol), a gadolinium-based contrast agent, for use in patients undergoing magnetic resonance imaging (MRI) of the central nervous system.

(Logo: http://photos.prnewswire.com/prnh/20090824/FDALOGO [1])

Gadavist was approved by the FDA on March 14. It provides contrast-enhanced imaging of the central nervous system, helping to detect and visualize lesions that disrupt the cell barrier that normally separates the brain from the blood stream. It also helps to detect and visualize abnormal blood supply and circulation of the central nervous system.

"Gadavist MRI scans improved the visualization of lesions in the central nervous system when compared to MRI scans without contrast," said Libero Marzella, M.D., acting division director, Division of Medical Imaging Products in the FDA's Center for Drug Evaluation and Research.

Gadavist is the sixth gadolinium-based contrast agent (GBCA) for use in patients undergoing magnetic resonance imaging of the central nervous system. It is indicated for adults and children ages 2 years and older. Gadavist is more concentrated than the other GBCAs and should be administered at half the volume. Two clinical studies involving 657 patients and other trial data established the safety and efficacy of Gadavist.

All GBCAs, including Gadavist, carry a boxed warning about the risk of nephrogenic systemic fibrosis (NSF), a rare, but serious, condition associated with the use of GBCAs in certain patients with kidney dysfunction. NSF is characterized by pain and thickening of the skin, and can cause fibrosis of internal organs. There is no known treatment for NSF. Gadavist is currently considered to be one of the GBCAs with a lower risk of NSF, and is not one of the GBCAs that is contraindicated in patients with acute kidne
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