FOR IMMEDIATE RELEASE

Bracco Diagnostics Inc. Announces Update on Product Portfolio

Strategic decisions enable Bracco to serve better the needs of healthcare providers and patients with its enhanced pipeline offering

MONROE TOWNSHIP, NJ, July 8, 2024 — Bracco Diagnostics Inc. (BDI), the U.S. subsidiary of Bracco Imaging S.p.A., a leading global company in the diagnostic imaging business, is pleased to provide an update on its barium product portfolio as part of a comprehensive rationalization process.

Bracco Diagnostics Inc. launched an initiative with its barium portfolio to invest in new and expanded product offerings driven by customer and patient demand. In addition, the company is pursuing FDA approval for its fourth product and expects to file for approval later this year. Upon anticipated approval, BDI will offer an enhanced line of FDA-approved barium products for abdominal imaging needs.

"We remain committed to advancing the barium and oral imaging field," said Cosimo De Pinto, Senior Vice President of Sales and Marketing at BDI. "Our ongoing investment in new and expanded product offerings reflects our dedication to supporting healthcare providers in delivering exceptional patient care."

At the same time, market changes and evolving procedural changes have led BDI to discontinue three of its non-FDA-approved barium products due to a significant decline in product usage. BDI does not anticipate discontinuing any additional barium products.

"We understand the importance of providing high-quality diagnostic imaging solutions to our customers," continued Cosimo De Pinto. "Our rationalization process was essential to ensure that our resources are allocated effectively to meet the evolving needs of the medical community."

As part of its commitment to innovation, BDI is excited to unveil its pipeline, providing a glimpse of its upcoming product launches over the next 24 months:

Q3 2024: CitraClear™, a gutsy filling beverage, designed to enhance patient satisfaction during preparation for imaging procedures.

Q4 2024: VARIBAR® (barium sulfate) “Mini” packaging, offering convenient and sustainable packaging options for healthcare facilities.

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2025: Introduction of a new flavor in our CT barium line, further enhancing the patient experience during imaging examinations.

BDI invites healthcare providers and industry partners to explore its barium pipeline and looks forward to continuing to collaborate in advancing diagnostic imaging technologies.

INDICATIONS for VARIBAR® (barium sulfate)

VARIBAR® THIN HONEY (barium sulfate) oral suspension, VARIBAR® NECTAR (barium sulfate) oral suspension, and VARIBAR® THIN LIQUID (barium sulfate) oral suspension are radiographic contrast agents indicated for use in modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients.

VARIBAR® HONEY (barium sulfate) oral suspension and VARIBAR® PUDDING (barium sulfate) oral paste are radiographic contrast agents indicated for use in modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients 6 months of age and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
These products should not be used in patients with known or suspected perforation of the gastrointestinal (GI) tract; known obstruction of the GI tract; high risk of GI perforation such as those with a recent GI perforation, acute GI hemorrhage or ischemia, toxic megacolon, severe ileus, post GI surgery or biopsy, acute GI injury or burn, or recent radiotherapy to the pelvis; high risk of aspiration such as those with known or suspected tracheo-esophageal fistula or obtundation; known severe hypersensitivity to barium sulfate or any of the excipients of the product used.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions
Barium sulfate preparations contain a number of excipients, including natural and artificial flavors, and may induce serious hypersensitivity reactions. The manifestations include hypotension, bronchospasm and other respiratory impairments, and dermal reactions including rashes, urticaria, and itching. A history of bronchial asthma, atopy, food allergies, or a previous reaction to a contrast agent may increase the risk for hypersensitivity reactions. Emergency equipment and trained personnel should be immediately available for treatment of a hypersensitivity reaction.

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Intra-abdominal Barium Leakage

The use of VARIBAR PRODUCTS is contraindicated in patients at high risk of perforation of the GI tract. Administration of VARIBAR PRODUCTS may result in leakage of barium from the GI tract in the presence of conditions such as carcinomas, GI fistula, inflammatory bowel disease, gastric or duodenal ulcer, appendicitis, or diverticulitis, and in patients with a severe stenosis at any level of the GI tract, especially if it is distal to the stomach. The barium leakage has been associated with peritonitis and granuloma formation.

Delayed Gastrointestinal Transit and Obstruction

Orally administered barium sulfate may accumulate proximal to a constricting lesion of the colon, causing obstruction or impaction with development of baroliths (inspissated barium associated with feces) and may lead to abdominal pain, appendicitis, bowel obstruction, or rarely perforation. Patients with the following conditions are at higher risk for developing obstruction or baroliths: severe stenosis at any level of the GI tract, impaired GI motility, electrolyte imbalance, dehydration, on a low residue diet, taking medications that delay GI motility, constipation, pediatric patients with cystic fibrosis or Hirschsprung disease, and the elderly. To reduce the risk of delayed GI transit and obstruction, patients should maintain adequate hydration after the barium sulfate procedure. When administering VARIBAR PUDDING, consider the administration of laxatives.

Aspiration Pneumonitis

The use of VARIBAR PRODUCTS is contraindicated in patients with trachea-esophageal fistula. Oral administration of barium is associated with aspiration pneumonitis, especially in patients with a history of food aspiration or with compromised swallowing mechanism. Vomiting following oral administration of barium sulfate may lead to aspiration pneumonitis. In patients at risk for aspiration, begin the procedure with a small ingested volume of VARIBAR PRODUCTS. Monitor the patient closely for aspiration, discontinue administration of VARIBAR PRODUCTS if aspiration is suspected, and monitor for development of aspiration pneumonitis.

Systemic Embolization

Barium sulfate products may occasionally intravasate into the venous drainage of the GI tract and enter the circulation as a "barium embolus" leading to potentially fatal complications which include systemic and pulmonary embolism, disseminated intravascular coagulation, septicemia and prolonged severe hypotension. Although this complication is exceedingly uncommon after oral administration of a barium sulfate suspension, monitor patients for potential intravasation when administering barium sulfate.

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ADVERSE REACTIONS
The most common adverse reactions are nausea, vomiting, diarrhea, and abdominal cramping. Serious adverse reactions and fatalities include aspiration pneumonitis, barium sulfate impaction, intestinal perforation with consequent peritonitis and granuloma formation, vasovagal and syncopal episodes.

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 VARIBAR® THIN LIQUID (barium sulfate) oral suspension.

Please click here for full Prescribing Information for VARIBAR® THIN HONEY (barium sulfate) oral suspension.

Please click here for full Prescribing Information for VARIBAR® NECTAR (barium sulfate) oral suspension.

Please click here for full Prescribing Information for VARIBAR® HONEY (barium sulfate) oral suspension.

Please click here for full Prescribing Information for VARIBAR® PUDDING (barium sulfate) oral paste.

VARIBAR is manufactured by E-Z-EM Canada Inc., for E-Z-EM, Inc., a subsidiary of Bracco Diagnostics Inc., Monroe Twp., NJ 08831.

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 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,

Bracco Diagnostics Inc. Media Relations (USA)
Kimberly Gerweck
Senior Manager, Marketing Communications
BDIMediaContact@diag.bracco.com
D: +1 609-524-2777

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