Bracco Delivers 3 Million VUEWAY® Doses, Meeting Patient Demand for Lower-Dose MRI Contrast

New National Survey Shows Patients Overwhelmingly Prefer Lower Gadolinium Dose and Are Willing to Travel for It

19 NOVEMBER 2025, PRINCETON, NJ – Bracco Diagnostics Inc., the U.S. subsidiary of Bracco Imaging S.p.A., a global leader in diagnostic imaging, announced today that more than three million doses[1] of its magnetic resonance imaging (MRI) agent, VUEWAY® (gadopiclenol) solution for injection, intravenous use, have been administered across 902 customer sites.[2] This milestone, since the U.S. Food and Drug Administration (FDA) approval of VUEWAY® injection, reflects both strong market adoption and growing patient preference for lower-dose contrast agents.

VUEWAY® injection, a macrocyclic gadolinium-based contrast agent (GBCA), offers effective contrast enhancement at half the gadolinium (Gd) dose (0.05 mmol/kg) compared to other macrocyclic GBCAs for approved indications in the U.S.[3,4,5] (0.1 mmol/kg), helping to reduce cumulative Gd exposure in patients without compromising image quality. With contrast-enhanced MRI playing a critical role in detecting and monitoring conditions such as breast cancer and multiple sclerosis, VUEWAY® injection is reshaping clinical practice by enabling patient-first innovation. VUEWAY® solution for injection is administered globally in the United States and most European Union countries.

"Innovation should always start with the patient, and the rapid adoption of VUEWAY® injection shows that the industry agrees," said Noelle Heber, Executive Director, Radiology Platform, Bracco Diagnostics Inc. *"This milestone of three million doses highlights the power of combining safety, efficacy, and patient preference in a single solution. We are grateful to the imaging community for their trust. Together, we are advancing patient-first care."*

Survey Shows Demand for Lower-Dose Contrast

A nationally representative survey commissioned by Bracco Diagnostics[6] targeting 300 recipients of MRI scans with contrast found overwhelming support for lower-dose gadolinium contrast agents*:

- **92%** were interested in an agent with half the gadolinium dose*[6]
- **92%** said they would likely request it for the procedure†[6]
- **91%** would consider switching MRI providers to access it†[6]
- **90%** were willing to travel at least 25 miles for a lower-dose option‡[6]
- Among patients with multiple sclerosis, **78%** preferred half dose Gd for repeated scans[6]
- Among those undergoing routine breast cancer screening, **85%** expressed a strong interest in a half-dose option[6]

Conducted via a web-based platform, the survey included only contrast MRI recipients from the past 12 months and included high-frequency users, including those with chronic conditions or undergoing routine screening. The survey aimed to assess patient preferences, demand for reduced gadolinium dosage with equivalent image quality, demand for a very stable agent, and willingness to act.[6]

These findings underscore a growing awareness among patients around MRI contrast agent safety and their willingness to take an active role in their care decisions.[6]

Safety Profile Backed by Real-World Data

In its first year of clinical use (February 2023-March 2024), a post-marketing safety study of VUEWAY® injection (gadopiclenol) in the United States evaluated 882,550 administrations using real-world data collected through pharmacovigilance databases of companies selling gadopiclenol.[7] These systems continuously monitor the safety of every product the companies market globally and aggregate data from all available sources, including spontaneous reports, scientific literature, social media, regulatory agency databases, clinical and epidemiological studies, and administrative claims data from health insurers.[7]

Adverse events (AEs) were classified as "serious" or "non-serious" by qualified pharmacovigilance personnel, in accordance with international regulatory definitions. All reported symptoms were coded using the internationally recognized Medical Dictionary for Regulatory Activities (MedDRA) system.[7]

The study observed:[7]

- Zero serious adverse events
- Only 32 patients experienced adverse events

Reporting rates were calculated by comparing the number of patients experiencing AEs to the number of gadopiclenol units sold in the U.S.—the only market where the product was available during the study period.[7]

This rigorous, real-world data reinforces the favorable safety profile of VUEWAY® injection and highlights Bracco's continued commitment to patient safety and innovation in diagnostic imaging.[7]

Todd Mulderink, MD, Chairman of the Department of Radiology at Corewell Health Grand Rapids, said, *"The availability of a [high-relaxivity] contrast agent that lowers gadolinium exposure without sacrificing imaging quality is a game-changer and a win for both patients and radiologists charged with their MR imaging care."*

With its unique combination of clinical efficacy, reduced gadolinium exposure, and strong patient support, VUEWAY® injection is emerging as the new standard and a highly desirable choice for patients who require multiple contrast MRI exams over time.

