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News Release

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Late-breaking data from QUANTI CNS (Central Nervous System) presented at ECR 2025

Positive results from Phase III study for Bayer's investigational contrast agent gadoquatrane

- First Phase III results from the clinical development program QUANTI on investigational MRI contrast agent gadoquatrane presented as late-breaking data during a scientific session at the 2025 European Congress of Radiology (ECR)
- QUANTI CNS met the primary endpoints of non-inferiority of gadoquatrane across visualization parameters using a 60 percent lower gadolinium dose compared to macrocyclic gadolinium-based contrast agents dosed at 0.1 mmol Gd/kg body weight and demonstrated superiority compared to unenhanced MRI
- Secondary endpoints sensitivity and specificity for the detection of lesions were met by showing non-inferiority to the comparator MRI contrast agents
- Bayer plans to submit the data to health authorities worldwide to secure marketing authorization for gadoquatrane

Berlin, February 26, 2025 – Bayer, a global leader in radiology, announced positive results from the Phase III study QUANTI CNS, which evaluated the investigational gadolinium-based contrast agent (GBCA) gadoquatrane in adults with known or suspected pathologies of the central nervous system undergoing contrast-enhanced magnetic resonance imaging (MRI). QUANTI CNS is part of Bayer’s pivotal QUANTI clinical development program consisting of two multinational Phase III studies in adults as well as a pediatric study. In all studies, gadoquatrane was investigated at a gadolinium dose of 0.04 mmol Gd/kg body weight which represents a gadolinium dose reduction of 60 percent compared to the macrocyclic GBCAs dosed at 0.1 mmol Gd/kg body weight. The detailed results of QUANTI CNS were revealed as late-breaking clinical trial data at this year’s annual European Congress of Radiology (ECR), taking place at Vienna, Austria, from February 26 to March 2, 2025.

“Contrast-enhanced magnetic resonance imaging is one of the most powerful diagnostic tools in contemporary clinical medicine, offering unparalleled insight into the human body,” said principal investigator Dr. Benjamin P. Liu, Associate Professor of Radiology and Radiation Oncology, Northwestern University Feinberg School of Medicine, Chicago, USA. “A reduced gadolinium dose could be particularly valuable for patients suffering from central nervous system pathologies, as many of them undergo multiple MRI examinations along their diagnostic and treatment pathway and it is always advisable to administer the lowest efficacious dose of any drug. The results of the QUANTI CNS study highlight the potential of a reduced gadolinium dose demonstrating non-inferiority to the other comparator gadolinium-based contrast agents in the clinical trial. This has the potential to benefit both current and future generations of patients and healthcare professionals.”

Detailed study results of QUANTI CNS evaluating the efficacy and safety of gadoquatrane in adults with known or suspected pathologies of the central nervous system undergoing a contrast-enhanced MRI show that gadoquatrane met all primary and secondary study objectives. Non-inferior diagnostic efficacy to comparator macrocyclic GBCAs (gadobutrol, gadoterate meglumine/gadoteric acid, gadoteridol) dosed at 0.1 mmol Gd/kg body weight was demonstrated by a blinded central independent read using the three established visualization parameters – contrast enhancement, delineation, and morphology. Gadoquatrane also achieved non-inferior diagnostic performance to the trial comparators based on the sensitivity and specificity for the detection or exclusion of lesions. When compared to MRIs without contrast injection, gadoquatrane demonstrated superiority based on the visualization parameters. In total, QUANTI CNS included 305 patients from 16 countries in Europe, Asia, and America.

The safety events observed with gadoquatrane were similar to those observed for the comparator macrocyclic GBCAs with a low incidence of intervention related treatment emergent adverse events and generally consistent with previous data on gadoquatrane and other macrocyclic GBCAs.

“The burden of neurological disorders impacts millions of patients around the world and is set to rise during the next decades,” said Dr. Konstanze Diefenbach, Head of Radiology Research & Development, Bayer. “We are very pleased about the positive results shown in QUANTI CNS. We look forward to working with regulatory authorities worldwide, aiming

to make gadoquatrane available for patients and their treating physicians as a new low dose option in contrast-enhanced MRI.”

In January 2025, Bayer announced positive topline data for the QUANTI study program, showing that gadoquatrane met the primary and main secondary endpoints of all studies. The results from QUANTI CNS were presented for the first time at ECR. The results of QUANTI OBR, which investigated the safety and efficacy of gadoquatrane in contrast-enhanced MRI of all other body regions, and QUANTI Pediatric assessing the pharmacokinetics and safety of gadoquatrane in children from birth to < 18 years of age are planned to be presented at upcoming scientific congresses. Bayer plans to submit a comprehensive data package which will include the study results to health authorities worldwide to secure marketing authorization for gadoquatrane.

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

As a true life-science company with a heritage of over 100 years in radiology, Bayer is committed to providing excellence – from innovative products to high-quality services – to support efficient and optimized patient care. Bayer offers a leading portfolio of contrast media for computed tomography (CT), X-ray, and magnetic resonance imaging (MRI), along with devices for their precise administration, informatics solutions, and a medical imaging platform delivering access to applications, including those enabled by AI. Bayer’s radiology products generated about € 2 billion euros in sales in 2023. Bayer is highly committed to research and development, which includes leveraging AI and driving innovation in medical imaging.

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 2023, the Group employed around 100,000 people and had sales of 47.6 billion euros. R&D expenses before special items amounted to 5.8 billion euros. For more information, go to www.bayer.com.

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