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Amidst Increase in MRI Procedures, New Survey Finds 55% of Radiologists Have Concerns About Contrast Agent Availability

Bracco Diagnostics Inc. releases data from 200 radiologists on the current state of their field

Milan, December 5, 2022 – Bracco Diagnostics Inc., a U.S. subsidiary of Bracco Imaging S.p.A., one of the world's leading companies in the diagnostic imaging business, announced over half (53%) of radiology professionals have seen an increase in MRI procedures over the last year and another one in two (55%) have concerns about the availability of gadolinium-based contrast agents (GBCAs) for use in magnetic resonance imaging (MRI) procedures. These topline findings come from a national quantitative survey, commissioned by Bracco in collaboration with Sermo, a global medical research company, that delve into the perspectives and expectations of 200 radiology professionals, with a specific focus on MRI contrast agents.

The shortage of iodinated contrast for computed tomography scans in early 2022 may be one aspect fueling concerns over supply chain disruptions. Radiologists in small hospitals express the highest level of concern (75%) about the availability of gadolinium-based contrast agents compared to 35% from radiologists at larger institutions. The survey also finds that 63% of radiologists believe it is important for contrast agents to be manufactured in the U.S, with 88% explaining products manufactured in the U.S. – through closed supply chains – are one option to lessen concerns about availability.

When asked to rank factors critical to the success of their radiology practices, professionals listed supply availability (87%), image quality (92%), and patient safety (93%) above other options such as revenue generation, staff training, and sustainable practices.

"We are continually listening to and value the needs of radiologists," said Cosimo De Pinto, Senior Vice President of Sales and Marketing at Bracco Diagnostics Inc. The results of this survey mirror what we have been hearing from our customers: HCPs are concerned about the availability and supply of contrast media, a key part of the diagnostic process. That is one of the key reasons we made a strategic, global collaboration with Guerbet in both research, development, and manufacturing of VUEWAY injection. This strategic collaboration will expand access to this important new contrast agent which has the potential to help improve diagnoses and ultimately improve patient care."

An astonishing 99% of radiologists confirm they are interested in using an MRI contrast agent that contains half the amount of gadolinium with the breakdown being 60% very interested and 39% somewhat interested.

Radiologists are confident about keeping pace with advancements in the field but acknowledge challenges and opportunities. Harnessing Artificial Intelligence (AI), healthcare spending, and attracting future talent are the foremost challenges.

"These survey results inspire us to continue advancing innovation in 2023 and beyond," said Fulvio Renoldi Bracco, Vice-Chairman & CEO of Bracco Imaging. "Whether we're talking about the promise of AI in diagnostic imaging or the clinical value of new contrast agents, a key takeaway for the diagnostic imaging industry at large, is that the road to innovation often lacks involvement from radiologists themselves. By bringing in the perspectives of those on the frontlines, through surveys such as this and other means, Bracco continues to hone our focus for where to improve techniques and processes in ways that will maximize clinical benefits."

Additional key insights from the survey include:

- More than a quarter (26%) of radiologists experienced issues with the availability of gadolinium-based contrast agents in the past few years.
- While there is some concern (46%) about the use of gadolinium-based contrast agents, there is greater concern about the amount of gadolinium-based contrast agents (86%).
- Just over a third of radiologists (35%) say their patients express concerns about MRI contrast agents used in their bodies – no surprise considering 41% of radiologists say their patients are more informed about MRI contrast agents than just a few years ago.
- More than a third of radiologists (35%) are thinking about environmental impact and sustainability more than they did a few years ago.

The online survey captures quantitative data from 200 radiologists (20 Technologists/Technicians, 164 MRI Radiologists/Chief Radiologists, and 16 Imaging Directors) between October 26 through November 4, 2022. The majority of respondents work in a hospital (147), with imaging centers (40) and outpatient departments (13) also being represented.

VUEWAY™ (gadopiclenol) injection Important Safety Information

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)

See full prescribing information for complete boxed warning

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.

The risk for NSF appears highest among patients with:

Chronic, severe kidney disease (GFR <30 mL/min/1.73 m²), 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 (for example, age >60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.

Indications and Usage

VUEWAY (gadopiclenol) injection is indicated in adult and pediatric patients 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 associated tissues), and the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system).

Contraindications

History of hypersensitivity reactions to VUEWAY.

Warnings and Precautions

- **Nephrogenic Systemic Fibrosis:** Gadolinium-based contrast agents (GBCAs) increase the risk for nephrogenic systemic fibrosis (NSF) among patients with impaired elimination of the drugs. Avoid use of GBCAs among these patients unless the diagnostic information is essential and not available with non-contrast MRI or other modalities. The GBCA-associated NSF risk appears highest for patients with chronic, severe kidney disease (GFR <30 mL/min/1.73 m2) as well as patients with acute kidney injury. The risk appears lower for patients with chronic, moderate kidney disease (GFR 30-59 mL/min/1.73 m2) and little, if any, for patients with chronic, mild kidney disease (GFR 60-89 mL/min/1.73 m2). NSF may result in fatal or debilitating fibrosis affecting the skin, muscle, and internal organs. Report any diagnosis of NSF following VUEWAY

administration to Bracco Diagnostics, Inc. (1-800-257-5181) or FDA (1-800-FDA-1088 or www.fda.gov/medwatch). Screen patients for acute kidney injury and other conditions that may reduce renal function. Features of acute kidney injury consist of rapid (over hours to days) and usually reversible decrease in kidney function, commonly in the setting of surgery, severe infection, injury or drug-induced kidney toxicity. Serum creatinine levels and estimated GFR may not reliably assess renal function in the setting of acute kidney injury. For patients at risk for chronically reduced renal function (e.g., age >60 years, diabetes mellitus or chronic hypertension), estimate the GFR through laboratory testing. Among the factors that may increase the risk for NSF are repeated or higher than recommended doses of a GBCA and the degree of renal impairment at the time of exposure. Record the specific GBCA and the dose administered to a patient. 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 prior to re-administration. For patients receiving hemodialysis, physicians may consider the prompt initiation of hemodialysis following the administration of a GBCA in order to enhance the contrast agent's elimination. The usefulness of hemodialysis in the prevention of NSF is unknown.

