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News Release

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2024 European Congress of Radiology:

Bayer driving progress in Radiology through innovation in research and Radiology AI

- New research and clinical development data on investigational compound gadoquatrane, Bayer's novel investigational MRI contrast agent in late-stage clinical development, as well as its approved MR contrast agent gadobutrol to be presented at ECR 2024
 - New partnerships with radiology AI technology providers Keya Medical Inc. and Circle Cardiovascular Imaging Inc. and launch of Cardiac Service Line for Bayer's medical imaging platform Calantic™ Digital Solutions as well as a comprehensive educational program on the implementation of AI in clinical practice
 - Launch of Bayer's own Medical Imaging Core Lab Services to external customers
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Berlin, February 21, 2024 – Bayer moves ahead with advancements across its comprehensive Radiology portfolio as well as expanded offering in its digital business and services. The company announced today that new clinical and pre-clinical data for gadoquatrane, Bayer's novel investigational macrocyclic gadolinium-based contrast agent currently in Phase III clinical development, will be presented at the 2024 European Congress of Radiology (ECR) – taking place from February 28 to March 3, 2024, in Vienna, Austria. Bayer also announced today new agreements with radiology AI technology providers Keya Medical Inc. and Circle Cardiovascular Imaging Inc. aimed at expanding the offerings on its medical imaging platform Calantic™ Digital Solutions, as well as the upcoming launch of its new Medical Imaging Core Lab Services at the congress.

The activities at ECR demonstrate Bayer's commitment as a leading company in pivotal areas of radiology, aiming to tackle current industry challenges and expedite innovation

for the benefit of healthcare providers and their patients, including leveraging the extensive potential of AI.

New insights on gadoquatrane and gadobutrol being presented at ECR 2024

Gadoquatrane, Bayer's novel investigational macrocyclic gadolinium-based contrast agent (GBCA) currently in Phase III, has the potential to enable a substantially lower clinical gadolinium (Gd) dose for patients undergoing a contrast-enhanced MRI. New preclinical and clinical data for gadoquatrane as well as literature-based reviews of published data on the safety and efficacy of Bayer's established macrocyclic GBCA gadobutrol are being presented at this year's ECR:

- ***Quantification and assessment of the chemical form of residual gadolinium in the skin after repeated administration of gadolinium-based contrast agents in rats***

This study investigated the distribution and chemical form of the applied Gd-based contrast agent gadobutrol (GBCAs) in the skin using matrix-assisted laser desorption/ionization mass spectrometry imaging. Results showed the chemical form of residual gadolinium being intact Gd-chelate. No indications for dechelation of free gadolinium were observed. Gadobutrol levels in the skin were low and almost at the level of detection within 5 weeks.

Abstract #12214

*Session: RPS 1711, CSF, glymphatic system and MR contrast agents,
2024-03-02 08:00 - 09:00*

- ***Gadolinium presence in bones: Evaluation of the novel, high relaxivity gadolinium-based contrast agents gadoquatrane and gadopichlenol***

This study focuses on the presence, dose-dependency, and distribution of Gd in the rat femur after administration of gadoquatrane and gadopichlenol – novel, macrocyclic GBCAs. The established macrocyclic GBCA gadobutrol serves as a standard of reference.

After receiving an equal dose of Gd, the concentration in rat femurs one week post-injection was 50% lower for gadoquatrane compared to gadobutrol. Gadopichlenol led to the highest Gd levels in the femur, showing a 5-fold increase over gadoquatrane and a 1.9-fold increase over gadobutrol.

Poster No.: C-18136 [Link](#)

- ***Comparison of physico-chemical properties of the novel, high relaxivity, macrocyclic gadolinium-based contrast agents, gadoquatrane and gadopiclesol***

A first assessment of the physico-chemical properties of both contrast agents gadoquatrane and gadopiclesol, regarding r1-relaxivity and complex stability, is presented. This study compared the physico-chemical properties of the new MRI contrast agents gadopiclesol and gadoquatrane, finding both have r1 relaxivities over twice that of gadobutrol, influenced by human plasma variability. The gadolinium release in blood plasma was below the lower limit of quantification for gadoquatrane, while gadopiclesol showed an observable gadolinium release over 15 days. Gadoquatrane's stability is further highlighted by its slower Gd³⁺ (Gadolinium) release at low pH compared to gadopiclesol.

Poster No.: C-16702 [Link](#)

- ***Assessment of Pharmacokinetics and Safety of Gadoquatrane in Renally Impaired Patients and its Dialyzability Using Clinical Trial Data, Modeling & Simulation Approaches and in-vitro Data.***

This study focused on the pharmacokinetics and safety of gadoquatrane in renally impaired patients, using clinical trial data with modeling and simulation approaches and in vitro testing for dialyzability assessment, leveraging the broad knowledge of the class of GBCAs avoiding exposure of vulnerable patient populations, i.e. with severe renal impairment, in clinical trials.

Abstract No. #16953

Session: RPS 1711, CSF, glymphatic system and MR contrast agents,

2024-03-02 08:00-09:00

- ***Gadobutrol: Review of over 25 Years of Use Exceeding 100 Million Administrations***

Gadobutrol has been administered over the last 25 years more than 100 million times worldwide. Purpose of two literature-based review papers that will be presented as Electronic Poster Sessions (EPOS) at ECR, was to perform a thorough review and status update on gadobutrol's clinical safety as well as its efficacy in nine approved indications and use in children. Once again it could be confirmed that the numerous clinical studies in a broad range of indications document the long-term experience and well-established benefit-risk profile in any

approved indication and populations with gadobutrol. The evaluated body of evidence focusing on efficacy, including 65 studies with 7,806 patients, thereof 271 children, showed that gadobutrol is an efficacious MRI contrast agent for all age groups in various approved indications throughout the whole body.

