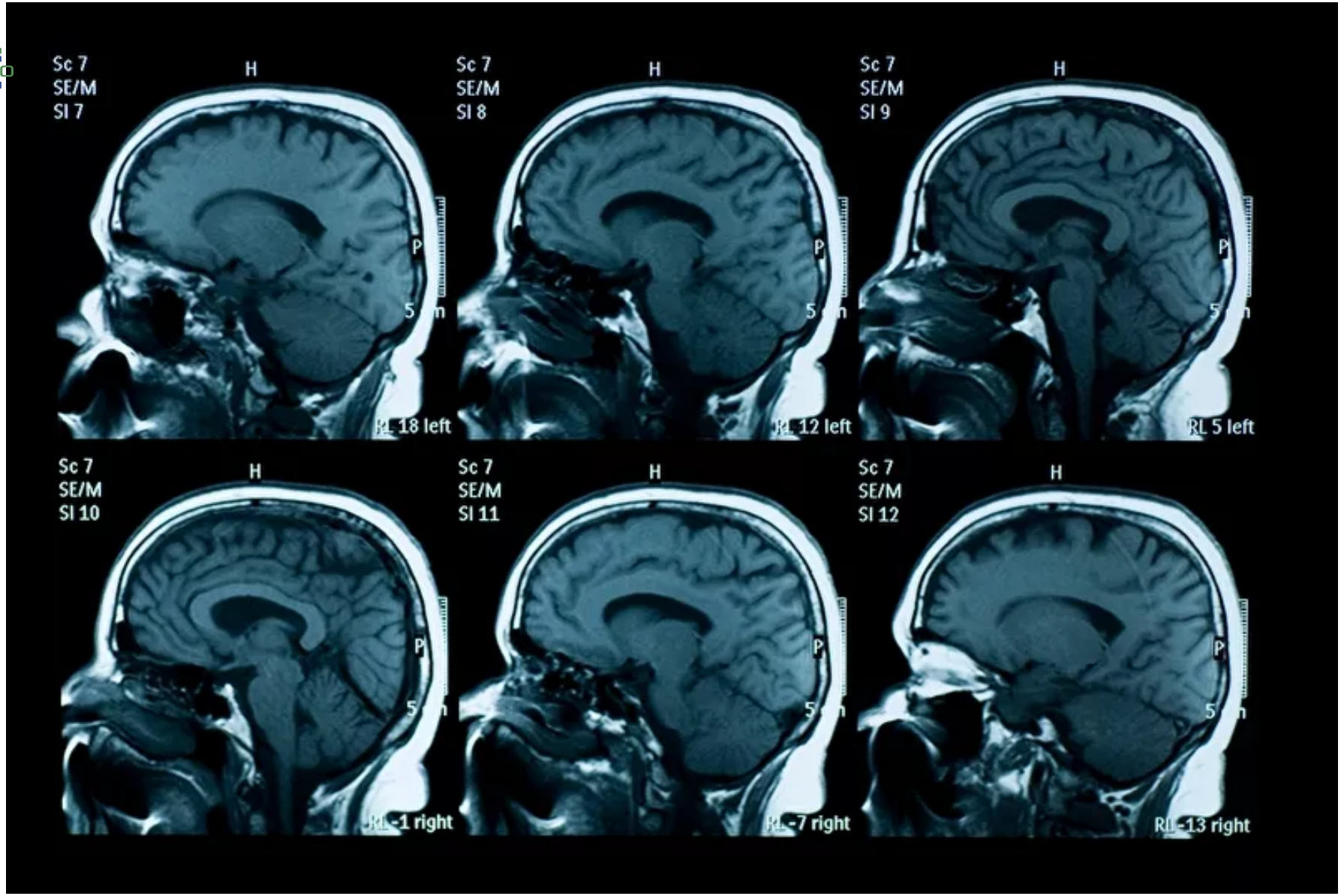
27 January 2023

Efficacy and Safety of Gadopiclenol

with Contrast-Enhanced MRI of the Central Nervous System (CNS) Published in Investigative Radiology



The results of the multicenter, multinational PICTURE clinical trial demonstrate that 0.05 mmol/kg gadopiclenol provides similar morphologic information about CNS lesions and greater contrast enhancement compared with 0.1 mmol/kg gadobutrol

