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Bayer HealthCare has announced that the US Food and Drug Administration (US FDA) has approved Gadavist (gadobutrol) injection for use with magnetic resonance imaging (MRI) in pediatric patients less than two years of age, including term neonates, to detect and visualise areas with disrupted blood brain barrier and/or abnormal vascularity of the central nervous system.

Gadavist was previously approved for this use in patient populations over the age of two. The FDA's priority review was based on a study showing that the pharmacokinetic (PK) and safety profiles in pediatric patients less than two years of age were similar to that of older children and adults at standard dose (0.1 mmol/kg).

"Gadavist is the first FDA-approved gadolinium-based contrast agent for pediatric patients under two years of age, including term neonates, and the approval provides guidance to physicians on how to use Gadavist in these young patients. With this label expansion, Gadavist is appropriate to use for MRI of the central nervous system at a standard dose of 0.1mmol/kg for patients of all ages - term neonates to adults," said Mr Christiane Pering, chief medical officer (CMO) and head of Innovation within Bayer HealthCare's Medical Care division.