PRESS RELEASE

FDA Approves Dotarem® (gadoterate meglumine), first macrocyclic and ionic gadolinium-based contrast agent in USA

Guerbet LLC, USA (March 21, 2013)

Guerbet announced today that the US Food and Drug Administration (FDA) has approved Dotarem® (gadoterate meglumine), a gadolinium-based contrast agent (GBCA) indicated for intravenous use with magnetic resonance imaging (MRI) in brain (intracranial), spine and associated tissues in adult and pediatric patients (2 years of age and older) to detect and visualize areas with disruption of the blood brain barrier (BBB) and/or abnormal vascularity.

Dotarem® -- which has been commercialized widely throughout the world since 1989 and more than 37 million doses administered[1] -- is the only macrocyclic and ionic GBCA. The recommended dose is 0.2 mL/kg (0.1 mmol/kg) body weight (BW). Dotarem® Injection 0.5 mmol/mL contains 376.9 mg/mL of gadoterate meglumine, and is available in vials and pre-filled syringes.

“This approval is a major milestone for Guerbet, which has a proud history of providing safe and effective contrast agents to patients worldwide,” said Yves L’Epine, CEO of Guerbet Group. “Dotarem® - already a leader in Europe – is a compelling new CNS imaging option for US healthcare providers and enriches our portfolio for improved patient management with diagnostic imaging in the US.”

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.

Important Safety Information

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)
See full prescribing information for complete boxed warning

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.

- The risk for NSF appears highest among patients with:
  - Chronic, severe kidney disease (GFR < 30 mL/min/1.73m^2), or

[1] Data of file as of January 1, 2013.

- Acute kidney injury.
- Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (for example, age > 60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing (5.1).
- For patients at highest risk for NSF, do not exceed the recommended DOTAREM dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration (5.1).

The possibility of serious or life-threatening anaphylactoid/anaphylactic reactions with cardiovascular, respiratory or cutaneous manifestations, ranging from mild to severe, including death, should be considered.

In patients with chronically reduced renal function, acute kidney injury requiring dialysis has occurred with the use of GBCAs. The risk of acute kidney injury may increase with increasing dose of the contrast agent; administer the lowest dose necessary for adequate imaging. Screen all patients for renal impairment by obtaining a history and/or laboratory tests. Consider follow-up renal function assessments for patients with a history of renal dysfunction.

Side effects to Dotarem® were uncommon in clinical trials. However, the most common adverse reactions associated with Dotarem® in clinical studies were nausea, headache, injection site pain, injection site coldness, and burning sensation.

For more information about Dotarem®, including full Boxed WARNING, please see the Full Prescribing Information.

Clinical Studies

The Dotarem® New Drug Application included two Phase III clinical studies. These studies evaluated the diagnostic efficacy and safety of Dotarem® for intravenous use with magnetic resonance imaging (MRI) in brain (intracranial), spine and associated tissues in adult and pediatric patients (2 years of age and older) to detect and visualize areas with disruption of the blood brain barrier (BBB) and/or abnormal vascularity. Both phase III 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 and safety of Dotarem®-enhanced MRI.

About Dotarem®

Commercialized widely in over 70 countries in Europe, Asia, Africa, Middle East and South America, more than 37 million doses of Dotarem® have been administered. The approved indications for Dotarem® may vary between countries. Dotarem® is the leading contrast agent in Europe with 47% market share in 2012[2].

[2] In MRI, in volume. ECMIG 2011.

About Guerbet

A pioneer in the field of contrast agents with more than 80 years of experience, Guerbet is the only pharmaceutical group fully dedicated to medical imaging worldwide. As such it has a complete offering of contrast products for Xray and MRI and for interventional radiology, along with a range of injectors and related medical equipment to provide improved diagnosis and treatment of patients.

To promote the discovery of new products and assure future growth, Guerbet devotes significant resources to research and development every year (approximately 10% of sales). Guerbet (GBT) is listed on NYSE Euronext Paris (Eurolist Segment B – Mid Caps) and had sales of €403 million in 2012 with a total workforce of 1,400 employees. Guerbet also markets Hexabrix®, Oxilan®, and Lipiodol® contrast agents in the US.

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Dotarem® is registered in U.S. Patent and Trademark Office by Guerbet.