Bracco will commercialize gadopiclenol as VUEWAY™ (gadopiclenol) injection and VUEWAY™ (gadopiclenol) Pharmacy Bulk Package in Q1 2023, following the approval granted by the United States Food and Drug Administration (US FDA) in September 2022

Gadopiclenol is highly stable and shows the highest relaxivity among the gadolinium-based contrast agents available for clinical use[1]

Monroe Township, NJ, January 27, 2023 – Bracco Imaging, an innovative world leader delivering end-to-end products and solutions through a comprehensive portfolio inclusive of precision diagnostic imaging modalities, announced today the recent publication of the PICTURE study in Investigative Radiology.[2]

The PICTURE study was a within-patient, crossover, blinded comparison of the safety and efficacy of 0.05 mmol/kg gadopiclenol (VUEWAY) with 0.1 mmol/kg gadobutrol (Gadavist®) in adult patients with suspected CNS disease. Despite being administered at half the dose of Gadavist, VUEWAY provided greater enhancement of contrast between the CNS lesions and the surrounding brain and spine structures, and similar quality of visualization of brain and spine disease.[2] The type and severity of adverse events (AEs) were similar with the two gadolinium-based contrast agents (GBCAs), with the AE rate being slightly lower following the administration of VUEWAY (4.9%) as compared with Gadavist (6.9%).

The positive results of this study, along with supporting findings from the Phase III PROMISE trial in MRI of the body,[3] were included in the regulatory application for gadopiclenol submitted to the US FDA, resulting in Priority Review and subsequent approval in 2022. Bracco will commercialize gadopiclenol as VUEWAY (gadopiclenol) injection and VUEWAY (gadopiclenol) Pharmacy Bulk Package in 2023.

“Following the FDA approval of gadopiclenol in September 2022, we are pleased to share these data, which further support the potential of VUEWAY as a new MRI contrast agent,” said Fulvio Renoldi Bracco, Vice-Chairman & CEO of Bracco Imaging. “By delivering the same diagnostic image quality at half the dose of Gadavist, VUEWAY now allows providers to reduce exposure without compromising the diagnostic quality of a contrast-enhanced MRI of the brain and spine.”

The PICTURE trial included 256 patients with known or highly suspected CNS lesion(s). All primary and secondary endpoints of the study were achieved. All blinded readers' evaluations indicated the superiority of the combined unenhanced/contrast-enhanced MRI with 005 mmol/kg gadopiclenol over unenhanced MRI alone for all lesion visualization criteria ($p<0.0001$). For all three blinded readers, non-inferiority of 0.05 mmol/kg gadopiclenol to 0.1 mmol/kg gadobutrol (Gadavist) was demonstrated for all lesion visualization criteria ($p<0.0001$). Results also indicated superior percent of contrast enhancement for all readers ($p<0.0001$), superior contrast-to-noise ratio for two out of three readers ($p<0.01$), and superior lesion-to-background contrast ratio with gadopiclenol for all readers ($p<0.0001$). In correlation with the greater contrast enhancement, the diagnostic quality of the images obtained with 0.05 mmol/kg gadopiclenol were in majority preferred over that provided by 0.1 mmol/kg gadobutrol by all three blinded readers ($p<0.001$).

"We are very pleased with the results of the PICTURE study, which shows that 0.05 mmol/kg VUEWAY provides greater contrast enhancement and similar quality of visualization of CNS lesions compared with a twice higher dose of gadobutrol (Gadavist)," said Alberto Spinazzi, MD, Chief Medical and Regulatory Officer at Bracco. "The higher potency of gadopiclenol is due to its markedly higher relaxivity compared with that of Gadavist and of the other GBCAs available in clinical use."[1]

VUEWAY will be manufactured in the U.S. with market availability anticipated in 2023. VUEWAY injection is approved for use in adult and pediatric patients aged 2 years and older with magnetic resonance imaging (MRI) of the CNS and the body (head and neck, thorax, abdomen, pelvis and musculoskeletal system).[4] Visit VUEWAY.com for more information, including full Prescribing Information.

