New Nationwide Real-World Data Validates the Safety of LUMASON® Ultrasound Enhancing Agent (UEA) in Contemporary Echocardiographic Practice

14 MAY 2025, PRINCETON, NJ – Bracco Diagnostics Inc., the U.S. subsidiary of Bracco Imaging S.p.A., a global leader in diagnostic imaging, announced today that the results of a nationwide real-world study**,** published by Dr. Strom et al. in the Journal of the American Heart Association on 14 May 2025,[1] provide valuable information on safety outcomes of cardiac ultrasound procedures in contemporary practice in the United States (U.S.).

According to the article, all-payor claims data from more than 11.4 million adult individuals were used to evaluate rates of death (primary endpoint) and other serious complications, i.e., anaphylaxis, myocardial infarction, ventricular tachycardia or cardiac arrest within 2 days of echocardiograms conducted between 2018 and 2022 in the U.S. Of the study population, a total of 500,073 had undergone echocardiograms with the use of an ultrasound enhancing agent.

Using rigorous data extraction, matching and statistical analysis methodology, the study conducted by Strom et al. showed:

- A very low rate of death or other serious complications,
- Lower odds of death when LUMASON® (an injectable suspension, sulphur hexafluoride lipid-type A microsphere for intravenous and intravesical use) and other UEAs are used,
- Similar rates of non-fatal serious complications between unenhanced and UEA-enhanced procedures, anaphylaxis included,
- Very low and similar rates of death and non-fatal serious complications between LUMASON UEA and the other two UEAs in clinical use in the U.S., and
- Similar rates of adverse events before, during and after the COVID-19 pandemic, anaphylaxis included.

  The Authors of the paper conclude that the results of the study overall underscore the continued safety of UEAs in contemporary clinical practice.

"*Understanding the safety and potential benefits of UEAs is crucial for our medical community*," says Dr. Jordan B. Strom, Director of the Echocardiography Laboratory, Section Head of Cardiovascular Imaging Research at the Smith Center at Beth Israel Deaconess Medical Center, and Associate Professor at Harvard Medical School. "*UEAs are associated with reduced downstream testing, and costs, and improve diagnoses and workflows. Our study not only reaffirms the safety of these agents but also highlights their association with reduced mortality. We believe that these findings will help pave the way for broader usage of UEAs to the benefit of our patients. The goal is to enhance diagnostic accuracy, improve patient outcomes, and ultimately, save more lives.*"

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[1] Strom JB, Mulvagh SL, Porter TR, et al. Contemporary safety of ultrasound enhancing agents in a nationwide analysis. *J Am Heart Assoc.* 2025;14:e039480. DOI: 10.1161/JAHA.124.039480
*Out of 11.4M patients, 500K patients received UEAs.

LUMASON® is the only UEA approved for use in multiple indications in adult and pediatric patients. In echocardiography, it is approved 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.[2]

"This nationwide large and rigorous analysis, broadly representative of healthcare activity in the entire U.S., provides new and valuable insights about the safety of ultrasound enhancing agents (UEAs) in echocardiography and reinforces our confidence in LUMASON UEA as an effective tool to drive better outcomes." said Alberto Spinazzi, MD, Chief Medical & Regulatory Officer at Bracco Imaging. "*Indeed, when LUMASON UEA was used, the odds of short-term mortality were reduced. Also, the exposure to LUMASON UEA was associated with a very low rate of serious complications, like that observed with the other UEAs in clinical use or even that of echocardiograms with no use of UEAs. Notably, no differences in the safety profile of the agent were apparent before, during, and after the COVID-19 pandemic."*

Please see the Important Safety Information below.

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

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

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. Most serious reactions occur within 30 minutes of administration.

- **Assess all patients for the presence of any condition that precludes administration**
- **Always have resuscitation equipment and trained personnel readily available**

Contraindications
LUMASON (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use is contraindicated in patients with known or suspected hypersensitivity to sulfur hexafluoride lipid microsphere or its components, such as polyethylene glycol (PEG).

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[2] LUMASON® (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use full Prescribing Information. Princeton, NJ: Bracco Diagnostics Inc.; August 2021.

Warnings

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or shortly following administration of ultrasound contrast agents, including LUMASON. Always have cardiopulmonary resuscitation personnel and equipment readily available prior to LUMASON administration and monitor all patients for acute reactions.

Post-marketing **hypersensitivity reactions**, including serious hypersensitivity reactions, have been observed during use or shortly following LUMASON administration. These reactions may occur in patients with no history of prior exposure to sulfur hexafluoride lipid-containing microspheres. LUMASON contains PEG. There may be increased risk of serious reactions including death in patients with prior hypersensitivity reaction(s) to PEG.

Systemic embolization may occur in patients with cardiac shunts. Assess patients with cardiac shunts for embolic phenomena following LUMASON administration.

There is a risk of **ventricular arrhythmia related to high mechanical index** in patients administered LUMASON. LUMASON is not recommended for use at mechanical indices greater than 0.8.

The most common adverse reactions (incidence ≥ 0.5%) are headache (1%) and nausea (0.5%).

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.

Please click here for full Prescribing Information for LUMASON ultrasound contrast agent, including BOXED WARNING on Serious Cardiopulmonary Reactions.

LUMASON is manufactured for Bracco Diagnostics Inc., Princeton, NJ 08540 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) or Bracco Imaging S.p.A. Via Ribes, 5, 10010 Colleretto Giacosa (TO), Italy (0.9% Sodium Chloride 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.

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

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Bracco is an **international Group** active in over 100 countries worldwide in the healthcare sector and a leader in **diagnostic imaging**. It has 3,700 employees and annual total consolidated revenues of around 1.8 billion euros, 88% of which are from international sales. In the Research and Development area, the company invests approximately 10% of reference turnover in the imaging diagnostics and medical devices sectors and has a portfolio comprising over 2,600 patents.