Medical Imaging Drugs Advisory Committee Recommends Approval of Guerbet NDA for Dotarem@ (gadoterate meglumine)

The Associated Press

Guerbet, the contrast agent specialist for medical imaging, today announced that the Medical Imaging Drugs Advisory Committee to US Food and Drug Administration (FDA) has voted unanimously by votes of 17 to 0 to recommend that FDA approve the New Drug Application (NDA) for Dotarem@ (gadoterate meglumine) for adults, and for pediatric use for children two years of age and older. The Committee voted 10 to 6 (with one member abstaining) not to recommend at this time approval of the indication for children under two years of age.

Dotarem@ is the only macrocyclic and ionic gadolinium-based contrast agent (GBCA) for the intravenous use with magnetic resonance imaging (MRI) in the brain (intracranial), spine and associated tissues in adults and pediatric patients to detect and visualize areas with disruption of the blood-brain barrier (BBB) and/or abnormal vascularity. The Guerbet NDA recommended dose is 0.1 mmol Gd/kg.

"Guerbet is very pleased with the Advisory Committee's recommendation to approve Dotarem@ based on our comprehensive presentation of clinical and post-marketing data," said Yves L'Epine, CEO of Guerbet Group. "If approved by FDA, we believe Dotarem can provide another CNS imaging option for US clinicians. We are disappointed that the recommendation does not include the indication for children under two years of age, but we take the Committee's comments very seriously and will work to address all FDA questions and concerns." The Dotarem@ data presented at today's advisory committee meeting included results from two well-controlled Phase III clinical studies.

These studies evaluated the diagnostic efficacy of Dotarem@ in magnetic resonance imaging of diseases of the central nervous system, such as primary or secondary tumors of the brain or spinal cord, inflammatory diseases such as multiple sclerosis and vascular brain diseases.

Both studies evaluated the superiority of the enhanced images over the unenhanced images for central nervous system (CNS) lesion visualization in all three co-primary endpoints. All defined primary and key secondary efficacy analyses were met and support the efficacy of Dotarem@ at a standard dose of 0.1 mmol/kg BW. In addition to these two studies, 21 supportive clinical studies evaluated the efficacy of Dotarem-enhanced MRI.

Efficacy of Dotarem@ in the CNS indication for the pediatric population from 0 to 17 years of age was assessed in pivotal study DGD-44-050 and in three open-label, single-group, non-randomized studies (DGD-3-15, DGD-3-16 and DGD-3-29).

Magnetic resonance imaging (MRI) has become the mainstay of central nervous system imaging since its introduction over 20 years ago. It is estimated that there were more than 10 million contrast enhanced MRI examinations performed in the US in 2011, with approximately 60% of these examinations performed to image the CNS.

The New Drug Application for gadoterate meglumine was submitted to the FDA on September 20, 2012 and received priority review due to no other GBCA's being approved for children 0-2. The Advisory Committee's recommendations are not binding, but FDA reviewers will consider the panel's recommendation in the final assessment of the NDA.

About Dotarem@
Dotarem@ is approved for use outside US in adults, children and infants in magnetic resonance imaging of brain and spinal diseases, and other whole body pathologies (including angiography).

Commercialized widely throughout the world since 1989, Dotarem@ has been administered to more than 30 million patients having received an MRI scan. The approved indications for Dotarem@ may vary between countries.

About Nephrogenic Systemic Fibrosis (NSF)
Cases of NSF have been reported after the injection of certain contrast agents containing gadolinium in patients with acute or chronic severe renal insufficiency (creatinine clearance < 30 mL/min/1.73 m2). The FDA has asked manufacturers to include a black box warning regarding NSF.

As of February 2013, there is no confirmed single-agent, unconfounded case of NSF associated with Dotarem@.

About Guerbet
A pioneer in the field of contrast agents with more than 80 years of experience, Guerbet is the only pharmaceutical group worldwide dedicated solely to medical imaging. It has a comprehensive range of X-ray and MRI contrast agents to enhance diagnosis and overall patient care. To discover new products and ensure its future development, Guerbet devotes significant resources to R&D every year: approximately 10% of its net sales. Guerbet, listed on the Euronext Paris Eurolist (compartment B), posted sales of ?403 million in 2012 with a 1,400-strong workforce. For more information on Guerbet, please go to www.guerbet.com.

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