Bracco will continue to invest in innovation, real-world research, and education to empower radiologists and patients alike in making safer, informed choices in imaging. Beyond VUEWAY® injection, Bracco continues to deliver innovation across its portfolio to support clinicians with the science, service, and breadth of solutions they need to advance care.

Please see Important Safety Information below.

VUEWAY® (gadopiclenol) solution for injection, intravenous use

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 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 (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 ≥ 0.5%) are injection site pain (0.7%), and headache (0.7%).

POST-MARKETING EVENTS
The following adverse reactions have been identified during postmarketing use of GBCAs.
Gastrointestinal Disorders: Acute pancreatitis with onset within 48 hours after GBCA administration.
Respiratory, Thoracic and Mediastinal Disorders: Acute respiratory distress syndrome, pulmonary edema.

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 (gadopiclenol) solution for injection, intravenous use, including BOXED WARNING on Nephrogenic Systemic Fibrosis.

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.

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

###

[1] Data on file. Three Million Doses. Bracco Diagnostics Inc.; September 2025.
[2] Data on file. No. of Accounts. Bracco Diagnostics Inc.; September 2025.
[3] VUEWAY® (gadopiclenol) solution for injection, intravenous use. Full Prescribing Information and Patient Medication Guide. Princeton, NJ: Bracco Diagnostics Inc.; March 2025.
[4] Loevner LA, Kolumban B, Hutóczki G, et al. Efficacy and safety of gadopiclenol for contrast-enhanced MRI of the central nervous system: the PICTURE randomized clinical trial. *Invest Radiol*. 2023 May;58(5):307-313.
[5] Kuhl C, Csőszi T, Piskorski W, Miszalski T, Lee JM, Otto PM. Efficacy and safety of half-dose gadopiclenol versus full-dose gadobutrol for contrast-enhanced body MRI. *Radiology*. 2023 Jul; 308(1): e222612
[6] Data on file. 2024 USA Bracco Quantitative VUEWAY® Report Study. Bracco Diagnostics Inc.; January 2025.
[7] Spinazzi A, Lancelot E, Vitali L, et al. Safety of gadopiclenol after its first year of clinical use. *Invest Radiol.* ():10.1097/RLI.0000000000001144, November 21, 2024. | DOI: 10.1097/RLI.0000000000001144
* Based on a 5-point interest scale: not at all interested, somewhat interested, interested, very interested, extremely interested
†Based on a 5-point likelihood scale: not at all likely, somewhat likely, likely, very likely, extremely likely
‡Based on a 5-point willingness to travel/distance scale: not at all willing to travel, willing to travel 25 miles, 50 miles, 75 miles, more than 75 miles

US-VW-2500020 11/25

Kimberly Gerweck
Media Relations (USA)
Sr. Compliance & Communications Manager
Bracco Diagnostics Inc.

T +1 609.524.2777
BDIMediaContact@diag.bracco.com

Follow us **bracco.com**

Bracco Imaging is a global leader in diagnostic imaging, dedicated to improving people's lives by shaping the future of prevention and precision medicine. With a strong passion for innovation, the company develops and provides a broad portfolio of pharmaceutical products for diagnostic imaging: contrast agents for X-ray, Computed Tomography (CT), and Magnetic Resonance Imaging (MRI), as well microbubbles for Contrast Enhanced Ultrasound (CEUS), and Molecular Imaging through radioactive tracers and novel PET imaging agents, alongside specialized medical devices and related services.

The company is committed to advancing radiology by sharing knowledge to cultivate future thought leaders, linking today's practice with tomorrow's progress. Since 1927, Bracco Imaging has grown to more than 3,800 employees and now supports patients and radiology professionals in over 100 countries.

Discover Bracco Imaging at www.bracco.com