FOR IMMEDIATE RELEASE

Bracco Announces U.S. FDA Approval of 20-Vial Configuration of LUMASON® (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use

20-vial pack provides a green packaging alternative and helps increase storage efficiency

Monroe Township, NJ, February 22, 2021 – 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 its ultrasound enhancing agent (UEA) LUMASON® (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use, received FDA approval on a new 20-vial pack configuration. This new product configuration provides customers with a green packaging alternative, increased storage space efficiency, and more SKU options.

"Bracco is proud to launch this new configuration of LUMASON UEA while still featuring our needleless, air sterile filtration Mini-Spike®, protecting you and your patients[1]," said Cosimo De Pinto, Vice President of Sales and Marketing at Bracco Diagnostics Inc. "Whether you are a nurse in the ICU or a sonographer in a high-volume lab where storage is limited and productivity is key, we are committed to providing options that meet our customers' needs."

LUMASON UEA, known globally as SonoVue®, has a proven safety profile and is the only agent that has multiple indications for adult and pediatric patients.[2] This new configuration features twenty vials of LUMASON UEA, each containing 25 mg of lipid-type A lyophilized powder and 60.7 mg sulfur hexafluoride headspace, and a corresponding Mini-Spike for each vial.[2]

Marketed since 2001 and available in more than 40 countries[3], LUMASON UEA is comprised 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.[4] The agent does not require refrigeration or mechanical agitation.

Please see Important Safety Information below.

LUMASON® (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use

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LIFE FROM INSIDE

INDICATIONS AND USAGE

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 and pediatric 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

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

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)].* Hypersensitivity reactions have uncommonly been observed following the injection of Lumason *[see Warnings and Precautions (5.2)].* The most common adverse reactions are headache and nausea *[see Adverse Reactions (6.1)].*

Please see full Prescribing Information for LUMASON ultrasound contrast agent including boxed **WARNING** at https://www.braccoimaging.com/us-en/products/contrast-enhanced-ultrasound/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.

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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).

LUMASON and SONOVUE are registered trademarks of Bracco Diagnostics Inc. and its affiliated entities.

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

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

*****About Bracco Imaging S.p.A.**
Bracco Imaging S.p.A., part of the Bracco Group, is a world-leading diagnostic imaging provider, headquartered in Milan, Italy.

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 and novel PET imaging agents. Our continually evolving portfolio is completed by a range of medical devices, advanced administration systems and dose-management software. The Company operates in over 100 markets worldwide, either directly or indirectly, through subsidiaries, joint ventures, licenses and distribution partnership agreements. Bracco Imaging has a strong presence in key geographies: North America, China, Europe, Japan, Brazil, Mexico and South Korea.

Bracco Imaging's manufacturing plants operate in full compliance with the best practices and sustainable eco-friendly production processes. Manufacturing sites are based in Italy, Switzerland, Germany, Canada, China, Japan, and the USA.

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 three centers based in Italy, Switzerland and the USA. To learn more about Bracco Imaging, visit www.braccoimaging.com.

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1. B.Braun Product Specification: Product Group: Mini-Spike, Data on File, 2012. pp. 2-4.
2. 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 2020.
3. Data on file. Bracco Diagnostics Inc. based on Global Contrast-Enhanced Ultrasound (CEUS) DOLAN, February 2021.
4. Data on file. Bracco Diagnostics Inc. May 2019. Geneva data 2019.

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