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News Release

Not intended for U.S. and UK Media

Bayer's low-dose MRI contrast agent gadoquatrane approved in U.S.

- Gadoquatrane from Bayer receives FDA approval for contrast-enhanced MRI to detect and visualize lesions with abnormal vascularity in the central nervous system and non-CNS body regions
- Gadoquatrane becomes the lowest-dose macrocyclic gadolinium (Gd)-based contrast agent (mGBCA) approved in the U.S., with a recommended dose of 0.01 mmol/kg actual body weight, corresponding to 0.04 mmol Gd/kg body weight
- Approval is supported by data from the Phase III QUANTI clinical studies, which demonstrated efficacy at a fraction of the dose compared to mGBCAs dosed at 0.1 mmol Gd/kg body weight
- Gadoquatrane received its first approval in Japan in March 2026, further submissions to health authorities worldwide are ongoing to secure marketing authorization in additional markets

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Berlin, June 15, 2026 – Bayer today announced that the U.S. Food and Drug Administration (FDA) approved gadoquatrane, a new, intravenous macrocyclic gadolinium (Gd)-based contrast agent (mGBCA) under the brand name Ambelvist™. The product is indicated for contrast-enhanced magnetic resonance imaging (MRI) to detect and visualize lesions with abnormal vascularity in the central nervous system (CNS) and non-CNS body regions in adult and pediatric patients, including term neonates. Gadoquatrane is a next-generation mGBCA with a novel tetrameric structure and high relaxivity (a measure of signal enhancement).

With this approval, gadoquatrane becomes the lowest dose mGBCA in the U.S. It has a recommended dose of 0.01 mmol/kg actual body weight (which corresponds to 0.04 mmol Gd/kg body weight), representing 60% less Gd compared to mGBCAs with a Gd content

of 0.1 mmol Gd/kg body weight and 20% less Gd compared to gadopiclenol dosed at 0.05 mmol Gd/kg body weight.

There is a rising need for medical imaging, driven by the increasing incidence of chronic diseases such as cancer and cardiovascular diseases. Contrast-enhanced MRI is a medical imaging examination often used by clinicians to gain insight into what's happening in the human body and can play an important role in detecting abnormalities, monitoring disease progression and informing treatment decisions. For some adults and children with chronic diseases or conditions that require close, long-term monitoring – such as multiple sclerosis, other neurological or spinal conditions as well as different types of cancer – regular, repeat administrations may be required.

"I often rely on contrast-enhanced MRI exams to inform clinical decision making," said Dr. Christopher Hancock, Director of Neuroradiology at HALO Diagnostics Desert Cities, USA, and an investigator for the QUANTI clinical studies. "With this approval, we now have an additional option that can help deliver contrast-enhanced images at the lowest macrocyclic GBCA dose, reducing gadolinium exposure while preserving the clinical information we often need."

"Bayer is a leader in radiology and has played a pioneering role in MRI contrast agent development, having launched the first gadolinium-based contrast agent in 1988," said Dr. Konstanze Diefenbach, Head of Radiology R&D at Bayer's Pharmaceuticals Division. "With gadoquatrane – a next generation high-relaxivity, low-dose MRI contrast agent demonstrating high stability – we continue driving advances for patients and their treating physicians. Reducing patients' lifetime exposure to gadolinium is an important consideration and reflects the growing clinical guidance to use the lowest gadolinium dose necessary to adequately image patients."

Gadoquatrane received its first approval in Japan in March 2026, and Bayer has submitted applications for marketing authorization in additional markets around the world, including the EU and China, with more to follow.

Key Clinical Trial Findings

The FDA's approval is based on the global pivotal Phase III QUANTI clinical studies, which evaluated the efficacy and safety of gadoquatrane in adult and pediatric patients, including term neonates, undergoing contrast-enhanced MRI. Key findings demonstrated:

- Increased lesion visualization with the combined pre-contrast and post-contrast MRI sets with the decreased Gd dose in gadoquatrane compared with only pre-contrast MRI images.
- Visualization scores and number of lesions identified per blinded independent reader for gadoquatrane dosed at 0.01 mmol/kg body weight (which corresponds to 0.04 mmol Gd/kg body weight) were similar to mGBCAs with a Gd content of 0.1 mmol Gd/kg body weight.
- Use in children is supported by evidence from adequate and well-controlled studies of gadoquatrane in adults, with additional pharmacokinetic and safety data from the pediatric study, including 93 patients aged 28 days to less than 18 years who received one 0.01mmol/kg dose and underwent MRI of any body region.

About gadoquatrane
Gadoquatrane is Bayer's extracellular macrocyclic contrast agent for contrast enhancement in MRI. This low-dose gadolinium-based contrast agent features a distinct tetrameric structure with high stability and high relaxivity.

The compound has been approved under the brand name Ambelvist™ in Japan in March 2026 and in the U.S. in June 2026. It has not been approved in any other jurisdiction. Bayer has submitted applications for marketing authorization of gadoquatrane in additional markets around the world.

About MRI
MRI is a non-invasive, radiation-free imaging method that provides detailed images of the body, helping to identify and distinguish potential abnormalities in organs and tissues. This supports physicians in answering critical medical questions related to the detection and monitoring of diseases. MRI contrast agents commonly contain gadolinium. For 2024, it is estimated that over 60 million doses of gadolinium-based contrast agents were administered worldwide. Cumulatively, since 1988, more than 900 million GBCA doses have been delivered globally.

About Radiology at Bayer
Building on a century of expertise, Bayer is committed to innovative products and high-quality services in diagnostic imaging to enhance patient care. Its leading radiology portfolio features contrast agents and devices for precise administration across modalities including computed tomography (CT), X-ray and magnetic resonance imaging (MRI), and

positron emission tomography (PET). Bayer's comprehensive offerings also include informatics solutions. In 2025, Bayer's radiology products generated €2.2 billion in sales. Bayer continues to advance research and innovation in medical imaging, including in molecular imaging and other promising fields.

About Bayer
Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, "Health for all, Hunger for none," the company's products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2025, the Group employed around 88,000 people and had sales of 45.6 billion euros. R&D expenses amounted to 5.8 billion euros. For more information, go to www.bayer.com.

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