FOR IMMEDIATE RELEASE

Bracco Diagnostics Inc. Obtains Hallmark Achievement of One Million Injections with its MRI agent VUEWAY® (gadopiclenol) solution for injection

One Million Patients Led to This Moment

PRINCETON, N.J., November 11, 2024—Bracco Diagnostics Inc., the U.S. subsidiary of Bracco Imaging S.p.A., a leading global company in the diagnostic imaging business, is proud to announce that its most recently FDA-approved magnetic resonance imaging (MRI) agent, VUEWAY® (gadopiclenol) solution for injection, has reached over one million patient injections at over 480 customer sites.[1] This hallmark achievement is significant as it helped address the unmet medical need to minimize gadolinium (Gd) exposure per MRI procedure without compromising image quality.

VUEWAY® (gadopiclenol) solution for injection, 485.1 mg/mL is a macrocyclic gadolinium-based contrast agent (GBCA) that 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.[2]

Ryan Murtagh, MD, Chief of Neuroradiology at Tampa General Hospital and Tampa General Hospital Imaging, said, "As one of the first facilities to adopt VUEWAY (gadopiclenol) solution for injection back in February 2023, we are honored to have administered the one-millionth dose here at Tampa General. VUEWAY injection, with its FDA-labeled dose at half the gadolinium of what other approved macrocyclic agents require in similar indications, has proven to be a game-changer in our practice. It underscores our commitment to advancing patient care by embracing innovation."

With its lower dose of the active ingredient, Gd, VUEWAY injection is a desirable choice for all MRI patients especially those who may require multiple MRI scans with contrast throughout their care.

"We at Bracco are delighted with the rapid adoption of this exciting product (VUEWAY injection) and sincerely thank the imaging community for embracing this approach to patient care," said Cosimo De Pinto, Senior Vice President of Sales and Marketing at Bracco Diagnostics Inc. "Our singular focus at Bracco is about improving patient lives and offering VUEWAY injection is a perfect example of this commitment. We're proud to support our customers by providing the highest level of service, science, and breadth of innovative products," concluded De Pinto.

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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 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.

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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%).

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POST-MARKETING EVENTS
Acute pancreatitis within 48 hours of GBCA administration has been reported.

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 including BOXED WARNING on Nephrogenic Systemic Fibrosis.

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.

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

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[1] Data on file. Bracco Diagnostics Inc. October 2024.
[2] VUEWAY® (gadopiclenol) solution for injection, 485.1 mg/mL. Full Prescribing Information and Patient Medication Guide. Princeton, NJ: Bracco Diagnostics Inc. July 2024.