

Press Contact:

Media Relations mediarelations.imaging@bracco.com +39-02-21771

FOR IMMEDIATE RELEASE

BRACCO RECEIVES MHRA APPROVAL FOR EXPANDED LABELING OF MULTIHANCE® (gadobenate dimeglumine) IN MAGNETIC RESONANCE IMAGING OF THE BREAST

MultiHance®, the Highest Relaxivity Contrast Agents for MRI of the Central Nervous System, Is Now Approved for Breast MRI

Milan (Italy), March 11, 2013 - Bracco Imaging S.p.A., a global leading company in the diagnostic imaging business, announced today that the Reference Member State (the U.K. Medicines and Health Care products Regulatory Agency - MHRA) has approved the use of MultiHance[®] (active ingredient: gadobenate dimeglumine) in Magnetic Resonance Imaging (MRI) of the breast in adult patients within a Mutual Recognition Procedure (MRP).

In the new prescribing information, MultiHance[®] will be indicated for "MRI of the breast, for the detection of malignant lesions in patients where breast cancer is known or suspected on the basis of previous mammography or ultrasound results."

Breast cancer continues to remain the most lethal malignancy in women across the world. In 2008, approximately 1.4 million women were diagnosed with breast cancer worldwide with corresponding 460,000 deaths [1]. Of these, approximately 450,000 women were diagnosed with the disease in Europe with a corresponding 140,000 deaths. MRI is known to be a very powerful tool in the detection of breast cancer nodules, and is used to treat the disease more effectively [2, 3]. MRI of the breast is a study that requires the administration of a gadolinium-containing contrast agent, like MultiHance[®]; otherwise the exam would be of no diagnostic value [2, 3].

"We are extremely happy for the decision of the MHRA, which recognizes the clinical utility of MultiHance® also in this relatively new, but extremely important imaging technique and look forward to the decision being implemented in the other European Concerned Member States in the regulatory approval process called "Mutual Recognition Procedure" - said Dr. Alberto Spinazzi, Head of Global Medical and Regulatory Affairs at Bracco - "This new indication will greatly benefit medical professionals and patients, who can now count on a high-relaxivity contrast agent specifically tested and approved for the diagnosis of breast cancer."

MultiHance[®] is the highest relaxivity gadolinium-based contrast agent (GBCA) available for use in MRI of the central nervous system (CNS) in adults and pediatric patients; also, MultiHance[®] was previously approved in Europe for its use in Magnetic Resonance Angiography (MRA) to evaluate adults with known or suspected renal or aorto-ilio-femoral occlusive disease, and for MRI of the liver.

According to the new labeling, when used in MRI of the female breast, MultiHance[®] increases the contrast between neoplastic breast tissues and adjacent normal tissues, thus improving the conspicuity of breast tumors. The pivotal phase III trial was an intra-individual, crossover comparison of 0.1 mmol/kg body weight MultiHance[®] vs 0.1 mmol/kg body weight of an established comparator agent (gadopentetate dimeglumine, Gd-DTPA) in MRI of patients with suspected or known breast cancer.

MultiHance[®] achieved significantly superior diagnostic performance in terms of sensitivity, specificity, positive and negative predictive value, and accuracy vs Gd-DTPA [4].

"Bracco has a long term commitment in all modalities of diagnostic imaging, and particularly in MRI" said Micol Fornaroli, Bracco Imaging Chief Strategy Officer; "this important result rewards the company's efforts and the vision of an investment strategy which is focused in the delivery of innovative solutions to serve a specific and demanding market segment."

"MultiHance[®] is already a leading product in Europe and in the United States, where our market shares and volumes keep growing steadily in spite of the difficult economic environment" concluded Fulvio Renoldi Bracco, Head of Global Business Unit Imaging at Bracco. "The broader field of approved uses, together with its proven efficacy and safety characteristics, will further enhance its presence in European hospitals and clinics as a standard choice for MRI."

Following the positive conclusion of the regulatory Mutual Recognition Procedure, the European member states that originally approved MultiHance^{®1} will implement the variation in their local prescribing information.

About MultiHance®

Bracco is a worldwide leading provider of solutions for contrast imaging. MultiHance[®] has been approved in 43 countries and administered to date to more than 15 million patients worldwide.

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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 over 90 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.

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¹ Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, Norway, Republic of Ireland, The Netherlands, Spain, Sweden, United Kingdom.

References:

- Ganiy Opeyemi Abdulrahman Jnr. and Ganiyu Adebisi Rahman, "Epidemiology of Breast Cancer in Europe and Africa," Journal of Cancer Epidemiology, vol. 2012, Article ID 915610, 5 pages, 2012. doi:10.1155/2012/915610
- 2. Sardanelli F et al. Magnetic resonance imaging of the breast: Recommendations from the EUSOMA working group. European Journal of Cancer 2010; 46: 1296-1316
- 3. Mann RM et al. Breast MRI; guidelines from the European Society of Breast Imaging. European Radiology 2008; 18: 1307-1318
- Martincich L et al. Multicenter, double-blind, randomized, intraindividual crossover comparison of gadobenate dimeglumine and gadopentetate dimeglumine for Breast MR imaging (DETECT Trial). Radiology 2011; 258: 396-408