BRACCO DIAGNOSTICS INC. RECEIVES U.S. FDA APPROVAL FOR NEW ULTRASOUND CONTRAST AGENT
*Lumason™ (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, Now Available for use in Adults with Suboptimal Echocardiograms*

Monroe Township, N.J., October 13, 2014 – 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 the U.S. Food and Drug Administration (FDA) has approved its new ultrasound contrast agent *Lumason™* (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, 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

There are an estimated 28 million echocardiograms annually performed in the United States; 10% or more of those exams are reported as suboptimal and, possibly inconclusive.² *Lumason™*, internationally known as *SonoVue®* in 39 countries, has an extensive and established safety profile and has been shown to convert suboptimal images into images of adequate diagnostic quality. "The approval of *Lumason™* offers an additional option to physicians and sonographers who are unable to obtain optimal quality echocardiograms due to patient habitus or clinical status." said Alberto Spinazzi, M.D., Head of Global Medical and Regulatory Affairs at Bracco.

*Lumason™* has been approved for use in adult patients with suboptimal echocardiograms, based on data submitted to the FDA from three multicenter controlled clinical trials showing significant improvement in image quality compared to unenhanced, native images.¹³

"We’re thrilled with the approval of *Lumason™* as it represents a significant milestone in the company’s history. Today’s approval follows a long-term strategy of delivering the benefits of our Contrast Enhanced Ultrasound agent also in the US. *Lumason™* - internationally known as *SonoVue®* - has a strong reputation and solid track record in many other key markets, confirming Bracco’s commitment to improve patient care on a global scale” said Fulvio Renoldi Bracco, Head of Global Business Unit Imaging at Bracco Imaging.

*Lumason™* is supplied as a 3-part kit. 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-Spike¹.

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

Please see Important Safety Information below.

**INDICATIONS¹**

All trademarks and registered trademarks are the property of their respective owners.
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/

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.

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 USA.

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