



## **FOR IMMEDIATE RELEASE**

### **Bracco Diagnostics Inc. Showcases Innovations and More at RSNA 2024 Annual Meeting**

*Bracco is propelling radiology forward through innovation, education, sustainability, and trust*

**MONROE TOWNSHIP, N.J., [November 4, 2024]** – Bracco Diagnostics Inc., the U.S. subsidiary of Bracco Imaging S.p.A., a leading global company in the diagnostic imaging business, is showcasing its purpose-driven approach and cutting-edge innovations across all imaging modalities at the Radiological Society of North America (RSNA) 2024 Annual Meeting, to be held December 1-5 in Chicago, Illinois. This year, Bracco’s activities at RSNA are captured by the theme, “Our journey to the future continues today, together”—underscoring Bracco’s commitment to partnering with its customers to advance the practice of radiology.

#### **Demonstrating Innovation in Practice at RSNA 2024**

VUEWAY® (gadopiclenol) solution for injection, a macrocyclic gadolinium-based contrast agent (GBCA) is about to achieve its millionth dose. VUEWAY® injection offers effective contrast enhancement at half the gadolinium (Gd) dose (0.05 mmol/kg) vs. a macrocyclic GBCA at a dose of 0.1 mmol/kg of other similar contrast media for approved indications in the U.S.,<sup>1</sup> which can help address the unmet medical need to minimize Gd exposure per MRI procedure and reduce the overall lifetime dose.

Ryan Murtagh, MD, Chief of Neuroradiology at Tampa General Hospital and Tampa General Hospital Imaging, said, "Since we started using the VUEWAY (gadopiclenol) solution for injection in February 2023, our experience has been exceptional. We are excited about delivering half the gadolinium compared to other approved macrocyclic agents in the U.S. VUEWAY injection has significantly given us the ability to reduce the gadolinium dose for our patients without compromising image quality. The Bracco team helped make the transition seamless, and our patients appreciate the reduced dose of gadolinium. We are very happy with the results."

Beyond VUEWAY injection, the Bracco MR portfolio will further expand its offering at RSNA 2024 with the two recently FDA-cleared solutions:

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LIFE FROM INSIDE

- AiMIFY™ is the new solution for AI-powered contrast enhancement in MR imaging in the U.S. exclusively from Bracco and Subtle Medical. It recently received FDA clearance as a class II software as a medical device and it is intended for image enhancement in brain MRI. AiMIFY™ amplifies image contrast enhancement up to two times the level obtained with a labeled dose of a GBCA, significantly improving the visibility of small and large lesions compared to standard post-contrast images.<sup>2</sup> For more information, visit the Bracco booth #3300 and the Subtle Medical booth #4739 in the South Hall, Level 3.
- Bracco is proud to offer the Max 3™, a Rapid Exchange and Syringeless MR Injector that recently received FDA 510(k) clearance and is a first of its kind in the MRI space, empowering intuitive, efficient, and easy-to-manage workflow and supporting best practices in radiology sustainability.

### **Products Looking to the Future, Across all Modalities**

Bracco supports its customers with the highest level of service, science, and breadth of innovative products across all modalities. Don't miss out on the following innovations at RSNA 2024:

- Bracco's contrast-enhanced ultrasound contrast agent offers a wide range of indications in cardiology and radiology that can be added to practitioners' diagnostic tools. Bracco is leading in expanding access to these contrast agents for radiologists by driving innovation with ultrasound original equipment manufacturers.
- In support of abdominal imagers, Bracco is proud to have launched CitraClear™, the gutsy-filling beverage, that will be available for a taste test at the BDI booth.
- Learn about Bracco's new partnership with ColoWatch® which makes implementing a Virtual Colonoscopy (VC) practice for imaging centers easy. With the recent U.S. Centers for Medicare and Medicaid Services recommendation that proposes Medicare reimbursement for colorectal cancer screening using VC, radiology can play an even bigger role in saving lives.

### **Driving Sustainability Forward**

Bracco recently won the EcoVadis Gold Medal Sustainability Award for the second year in a row for its accomplishments in the environment, ethics, labor and human rights, and sustainable procurement. This award puts Bracco in the top 5% of the 100,000 global companies certified by EcoVadis, the world's largest and most trusted provider of business sustainability ratings.

Bracco also has multiple initiatives in packaging, product development, and upcoming product launches grounded in sustainability as their guiding principle.

