THE CENTERS FOR MEDICARE & MEDICAID (CMS) APPROVED BRACCO DIAGNOSTICS INC. ULTRASOUND CONTRAST AGENT, LUMASON® (SULFUR HEXAFLUORIDE LIPID-TYPE A MICROSHERES) FOR INJECTABLE SUSPENSION, FOR REIMBURSEMENT, UNDER THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM (HOPPS)

Monroe Township, NJ, October 12, 2015 – Bracco Diagnostics Inc., the U.S. subsidiary of Bracco Imaging S.p.A., a global leading company in the diagnostic imaging business, today announced that Lumason® was approved by the CMS for pass-through status under the HOPPS. Lumason is an ultrasound contrast agent indicated for use in adults with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.¹

Effective October 1, 2015, Lumason can be assigned Healthcare Common Procedure Coding System (HCPCS) code C9457, per mL, when a hospital uses Lumason during an echocardiogram study. By doing so, when the hospital reports code C9457 for Lumason, the hospital will receive a total of $165.30 per the 5 mL vial ($33.06 per mL), in addition to the payment for the echocardiogram for Medicare patients. This additional payment is unique to Lumason due to its new technology status.

“Obtaining approval of Lumason for coverage and payment for echocardiography for suboptimal echocardiograms represents a milestone in this product’s recent introduction into the U.S. market,” said Vittorio Puppo, CEO and President, Bracco Diagnostics Inc. “Today’s approval follows a long-term strategy of delivering the benefits of our contrast enhanced ultrasound agent also in the U.S.”

Lumason, internationally known as SonoVue®, has a strong reputation and solid track record in over 30 countries worldwide, confirming Bracco’s commitment to improve patient care on a global scale.

Lumason is supplied as a 3-part step-saving procedural kit. Each kit contains a Lumason vial containing 25 mg of lipid-type A lyophilized powder with headspace filled with 60.7 mg sulfur hexafluoride gas, a prefilled syringe containing 5 mL of Sodium Chloride 0.9% Injection, USP (Diluent) and a Mini-Spike.¹

For additional information about Lumason, please contact Bracco Diagnostics at: Services.Professional@diag.bracco.com.

Please see Important Safety Information below.
INDICATIONS AND USAGE

Lumason is an ultrasound contrast agent indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.

CONTRAINDICATIONS

Do not administer Lumason to patients with:
- known or suspected right-to-left, bi-directional, or transient right-to-left cardiac shunts,
- history of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in Lumason.

Do not administer by intra-arterial injection.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS CARDIOPULMONARY REACTIONS

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following the injection of ultrasound contrast agents, including sulfur hexafluoride lipid microspheres [see Warnings and Precautions (5.1)]. Most serious reactions occur within 30 minutes of administration [see Warnings and Precautions (5.1)].

- Assess all patients for the presence of any condition that precludes administration [see Contraindications (4)].
- Always have resuscitation equipment and trained personnel readily available [see Warnings and Precautions (5.1)].

The risk for serious cardiopulmonary reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias) [see Warnings and Precautions (5.1)].

1. Please see full Prescribing Information including boxed WARNING at http://imaging.bracco.com/us-en/lumason

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.

Lumason is manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831 by Bracco Suisse SA, Plan-les-Ouates Geneve, Switzerland (Lumason lyophilized powder vial-25 mg lipid-type A/60.7 sulfur hexafluoride gas); Vetter Pharma-Fertigung GmbH & Co. KG, 88212 Ravensburg, Germany (Sodium Chloride 0.9% Injection, USP); B. Braun Melsungen AG, 34212 Melsungen, Germany (Mini-Spike).
SonoVue is a registered trademark of Bracco Suisse S.A.
Lumason is a registered trademark of Bracco Diagnostics Inc.

1 Lumason (sulfur hexafluoride lipid-type A microspheres) for injectable suspension full Prescribing Information. Monroe Twp., NJ: Bracco Diagnostics Inc.; October 2014.

About Bracco Imaging

Bracco Imaging S.p.A., part of the Bracco Group, is one of the world’s leading companies in the diagnostic imaging business. Headquartered in Milan, Italy, Bracco Imaging develops, manufactures and markets diagnostic imaging agents and solutions that meet medical needs.

Bracco Imaging offers a product and solution portfolio for all key diagnostic imaging modalities: X-ray Imaging (including Computed Tomography-CT, Interventional Radiology, and Cardiac Catheterization), Magnetic Resonance Imaging (MRI), Contrast Enhanced Ultrasound (CEUS), Nuclear Medicine through radioactive tracers, and Gastrointestinal Endoscopy. The diagnostic imaging offer is completed by several medical devices and advanced administration systems for contrast imaging products in the fields of radiology.

The Company operates in more than 100 markets worldwide, either directly or indirectly, through subsidiaries, joint ventures, licenses and distribution partnership agreements. With an on-going research covering all key modalities, Bracco Imaging has a strong presence in key geographies: North America, Europe and Japan operating through the Joint Venture Bracco-Eisai Co. Ltd. The Company also operates in Brazil, South Korea, and China through the Joint Venture Bracco Sine Pharmaceutical Corp. Ltd.

Operational investments have been made in order to achieve top quality and compliances with a sustainable eco-friendly production. Manufacturing activities are located in Italy, Switzerland, Japan, China, and Germany.

Bracco Imaging is an innovative Research and Development (R&D) player with an efficient process oriented approach and a track record of innovation in the diagnostic imaging industry. R&D activities are managed in the three Research Centres located in Italy, Switzerland, and the USA.

To learn more about Bracco Imaging, visit www.braccoimaging.com.

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