FOR IMMEDIATE RELEASE

Public statement of Bracco Imaging
with regard to the Pharmacovigilance Risk Assessment Committee
Recommendations on Gadolinium-Based Contrast Agents

On March 10, 2017 the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) recommended the suspension of the marketing authorizations of MultiHance® (active ingredient: gadobenate dimeglumine) and three other gadolinium-based contrast agents (GBCAs) because of evidence that small amounts of gadolinium complexes may be retained in brain tissues after their intravenous use.

It is important to note that:

a) the PRAC took this precautionary approach in the absence of known symptoms or diseases linked to gadolinium complexes in the brain;

b) this recommendation does not represent the final decision of the European Authorities on the benefit-risk balance of the GBCAs available in the European Union (EU). The final position of the EU Authorities will be taken at the end of a regulatory procedure called Referral, governed by article 31 of Directive 2001/83/EC;

c) additional assessments will be made to complete this procedure to arrive at the final decisions on the various GBCAs;

d) Bracco will stay focused on all the available evidence on gadolinium retention throughout the next steps of the Referral procedure, and continues to be fully committed to support Regulatory Authorities in their assessments and to foster advances in scientific knowledge, always in the best interest of patients.

Based on the available evidence, Bracco firmly believes that the benefit-risk balance of the intravenous use of MultiHance® in the approved indications is positive.

The opinion of PRAC has no impact on the ongoing validity of the marketing authorization for MultiHance®. During the Referral Procedure MultiHance® will remain fully available for clinical use in the approved indications.
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.

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