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### **Supporting the Growth of Radiology**

Bracco is dedicated to advancing the field of radiology by sharing knowledge to build expertise. The company remains committed to fostering the exchange of expertise with the imaging community across generations as Bracco strongly believes knowledge sharing contributes to medical progress. As new generations and technologies come about, the need for education is paramount.

The *Applied Radiology* “Leaders on the Horizon” Residency Program, which Bracco supports through an unrestricted educational grant, provides scholarships to six radiology resident applicants whose submitted research papers (three clinical research papers and three clinical review articles) are selected for publication by *Applied Radiology*. These distinguished individuals will be honored at an evening reception hosted by *Applied Radiology* during RSNA 2024.

Bracco is also proud to enter the fifth year of its 10-year commitment to donate \$450,000 to the RSNA Research & Education Foundation.

“At this year’s RSNA meeting, we are again pleased to demonstrate our unwavering commitment to our customers and the industry. As a global leader in imaging our singular focus is to improve people’s lives by shaping the future of prevention and precision imaging,” said Cosimo De Pinto, Senior Vice President of Sales and Marketing at Bracco Diagnostics Inc. “We are proud to strengthen the radiology community through our strategic collaborations, which allow our company to bring cutting-edge practical solutions to the market.”

**Visit Bracco’s Booth (#3300):** Bracco’s booth experience will highlight its four pillars:

- **Innovation:** Bracco is embracing the era of precision medicine through continuous innovation, as demonstrated by its latest product advancements.
- **Education:** Bracco continues its tradition of nurturing education because the value of knowledge lies in sharing.
- **Sustainability:** which is built into everything Bracco does: caring for the patient, the medical ecosystem, and the future of the planet.
- **Trust:** the driving force strengthening Bracco’s bond within the industry.

Throughout the RSNA conference, short presentations on each of these pillars will be delivered live at their booth throughout the day.

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

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## **VUEWAY® (gadopiclesol) 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 associated tissues),
- the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system).

### **IMPORTANT SAFETY INFORMATION**

#### **WARNING: RISK ASSOCIATED WITH INTRATHECAL USE and NEPHROGENIC SYSTEMIC FIBROSIS**

#### **Risk Associated with Intrathecal Use**

**Intrathecal administration of gadolinium-based contrast agents (GBCAs) can cause serious adverse reactions including death, coma, encephalopathy, and seizures. VUEWAY is not approved for intrathecal use.**

#### **NEPHROGENIC SYSTEMIC FIBROSIS**

**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<sup>2</sup>), 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 and Precautions**

There are **risks associated with intrathecal use** of GBCAs that can cause serious adverse reactions including death, coma, encephalopathy, and seizures. The safety and effectiveness of VUEWAY have not been established with intrathecal use and VUEWAY is not approved for intrathecal use.

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.

**Extravasation and injection site reactions** can occur with administration of VUEWAY. Ensure catheter and venous patency before the injection of VUEWAY.

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%).

### **POST-MARKETING EVENTS**

Acute pancreatitis within 48 hours of GBCA administration has been reported.

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**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

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

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

AiMIFY is manufactured for Bracco Diagnostics Inc. by Subtle Medical Inc. – Menlo Park, CA, USA 94025.

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

CITRACLEAR is manufactured by E-Z-EM Canada Inc. for Bracco Diagnostics Inc.

CITRACLEAR is a trademark of E-Z-EM, Inc.

ulricheasyINJECT Max 3™ is manufactured by ulrich GmbH & Co. KG.

ulricheasyINJECT Max 3 is a trademark of ulrich GmbH & Co. KG

ulricheasyINJECT Max 3™ is distributed by Bracco Diagnostics Inc.; 510 Carnegie Center, Suite 300, Princeton, NJ 08540 USA; Phone: (800) 631-5245; Fax: (609) 514-2424; Customer Service: 1-877-BRACCO 9 (1-877-272-2269); Scientific Information: 1-800-257-5181 (Option 2); Website: <https://smartinject.com/>

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**For additional information about Bracco's products, and for full prescribing information, please visit <http://imaging.bracco.com/us-en>.**

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### **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 3,800 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. Discover Bracco at [www.bracco.com](http://www.bracco.com)

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<sup>1</sup>Loevner LA, Kolumban B, Hutóczki G, et al. Efficacy and safety of gadopiclesol for contrast-enhanced MRI of the central nervous system: the PICTURE randomized clinical trial. *Invest Radiol.* 2023 May;58(5):307-313.

<sup>2</sup>Please refer to the AiMIFY User Manual for full safety and use information