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News Release

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Gadoquatrane submitted for marketing authorization in Japan

- Marketing authorization application seeking approval for low-dose contrast agent gadoquatrane for contrast-enhanced MRI of all body regions for adults and pediatric patients including neonates
- Submitted dose corresponds to a 60 percent reduction in gadolinium compared to standard of care macrocyclic gadolinium-based contrast agents dosed at 0.1 mmol gadolinium per kilogram of body weight
- Japan has highest number of MRI scanners per capita worldwide, performing about 20 million procedures annually

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Berlin, June 2, 2025 – Bayer today announced the submission of a marketing authorization application to the Ministry of Health, Labour, and Welfare (MHLW) in Japan for its investigational contrast agent gadoquatrane for contrast enhancement in magnetic resonance imaging (MRI) 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 (Gd) dose reduction of 60 percent compared to the standard of care macrocyclic contrast agents dosed at 0.1 mmol Gd/kg body weight.

“As a leader in radiology, we are committed to bringing forward innovations for the benefit of patients, including potential options to reduce the gadolinium dose,” said Dr. Konstanze Diefenbach, Head of Radiology Research & Development, Bayer. “If approved, gadoquatrane would offer radiologists in Japan a low-dose option to assist in diagnosing their patients. A low-dose option could be particularly valuable for patients undergoing multiple MRI examinations in their lifetime, as well as for children.”

Currently, there are no low-dose MRI contrast agents available in Japan. With an aging population and an increase in chronic diseases such as cancer and heart disease, Japan

has the highest number of MRI scanners per capita worldwide, performing about 20 million procedures annually.

The submission of gadoquatrane to the MHLW 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. 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. The submission in Japan is the first application 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. In Japan, 27 sites were included.

In January 2025, Bayer announced positive topline data for the QUANTI study program, with results showing that gadoquatrane met the primary and secondary efficacy endpoints of the studies assessing visualization parameters and lesion detection, demonstrating non-inferior efficacy to the trial comparators. The safety events observed with gadoquatrane 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.

About gadoquatrane

Gadoquatrane is Bayer's investigational extracellular macrocyclic contrast agent in clinical development for contrast enhancement in MRI. This 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
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