



FOR IMMEDIATE RELEASE

Bracco Features its Mission of 'No Compromise in MRI' at the 2022 Radiological Society of North America Annual Congress

Bracco's attendance at RSNA follows FDA approval of Gadopichlenol injection, a novel macrocyclic high-relaxivity gadolinium-based contrast agent which will be commercialized as VUEWAY™ (gadopichlenol) injection by Bracco^{i,ii}

Monroe Township, NJ, October 17, 2022 – Bracco Diagnostics Inc., the U.S. subsidiary of Bracco Imaging S.p.A., a leading global company in the diagnostic imaging business, announced today that it will feature the recently approved Gadopichlenol Injection, a novel, highly stable macrocyclic gadolinium-based contrast agent (GBCA), commercialized as VUEWAY™ (gadopichlenol) injection by Bracco, among a robust line of imaging products, devices, and support solutions, at the 2022 Radiological Society of North America (RSNA) annual congress, held November 27 through December 1.^{i,ii} Gadopichlenol Injection shows the highest relaxivity and highest kinetic stability of all GBCAs in the marketⁱ at half the approved dose of Gadobutrol injection and Gadobenate dimeglumine injection, another high-relaxivity agent.^{iii,iv,v} Please see Indications and Important Safety Information below, including Boxed Warning.

Bracco is having the following engagement opportunities at the 2022 RSNA:

- **Meet and Connect with Peers** during a media briefing that will profile 'No Compromise in Magnetic Resonance Imaging (MRI),' to summarize the company's comprehensive support and education, and spotlight the new category that VUEWAY injection creates for imaging agents. The event will take place on Monday, November 28 at the Hyatt McCormick from 6:30 AM-7:30 AM CST.
- **Celebrate our Leaders on the Horizon**, an exclusive radiology residency program in which continuing education scholarships are awarded to five radiology residents whose submitted research papers are selected for publication in a special supplement to *Applied Radiology*. The funding for this has been made possible through an unrestricted grant by Bracco Diagnostics. The top two authors will attend RSNA and be honored at a special evening reception hosted by *Applied Radiology* during the congress.

Visit the Bracco booth (#4100) to learn about Bracco's commitment to innovation throughout all diagnostic imaging modalities, including its Smartinject contrast delivery platforms, innovative informatics solutions, and best-in-class service offerings.



“We can think of no better venue to further educate and connect with our peers and industry partners than at RSNA, the world’s largest medical imaging forum,” said Cosimo De Pinto, Senior Vice President, Sales and Marketing at Bracco Diagnostics Inc. “We’ve taken this year’s congress theme of ‘empowering patients and partners in our care’ to heart, working hard to ensure our customers can look deeper and remain confident in the care they provide their patients. We are united in driving forward the next generation of diagnostic solutions as we unveil VUEWAY injection and work to fulfill our own mission of ‘No Compromise in MRI.’”

Bracco is also proud to announce it will be entering the third year of its 10-year commitment to donate \$450,000 to the RSNA Research & Education (R&E) Foundation in support of the next generation of imaging professionals to advance radiologic research and innovation.

Connect with Bracco on [LinkedIn](#) and follow #BraccoImaging for more RSNA news.

About Leaders on the Horizon

The "Leaders on the Horizon" residency program is a flagship Bracco initiative designed to nurture future thought leaders in MRI and computed tomography (CT). Residents from the top-rated radiology programs in the United States will be selected by their program directors to write an original research paper suitable for publication in a supplement to *Applied Radiology*.

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 ($\text{GFR} < 30 \text{ mL/min/1.73 m}^2$), 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 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 $\geq 0.5\%$) 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.

VUEWAY is a trademark of Bracco Imaging S.p.A.

All other trademarks and registered trademarks are the property of their respective owners.

About Bracco Imaging

Bracco Imaging S.p.A. ("Bracco Imaging"), part of the Bracco Group, is an innovative world leader delivering end-to-end products and solutions through its comprehensive portfolio across diagnostic imaging modalities. Headquartered in Milan, Italy, Bracco Imaging's purpose is to improve people's lives by shaping the future of prevention and precision diagnostic imaging. The Bracco Imaging portfolio includes products and solutions for all key diagnostic imaging modalities: X-ray imaging, magnetic resonance imaging (MRI), Contrast Enhanced Ultrasound (CEUS), and Nuclear Medicine through radioactive tracers and novel PET imaging agents. Bracco Imaging has approximately 3,600 employees and operates in more than 100 markets globally. Bracco Imaging has a well-skilled and innovative Research and Development (R&D) organization with an efficient process-oriented approach and track record in the diagnostic imaging industry. R&D activities are located in four centers based in Italy, Switzerland, the United Kingdom, and the United States. Bracco Group global revenues were 1.4 billion Euros in 2020. To learn more about Bracco Imaging, visit www.braccoimaging.com.

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- ⁱ Robic C, Port M, Rousseaux O, et al. Physicochemical and Pharmacokinetic Profiles of Gadopiclesol: A New Macrocyclic Gadolinium Chelate With High T1 Relaxivity. *Invest Radiol* 2019; 54: 475-484.
- ⁱⁱ Vueway™ (gadopiclesol) injection Full Prescribing Information. Monroe Twp., NJ: Bracco Diagnostics Inc.; September 2022.
- ⁱⁱⁱ Clinical Study Report of Study GDX-44-011. Data on file.
- ^{iv} Clinical Study Report of Study GDX-44-010. Data on file.
- ^v Bendszus M, Roberts D, Kolumban B, et al. Dose Finding Study of Gadopiclesol, a New Macrocyclic Contrast Agent, in MRI of Central Nervous System. *Invest Radiol*. 2020 Mar;55(3):129-137.