HealthManagement
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Bayer receives EU approval for Gadovist® for use in pediatric patients less than 2 years of age

- Approval based on data demonstrating the pharmacokinetic and safety profiles of Gadovist at standard dose (0.1 mmol/kg) were similar to adults and children 2 years of age and older
- Diagnostic use in approved indications has been expanded to include use in pediatric patients less than 2 years of age, including term newborns
- New expanded use was confirmed through EU variation procedure

Not intended for U.S. and UK Media

Bayer HealthCare has announced that Gadovist® (gadobutrol) has received a label extension in the European Union (EU) for diagnostic use with magnetic resonance imaging (MRI) or magnetic resonance angiography (MRA) in pediatric patients less than 2 years of age, including term newborns. Gadovist was approved for this expanded use through an EU variation procedure in which Germany acted as the reference member state. Country approvals by regulatory bodies across the EU will follow.

“This approval provides radiologists in Europe with an important diagnostic tool for use in the youngest pediatric population,” said Dr. Gabriele Hahn, study investigator and radiologist, University of Dresden, Germany. “The study data confirm the safety profile, dose and efficacy of gadobutrol in young patients under the age of 2, including newborns.”

The approval was based on an international multi-center study showing that the pharmacokinetic (PK) and safety profiles of Gadovist in pediatric patients less than 2 years of age were similar to that of older children and adults at standard dose (0.1 mmol/kg), confirming that the same weight-based dosing of Gadovist can be used as in older children and adults.1 The expanded use is for existing approved contrast-enhanced MRI diagnostic imaging indications in older populations, for example contrast-enhanced MRA and MRI of the central nervous system (CNS), liver, kidneys and other regions of the whole body.

“To date there were only limited data regarding the use of gadolinium-based contrast agents in pediatric patients younger than 2 years of age available, and there has been a significant need to better understand how they work in the youngest of patients,” said Dr. Christiane Pering, Chief Medical Officer (CMO) and Head of Innovation within Bayer HealthCare’s Medical Care division. “This study and authorization by health authorities are important in supporting pediatric radiologists with an approved contrast agent for use in all their pediatric patients.”

About Pharmacokinetics

Pharmacokinetics (PK) is the study of the movement of a drug in the body, including the process of distribution and elimination, and it is dependent on patient-related factors, as well as the drug’s chemical properties.

About the Study

The study enrolled 47 pediatric patients with ages spanning from term newborns to 23 months with normal renal function from nine centers across Europe, the U.S. and Canada. Forty-four pediatric patients were evaluated for safety and efficacy and 43 were eligible for a PK profile evaluation, including nine term newborns less than 2 months of age.[1]

The data showed that the Gadovist PK profile in pediatric patients under 2 was similar to the PK profile in older pediatric patients and adults. A similar safety profile was observed for Gadovist in this study as compared to the safety profile for older children and adults.[1]

The study found that the Gadovist adverse event (AE) profile was consistent with what has been seen in older populations. In one patient vomiting was reported as a mild adverse drug reaction (ADR) to Gadovist. The most common non-serious AEs unrelated to Gadovist were cough, nasopharyngitis, rhinitis, pyrexia and vomiting. Serious AEs were unrelated to Gadovist and were reported in three out of 44 patients.[1]

About Gadovist

Gadovist (gadobutrol) was first approved in Switzerland in 1998. In 2000, it was approved in the European Union (Germany) for contrast enhancement in cranial and spinal magnetic resonance imaging (MRI) and in 2003 the indication was extended to include contrast-enhanced magnetic resonance angiography (MRA). In 2006, Gadovist was approved for patients with high suspicion or evidence of having benign or malignant focal lesions in the liver or kidneys. Gadovist was further approved for MRI of pathologies of the whole body in 2012. The expanded use of Gadovist in pediatric populations under 2 years of age, including term neonates, was first approved in the U.S. in December 2014. Gadovist, also known as Gadavist® in the U.S. and Gadovist® 1.0 in other regions, is the brand name of the aqueous 1.0M solution of gadobutrol, a gadolinium (Gd)-based extracellular contrast agent for MRI with a macrocyclic structure. The safety profile of Gadovist has been established in clinical trials involving more than 6,800 patients.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of around EUR 20.0 billion (2014), 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, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare’s aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 60,700 employees (Dec 31, 2014) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

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