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# News Release

**Not intended for U.S. and UK Media**

## Bayer files for EU approval of gadoquatrane

- Submission of marketing authorization application to the European Medicines Agency (EMA) seeking approval for investigational low dose gadoquatrane for contrast-enhanced magnetic resonance imaging (MRI) of all body regions for adults and pediatric patients including neonates
- Submitted dose corresponds to a 60 percent reduction in gadolinium (Gd) compared to standard of care macrocyclic gadolinium-based contrast agents (GBCAs) dosed at 0.1 mmol gadolinium per kilogram of body weight

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**Berlin, July 10, 2025** – Bayer today announced the submission of a marketing authorization application to the European Medicines Agency for its investigational contrast agent gadoquatrane for contrast enhancement in magnetic resonance imaging to detect and visualize known or suspected pathologies in all body regions and the central nervous system (CNS) in adults and pediatric patients including neonates. The submitted dose of 0.04 mmol gadolinium per kilogram body weight represents a gadolinium dose reduction of 60 percent compared to the standard of care macrocyclic contrast agents dosed at 0.1 mmol Gd/kg body weight. If approved, gadoquatrane would become the lowest dose macrocyclic GBCA available in the European Union.

“With this submission, Bayer is seeking to offer a low dose option for patients and their treating physicians in the EU,” said Dr. Konstanze Diefenbach, Head of Radiology Research & Development, Bayer. “This commitment aligns with recommendations from health authorities and guidelines from scientific bodies in Europe and beyond, which recommend using the minimum dose necessary to acquire the needed clinical information. Patients, particularly those with chronic conditions who need multiple contrast-enhanced MRI scans over their lifetime, can benefit from a reduction in dosage.”

An estimated 16 million contrast-enhanced MRI scans are conducted annually within the European Union. Over the past five years, the number of contrast-enhanced MRI procedures has experienced an annual growth rate of around 5 percent there. The submission of gadoquatrane to the European Medicines Agency is based on positive data from the pivotal Phase III QUANTI studies evaluating the efficacy and safety of gadoquatrane across a broad range of indications in adult and pediatric patients globally. Bayer recently announced the submissions of gadoquatrane in Japan and the U.S., marking the first applications for marketing authorization for the investigational contrast agent. 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. 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 and safety profile of gadoquatrane in children is similar to that in adults. The safety events observed with gadoquatrane in the program were similar to those observed for the comparator macrocyclic gadolinium-based contrast agents with a low incidence of intervention related treatment emergent adverse events and generally consistent with previous data on gadoquatrane and other macrocyclic gadolinium-based contrast agents. No new safety signals were observed.

First results from the Phase III QUANTI CNS study were presented at the European Congress of Radiology (ECR) in February of this year and further results 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**

With an estimated 65 million procedures performed annually worldwide, contrast-enhanced MRI plays a key role in the healthcare continuum. 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, characterization, 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**
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.