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

News Release

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Bayer's investigational MRI contrast agent gadoquatrane meets primary and main secondary endpoints in pivotal Phase III studies

- QUANTI clinical development program evaluated the efficacy and safety of the investigational MRI contrast agent gadoquatrane for a broad range of potential indications and in pediatric and adult patients
- In the studies, gadoquatrane met diagnostic efficacy endpoints in patients using a 60 percent lower gadolinium dose compared to macrocyclic gadolinium-based contrast agents dosed at 0.1 mmol Gd/kg body weight

Berlin, January 10, 2025 – Bayer, a global leader in radiology, today announced positive topline results of the pivotal Phase III QUANTI studies evaluating the efficacy and safety of gadoquatrane, an investigational gadolinium-based contrast agent (GBCA) for use in magnetic resonance imaging (MRI). All QUANTI studies investigated gadoquatrane 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. Gadoquatrane successfully met the primary and main secondary endpoints of all QUANTI studies.

The QUANTI clinical development program encompassed two multinational Phase III studies, QUANTI CNS (central nervous system) and QUANTI OBR (other body regions) in adult patients, as well as QUANTI Pediatric, a study investigating pharmacokinetics and safety in pediatric patients from birth to < 18 years of age in all body regions.

In QUANTI CNS and QUANTI OBR, researchers investigated the ability to visualize and detect known or suspected disease on MRI scans using gadoquatrane (0.04 mmol Gd/kg body weight) compared to scans without contrast injection and compared to scans using macrocyclic GBCAs dosed at 0.1 mmol Gd/kg body weight. Topline results show that gadoquatrane met the primary and main 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.

“Contrast-enhanced MRI is a key diagnostic tool and particularly important to help define the treatment pathway for patients potentially suffering from severe illnesses such as cancer, cardiovascular disease or CNS-related disorders,” said principal investigator Prof. Julian A. Luetkens, University Hospital Bonn, Germany. “The QUANTI clinical development program is a key step in exploring a reduced gadolinium dose for patients in clinical practice while demonstrating similar efficacy to the trial comparators. This is especially important for patients in need for repeat contrast-enhanced MRI examinations as well as vulnerable populations such as pediatric patients.”

“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. “We are very pleased with the positive topline results of the QUANTI studies and are looking forward to sharing the data with the scientific community.”

Bayer plans to submit a comprehensive data package which will include the QUANTI study results to health authorities worldwide to secure marketing authorization.

About the Phase III development program for gadoquatrane
The QUANTI clinical development program consisted of two large multicenter, randomized, prospective double-blind, cross-over Phase III studies – QUANTI CNS and QUANTI OBR – as well as the QUANTI Pediatric study. In total, 808 patients in 15 countries were included in the program.

QUANTI CNS evaluated the efficacy and safety of gadoquatrane in adults with known or highly suspected pathologies of the central nervous system undergoing a contrast-enhanced MRI. In common CNS disorders, such as brain tumors, brain metastasis and multiple sclerosis, MRI plays a key role in diagnosis and treatment decisions.

QUANTI OBR investigated the safety and efficacy of gadoquatrane in contrast-enhanced MRI of all other body regions, including head and neck, thorax including the breast and the heart, abdomen, pelvis, and extremities, as well as blood vessels with magnetic resonance angiography (MRA).

QUANTI Pediatric assessed the pharmacokinetics and safety of gadoquatrane in children from birth to < 18 years of age undergoing contrast-enhanced MRI.

The design and dosing of the Phase III clinical development program was based on the positive data from the Phase II study evaluating efficacy and safety of gadoquatrane at a dose of 0.04 mmol Gd/kg body weight. The Phase II study was a multicenter, single-blind, adaptive dose-finding study of single intravenous injections of gadoquatrane with corresponding blinded review in adult patients with known or highly suspected CNS lesions referred for contrast-enhanced MRI.

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.

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

Bayer Contact for US media inquiries:
Jennifer May, phone +1 (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/en/investors/ir-team

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Forward-Looking Statements
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