Poster Numbers: C-22431 & C-11854 [Link](#)

Driving progress in Radiology through AI innovation

At Bayer's booth (X5-517), once again, visitors can take an immersive tour through their evolving radiology clinic of the future, the Bayer Experience Center. At the AI Theatre (in X1) experts come together to discuss burning questions on the role of AI in radiology and its implementation in clinical practice – like data privacy and ethics, benchmarking and monitoring as well as the crucial role of education on AI. At a joint roundtable, experts from Bayer and the company's partner Google Cloud will talk about myths and facts of cloud technology in radiology. [Link to full AI agenda](#)

On the occasion of ECR 2024, Bayer also announced an extension of its medical imaging platform Calantic™ Digital Solutions (booth X1 AI-01): radiology AI technology providers Keya Medical and Circle Cardiovascular Imaging will build the new Cardiac Service Line on the platform. Clinical Service lines bundle individual AI algorithms aiding in the diagnostic procedures relevant for specific body regions.

Launch of Bayer's Medical Imaging Core Lab Services

For the first time, Bayer is also presenting its Medical Imaging Core Lab Services at ECR. Half of all ongoing clinical trials across the industry today, and 90% of oncology trials, use medical imaging as an essential means of evaluating the safety and efficacy of investigational medicines, and in supporting the overall conclusions of a study. Over the past decade, the number of clinical trials utilizing medical imaging has increased by 500%. Next to medical imaging services to clinical trials, the integrated service provides end-to-end imaging core lab solutions, scientific consulting, cloud-based image acquisition, quality control, evaluation and management as well as real-time operational and quality metrics. Its network of over 40 core experts, and more than 100 additional internal and external associated physicians and radiologists, is currently involved in more than 50 clinical trials from Bayer and its platform companies as well as internal

developments of Software as Medical Device (SaMD). With the official launch at ECR 2024, Bayer's Imaging Core Lab Services will be made available to external customers.

About Bayer's clinical development program for gadoquatrane

Bayer, a global leader in radiology, started the Phase III clinical development program QUANTI in June 2023, aiming to evaluate the efficacy and safety of gadoquatrane, a next-generation, extracellular, macrocyclic, gadolinium-based contrast agent (GBCA) for use in magnetic resonance imaging (MRI). Gadoquatrane is a highly stable MRI contrast agent featuring high relaxivity that has the potential to enable a substantially lower gadolinium (Gd) dose for patients undergoing a contrast-enhanced MRI.

The QUANTI clinical development program encompasses two multinational Phase III studies, QUANTI CNS (central nervous system) and QUANTI OBR (other body regions), as well as one pediatric study, all investigating gadoquatrane at a dose of 0.04 mmol Gd/kg body weight (BW). This represents a gadolinium dose reduced by 60 percent in contrast-enhanced MRI compared to standard dosing (0.1 mmol Gd/kg BW) of established macrocyclic GBCAs, which, if successfully tested, would constitute the lowest gadolinium dose for a multipurpose MRI contrast agent.

Contrast-enhanced MRI plays a key role in the healthcare continuum, providing a radiation-free, non-invasive method of obtaining detailed images of the body, helping to distinguish and identify potential abnormalities within organs and tissues and supporting physicians in answering critical medical questions in the detection, characterization, and monitoring of disease.

About AI in Radiology

The overall global medical imaging AI field, with sales of more than USD 500 million in 2022, is expected to continue growing dynamically. With an estimated compounded annual growth rate of 25 percent, the market is forecast to reach USD 1.7 billion by 2027. Innovation powered by AI is needed more than ever. Aging populations and changing lifestyles are leading to an increase in chronic conditions, such as cardiovascular disease and cancer. Consequently, the demand for medical imaging to detect diseases, guide treatment decisions and support therapy planning is growing. AI comes with the value proposition of aiding diagnosis and increasing the throughput of radiological examinations.

This is particularly important because time pressure and workload are contributing to the prevalence of burn-out among radiologists. This situation is aggravated by the fact that there is a shortage of trained radiologists. In addition, publications show that the rate of diagnostic errors rise with long hours of overtime; a publication from 2018 mentions approximately 40 million diagnostic errors annually worldwide, involving imaging. Digital technologies can help manage the mounting workload of radiologists and their teams, with the ultimate aim of improving patient care.

About Calantic™ Digital Solutions

Calantic Digital Solutions is a suite of digital radiology AI-enabled applications that assist radiologists and their teams at critical steps within a patient's treatment journey. The vendor-neutral, cloud-hosted platform includes a growing number of applications designed to aid in prioritization, lesion detection and quantification, as well as apps that automate routine tasks and measurements, improve radiology suites' workflow, and free up time for radiologists and their teams. The offering is orchestrated by body region and will include tools designed to help with thoracic, neurological, breast, prostate, cardiac and liver imaging.

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 close to €2bn sales in 2022. Based on the company's ambition to outperform the radiology market's average annual growth rate of 5 percent, Bayer is highly committed to research and development, which includes leveraging AI and driving innovation in medical imaging. Each of these offerings provides effective tools to support radiologists in their mission to deliver treatment-critical answers and a clear direction – from diagnosis to care.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its 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 2022, the Group employed around 101,000 people and had sales of 50.7 billion euros. R&D expenses before special items 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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