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**First Approval by U.S. Food and Drug Administration for Contrast Enhanced
Ultrasonography of the Liver Received by Bracco Diagnostics Inc. for LUMASON®
(sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for
intravenous use**

Monroe Township, NJ, April 4, 2016– Bracco Diagnostics Inc., the U.S. subsidiary of Bracco Imaging S.p.A., one of the world’s leading companies in the diagnostic imaging business, announced today that LUMASON is now approved for use in ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients.

In October 2014 LUMASON, known globally as SonoVue®, was approved by the FDA for use in adults with suboptimal echocardiograms, to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border in adult patients. LUMASON is now the first ultrasound contrast agent to obtain FDA approval for use in liver imaging, to improve the sensitivity and specificity of ultrasonography for the differentiation between malignant and benign focal hepatic lesions. This approval also makes LUMASON the first ultrasound contrast agent approved for use in the pediatric population.

“Bracco is delighted to obtain FDA approval for the use of LUMASON in liver imaging for both adult and pediatric patients,” said Fulvio Renoldi Bracco, Head of Global Business Unit Imaging at Bracco Imaging. “The use of contrast-enhanced ultrasound for characterization of focal liver lesions is already established in several countries in Europe and Asia, and Bracco is glad to offer this diagnostic option to U.S. patients.”

“We are proud to be the first company to obtain FDA approval for this important clinical use of ultrasound contrast both in adults and children,” said Alberto Spinazzi, MD, Senior Vice President, Global Medical and Regulatory Affairs, Bracco Group. “This new indication for LUMASON reflects our efforts and investments to expand the range of approved clinical indications for contrast-enhanced ultrasound in the United States. We are very pleased with the collaborative work with the FDA whose review is critical to ensuring the safety and efficacy of any use of imaging products to the healthcare community.”

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LIFE FROM INSIDE

“The expanded indication for LUMASON now offers healthcare professionals and their patients further benefits of our ultrasound contrast agent,” said Vittorio Puppo, CEO and President, Bracco Diagnostics Inc. “This approval demonstrates Bracco’s leadership and commitment to the imaging community, across imaging modality service lines. We are proud to be a leader in contrast imaging and delivery systems and of our continuous investment in imaging activities to help improve patient care in the U.S.”

LUMASON, which has been marketed for over 14 years in more than 40 countries, is a contrast agent made up of gas-filled microspheres that reflect sound waves to enhance the image in ultrasonography.

With a proven safety and efficacy profile in echocardiography and ultrasonography of the liver, LUMASON is packaged in a convenient three-part kit that does not require refrigeration or mechanical agitation. Each kit includes a LUMASON vial containing 25 mg of lipid-type A lyophilized powder and 60.7 mg sulfur hexafluoride headspace; a prefilled syringe containing 5 mL of Sodium Chloride 0.9% Injection, USP (Diluent); and a Mini-Spike.¹

In late 2015, the Centers for Medicare and Medicaid Services granted “pass-through” status for LUMASON reimbursement, under the Hospital Outpatient Prospective Payment System (OPPS). Contrast material is not separately paid by Medicare for outpatient hospitals under OPPS unless the product has “pass-through” status. This additional payment is unique to LUMASON among contrast agents used in ultrasound procedures.

Please see Important Safety Information below.

About LUMASON

INDICATIONS AND USAGE¹

LUMASON is an ultrasound contrast agent indicated for use:

- in echocardiography to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border in adult patients with suboptimal echocardiograms
- in ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients

CONTRAINDICATIONS¹

- 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

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IMPORTANT SAFETY INFORMATION¹

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

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.

¹LUMASON (sulfur hexafluoride lipid-type A microspheres) for injectable suspension full Prescribing Information. Monroe Twp., NJ: Bracco Diagnostics Inc.; March, 2016.

Please see full Prescribing Information including boxed WARNING at <http://imaging.bracco.com/us-en/LUMASON>. For additional information about Bracco's products, and for full prescribing information, please visit <http://imaging.bracco.com/us-en>. If you have any questions or require additional information about any Bracco product, please contact Bracco Professional Services at 1-800-257-5181, option 2.



LIFE FROM INSIDE

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), and Nuclear Medicine through radioactive tracers. The diagnostic imaging portfolio is completed by a range of medical devices and advanced administration systems for contrast imaging products.

The Company operates in over 100 markets worldwide, either directly or indirectly, through subsidiaries, joint ventures, licenses and distribution partnership agreements. With 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, compliant and 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) structure 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 Centers located in Italy, Switzerland, and the USA.

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

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