



**Press Contact:**

Kimberly Gerweck  
Bracco Diagnostics Inc.  
Kimberly.Gerweck@diag.bracco.com

**The FDA removes the contraindication for use of Bracco Diagnostics Inc.'s LUMASON® (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use, in patients with cardiac shunts**

Monroe Township, NJ, January 11, 2017– 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 the U.S. Food and Drug Administration (FDA) has removed the contraindication for use of LUMASON in patients with known or suspected right-to-left, bi-directional, or transient right-to-left cardiac shunts.

In view of a potential safety hazard deriving from the use of LUMASON in this patient population, i.e., some of the intravenously injected microspheres bypassing the filtering by the lung and entering the arterial circulation, a specific warning has been maintained in the approved labeling of the agent (WARNINGS AND PRECAUTIONS section, 5.3: Systemic Embolization). Also, LUMASON must not be administered by intra-arterial injection.

"The removal of this contraindication implies that the FDA has determined that the benefits from the diagnostic information that could be obtained through the use of LUMASON in patients with cardiac shunts may outweigh the risk for systemic embolization," stated Alberto Spinazzi, MD, Head, Global Medical and Regulatory Affairs, Bracco Group. "FDA review is critical to ensuring the quality, safety and efficacy of contrast agents like LUMASON, and, in general, of medicinal products."

LUMASON, known globally as SonoVue®, which has been marketed since 2001 and now in more than 30 countries, was initially approved in October 2014 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. LUMASON then gained FDA approval in March 2016 for use in ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients, and in December 2016, for use for the evaluation of suspected or known vesicoureteral reflux in pediatric patients.

- more -



LIFE FROM INSIDE

With a proven safety profile, LUMASON is an ultrasound contrast agent made up of gas-filled microspheres that reflect the sound waves to enhance the echogenicity of the blood or urine, which results in an improvement in the diagnostic quality of the ultrasound images. The agent is packaged in a convenient three-part portable kit that does not require refrigeration or mechanical agitation. Each kit contains 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.<sup>1</sup>

In late 2015, the Centers for Medicare and Medicaid Services (CMS) granted “pass-through” status for LUMASON reimbursement, under the Hospital Outpatient Prospective Payment System (HOPPS). Contrast material is not separately paid by Medicare for outpatient hospitals under HOPPS unless the product has “pass-through” status. This additional payment is unique to LUMASON due to its new technology status. Effective October 1, 2016, CMS approved the request for coverage and coding for liver and/or abdominal ultrasound with contrast under the HOPPS indicating that Healthcare Common Procedure Coding System (HCPCS) code C9744 can be assigned for these procedures when performed in the hospital outpatient setting.

**Please see Important Safety Information below.**

#### **INDICATIONS AND USAGE<sup>1</sup>**

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
- in ultrasonography of the urinary tract for the evaluation of suspected or known vesicoureteral reflux in pediatric patients

#### **CONTRAINDICATIONS<sup>1</sup>**

LUMASON is contraindicated in patients with:

- history of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON

- more -



LIFE FROM INSIDE

### IMPORTANT SAFETY INFORMATION<sup>1</sup>

#### **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)].<sup>1</sup>

Please see full Prescribing Information including boxed WARNING at <http://www.braccoimaging.com/us-en/products-and-solutions/contrast-enhanced-ultrasound/lumason/prescribing-information>

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

LUMASON is manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831 by Bracco Suisse S.A., 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.

**For additional information about Bracco's products, and for full prescribing information, please visit <http://imaging.bracco.com/us-en>.**

- more -



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](http://www.braccoimaging.com).

###

---

<sup>1</sup>. LUMASON (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use full Prescribing Information. Monroe Twp., NJ: Bracco Diagnostics Inc.; December 2016.