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News Release

Not intended for UK Media

Gadoquatrane New Drug Application Accepted for Review by U.S. FDA

- New Drug Application (NDA) for low dose contrast agent gadoquatrane seeks approval for contrast-enhanced magnetic resonance imaging (MRI) of the central nervous system (CNS) and other body regions for adults and pediatric patients including neonates
- Submitted dose corresponds to a 60 percent reduction in gadolinium compared to macrocyclic gadolinium-based contrast agents (GBCAs) dosed at 0.1 mmol gadolinium per kilogram of body weight

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Berlin, August 27, 2025 – Bayer today announced that a New Drug Application (NDA) for its investigational contrast agent gadoquatrane has been accepted for review by the U.S. Food and Drug Administration (FDA). The NDA for gadoquatrane has been filed for contrast-enhanced magnetic resonance imaging of the CNS and other body regions in adults and pediatric patients, including neonates.

If approved, gadoquatrane would become the lowest dose macrocyclic gadolinium-based contrast agent (GBCA) available in the U.S. The submitted dose is 0.04 mmol gadolinium per kilogram body weight, corresponding to a 60 percent reduction compared to macrocyclic GBCAs dosed at 0.1 mmol Gd/kg body weight.

“Chronic diseases like cancer, neurological disorders like multiple sclerosis and cardiovascular conditions are on the rise, leading to an increase in medical imaging. Patients, especially those who require multiple examinations over the course of their lives, can benefit from a reduced contrast media dosage,” said Dr. Konstanze Diefenbach, Head of Radiology Research & Development at Bayer’s Pharmaceuticals Division.

Since their introduction in 1988, more than 800 million GBCA doses have been administered worldwide, with an estimated 63 million doses in 2023. Approximately 12-18 million contrast-enhanced MRI scans are performed annually in the United States. The submission of gadoquatrane to the U.S. FDA is based on positive data from the pivotal Phase III QUANTI studies evaluating the efficacy and safety of gadoquatrane in adult and pediatric patients globally. Additionally, the healthcare authorities in Japan, the European Union and other countries are currently reviewing applications for marketing authorization for gadoquatrane. Further regulatory applications to health authorities worldwide are planned for the coming months.

About the Phase III development program QUANTI

The pivotal QUANTI clinical development program investigated gadoquatrane at a dose of 0.04 mmol Gd/kg body weight, which represents a 60 percent lower gadolinium dose compared to macrocyclic contrast agents dosed at 0.1 mmol Gd/kg body weight. QUANTI consisted of two large multinational, randomized, prospective double-blind, crossover Phase III studies – QUANTI CNS (Central Nervous System) and QUANTI OBR (Other Body Regions) – as well as the QUANTI Pediatric study. In total, 808 patients in 15 countries participated in the program. The QUANTI study results show that gadoquatrane met the primary and secondary efficacy endpoints of the studies assessing visualization parameters and lesion detection. Results of QUANTI Pediatric demonstrated that the pharmacokinetic behavior of gadoquatrane in children is similar to that observed in adults.

The observed safety profile in adults as well as pediatric patients from birth to < 18 years of age in the QUANTI studies was generally consistent with previous data on gadoquatrane and other macrocyclic GBCAs. No new safety signals were observed.

With first results from the Phase III QUANTI CNS study revealed at the European Congress of Radiology (ECR) in February of this year, further study data are planned to be presented at upcoming scientific meetings.

About gadoquatrane

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

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.

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 and a medical imaging platform with digital and artificial intelligence (AI) powered applications. In 2024, Bayer's radiology products generated €2.1 billion in sales. Bayer continues to advance research and innovation in medical imaging, including the integration of AI.

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 2024, the Group employed around 93,000 people and had sales of 46.6 billion euros. R&D expenses amounted to 6.2 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements
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