Bayer AG
Communications
51368 Leverkusen
Germany
Phone +49 214 30-1
www.bayer.com/en/media

News Release

Not intended for US and UK Media

Bayer files for approval of gadoquatrane in the U.S.

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

---

Berlin, June 17, 2025 – Bayer today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its investigational contrast agent gadoquatrane for contrast-enhanced magnetic resonance imaging of the CNS and other body regions in adults and pediatric patients including term neonates. The submitted dose is 0.04 mmol gadolinium per kilogram body weight. If approved, gadoquatrane would become the lowest dose macrocyclic GBCA available in the U.S., corresponding to a 60 percent reduction compared to standard of care macrocyclic GBCAs dosed at 0.1 mmol Gd/kg body weight.

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. The 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.

Nearly 40 million MRI scans are performed each year in the United States. “There is a rising need for medical imaging, among others driven by the increasing incidence of chronic diseases such as cancer and cardiovascular diseases,” said Dr. Konstanze Diefenbach, Head of Radiology Research & Development, Bayer. “As a leader in

radiology, we are committed to advancing innovation in this field, including options to reduce the gadolinium dose. Patients can benefit from a dose reduction, especially patients with chronic conditions who require multiple contrast-enhanced MRI examinations during their lifetime. This is in line with guidance from health authorities and guidelines from scientific bodies which recommend using the lowest dose required to obtain the needed clinical information."

Bayer recently announced the submission of gadoquatrane to the Ministry of Health, Labour, and Welfare (MHLW) in Japan, marking the first application 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, 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 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.

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 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.

Contact for media inquiries:
Victoria Vigener, phone +49 151 23438911
Email: victoria.vigener@bayer.com

Contact for U.S. media inquiries:
Jennifer May, phone, 412-656-8192
Email: jennifer.may@bayer.com

Contact for investor inquiries:
Bayer Investor Relations Team, phone +49 214 30-72704
Email: ir@bayer.com
www.bayer.com/de/investoren/ir-team

Find more information at https://pharma.bayer.com/
Follow us on Facebook: http://www.facebook.com/bayer

vig (2025-0117e)