The Bracco Imaging and Guerbet Collaboration / The Guerbet and Bracco Imaging Collaboration

Bracco Imaging and Guerbet in December 2021 entered a worldwide collaboration on Gadopiclenol manufacturing and research and development activities. Gadopiclenol will be commercialized independently under separate brands. Both Guerbet and Bracco Imaging each own valuable intellectual property on Gadopiclenol. Furthermore, after an agreed transition period when Guerbet manufactures Gadopiclenol for both Guerbet and Bracco, both companies will manufacture the Gadopiclenol active ingredient and finished product.

The strategic collaboration is expected to accelerate access to Gadopiclenol and deliver innovation, as well as better care to patients and caregivers alike.

VUEWAY™ (gadopiclenol) solution for injection

Indications

VUEWAY injection is indicated in adults and children aged 2 years and older for use with magnetic resonance imaging (MRI) to detect and visualize lesions with abnormal vascularity in:

- the central nervous system (brain, spine and surrounding tissues),
- the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system).

IMPORTANT SAFETY INFORMATION
WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)

Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle and internal organs.

- **The risk for NSF appears highest among patients with:**
- **Chronic, severe kidney disease (GFR < 30 mL/min/1.73 m^2), or**
- **Acute kidney injury.**
- **Screen patients for acute kidney injury and other conditions that may reduce renal function.**

For patients at risk for chronically reduced renal function (e.g. age > 60 years, hypertension, diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.

- **For patients at highest risk for NSF, do not exceed the recommended VUEWAY dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.**

Contraindications

VUEWAY injection is contraindicated in patients with history of hypersensitivity reactions to VUEWAY.

Warnings

Risk of **nephrogenic systemic fibrosis** is increased in patients using GBCA agents that have impaired elimination of the drugs, with the highest risk in patients with chronic, severe kidney disease as well as patients with acute kidney injury. Avoid use of GBCAs among these patients unless the diagnostic information is essential and not available with non-contrast MRI or other modalities.

Hypersensitivity reactions, including serious hypersensitivity reactions, could occur during use or shortly following VUEWAY administration. Assess all patients for any history of a reaction to contrast media, bronchial asthma and/or allergic disorders, administer VUEWAY only in situations where trained personnel and therapies are promptly available for the treatment of hypersensitivity reactions, and observe patients for signs and symptoms of hypersensitivity reactions after administration.

Gadolinium retention can be for months or years in several organs after administration. The highest concentrations (nanomoles per gram of tissue) have been identified in the bone, followed by other organs (brain, skin, kidney, liver and spleen). Minimize repetitive GBCA imaging studies, particularly closely spaced studies, when possible.

Acute kidney injury requiring dialysis has occurred with the use of GBCAs in patients with chronically reduced renal function. The risk of acute kidney injury may increase with increasing dose of the contrast agent.

Ensure catheter and venous patency before injecting as **extravasation** may occur, and cause tissue irritation.

VUEWAY may **impair the visualization of lesions** seen on non-contrast MRI. Therefore, caution should be exercised when VUEWAY MRI scans are interpreted without a companion non-contrast MRI scan.

The most common adverse reactions (incidence ≥ 0.5%) are injection site pain (0.7%), and headache (0.7%).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please click here for full Prescribing Information for VUEWAY, including BOXED WARNING on Nephrogenic Systemic Fibrosis.

Manufactured for Bracco Diagnostics Inc. by Liebel-Flarsheim Company LLC - Raleigh, NC, USA 27616.

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[1]Robic C, Port M, Rousseaux O, et al. Physicochemical and Pharmacokinetic Profiles of Gadopiclenol: A New Macrocyclic Gadolinium Chelate with High T1 Relaxivity. Invest Radiol 2019; 54: 475-484.
[2] Loevner L, Kolumban B, Hutoczki G, et al. Efficacy and Safety of Gadopiclenol for Contrast-Enhanced MRI of the Central Nervous System. The PICTURE Randomized Clinical Trial. Invest Radiol. 2022 Dec.
[3] Clinical Study Report of Study GDX-44-011. Data on file.
[4] Vueway™ (gadopiclenol) injection Full Prescribing Information. Monroe Twp., NJ: Bracco Diagnostics Inc.; September 2022.

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The Bracco Group is an international group of highly specialized companies. We are an active part of the healthcare sector, and a global leader in diagnostic imaging.

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