- **Hypersensitivity Reactions:** With GBCAs, serious hypersensitivity reactions have occurred. In most cases, initial symptoms occurred within minutes of GBCA administration and resolved with prompt emergency treatment. Before VUEWAY administration, assess all patients for any history of a reaction to contrast media, bronchial asthma and/or allergic disorders. These patients may have an increased risk for a hypersensitivity reaction to VUEWAY.
- **Gadolinium Retention:** Gadolinium is retained for months or years in several organs. Linear GBCAs cause more retention than macrocyclic GBCAs. Consequences of gadolinium retention in the brain have not been established. Pathologic and clinical consequences of GBCA administration and retention in skin and other organs have been established in patients with impaired renal function. While clinical consequences of gadolinium retention have not been established in patients with normal renal function, certain patients might be at higher risk. These include patients requiring multiple lifetime doses, pregnant and pediatric patients, and patients with inflammatory conditions. Consider the retention characteristics of the agent when choosing a GBCA for these patients. Minimize repetitive GBCA imaging studies, particularly closely spaced studies when possible.
- **Acute Kidney Injury:** In patients with chronically reduced renal function, acute kidney injury requiring dialysis has occurred with the use of GBCAs. The risk of acute kidney injury may increase with increasing dose of the contrast agent. Do not exceed the recommended dose.
- **Extravasation and Injection Site Reactions:** Injection site reactions such as injection site pain have been reported in the clinical studies with VUEWAY. Extravasation during VUEWAY administration may result in tissue irritation. Ensure catheter and venous patency before the injection of VUEWAY.
- **Interference with Visualization of Lesions Visible with Non-Contrast MRI**: As with any GBCA, VUEWAY may impair the visualization of lesions seen on non-contrast MRI. Therefore, caution

should be exercised when Gadopiclenol MRI scans are interpreted without a companion non-contrast MRI scan.

Adverse Reactions:
In clinical trials, the most frequent adverse reactions that occurred in > 0.2% of patients who received VUEWAY included: injection site pain, headache, nausea, injection site warmth and coldness, dizziness, and localized swelling.
Adverse reactions that occurred with a frequency ≤ 0.2% in patients who received 0.05 mmol/kg BW VUEWAY included: maculopapular rash, vomiting, worsened renal impairment, feeling hot, pyrexia, oral paresthesia, dysgeusia, diarrhea, pruritus, allergic dermatitis, erythema, injection site paresthesia, Cystatin C increase, and blood creatinine increase.

Use in Specific Populations
Pregnancy: GBCAs cross the human placenta and result in fetal exposure and gadolinium retention. There are no available data on VUEWAY use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes.
Lactation: There are no data on the presence of VUEWAY in human milk, the effects on the breastfed infant, or the effects on milk production. However, published lactation data on other GBCAs indicate that 0.01 to 0.04% of the maternal gadolinium dose is present in breast milk.

Pediatric Use: The safety and effectiveness of VUEWAY have not been established in pediatric patients younger than 2 years of age.

Geriatric Use: This drug is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function.

Renal Impairment: In patients with renal impairment, the exposure of gadopiclenol is increased compared to patients with normal renal function. This may increase the risk of adverse reactions such as nephrogenic systemic fibrosis (NSF). Avoid use of GBCAs among these patients unless the diagnostic information is essential and not available with non-contrast MRI or other modalities. No dose adjustment of VUEWAY is recommended for patients with renal impairment. VUEWAY can be removed from the body by hemodialysis

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.

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About Bracco Imaging

Bracco Imaging S.p.A., part of the Bracco Group, is a world-leading diagnostic imaging provider. Headquartered in Milan, Italy, Bracco Imaging develops, manufactures, and markets diagnostic imaging agents and solutions. It offers a product and solution portfolio for all key diagnostic imaging modalities: X-ray imaging (including Computed Tomography-CT, Interventional Radiology, and Cardiac Catheterization), Magnetic Resonance Imaging (MRI), Contrast Enhanced Ultrasound (CEUS), and Nuclear Medicine through radioactive tracers and novel PET imaging agents to inform clinical management and guide care for cancer patients in areas of unmet medical need. Our continually evolving portfolio is completed by a range of medical devices, advanced administration systems, and dose-management software. In 2019, Bracco Imaging enriched its product portfolio by expanding the range of oncology nuclear imaging solutions in the urology segment and other specialties with the acquisition of Blue Earth Diagnostics. In 2021, Bracco Imaging established Blue Earth Therapeutics as a separate, cutting-edge biotechnology dedicated to advancing next-generation targeted radiotherapeutics to treat patients who have cancer. Visit: https://www.bracco.com/.

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