GE Healthcare Files Supplemental New Drug Application for Its Own Manufacturing of Optison™ (Perflutren Protein-Type A Microspheres Injectable Suspension, USP)

Upon Approval, GE Healthcare's Oslo Facility Will Provide Stock to the US Becoming Only Contrast Media Manufacturer to Supply Its Own Stock to the US Market

PRINCETON, NJ, January 15, 2013 – GE Healthcare today announced that it has filed a supplemental new drug application (sNDA) that will allow the company to manufacture Optison™ (Perflutren Protein-Type A Microspheres Injectable Suspension, USP), within its own facility. Optison is a contrast agent that may improve the visualization of the left ventricular border – an area of the heart that is critical to see in order to assess and diagnose certain heart diseases. Upon approval, GE Healthcare will provide supply of Optison to the US market from its manufacturing facility in Oslo, becoming the only contrast media manufacturer to supply its own stock for the US.

Optison is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricle and to improve delineation of the left ventricular endocardial borders. Optison is not for use in patients with known or suspected: (1) Right-to-left, bi-directional, or transient right-to-left cardiac shunts, or (2) hypersensitivity to perflutren, blood, blood products or albumin. It should not be administered by intra-arterial injection. As for all ultrasound contrast agents, Optison has a boxed warning indicating that serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following perflutren-containing microsphere administration. Most serious reactions occur within 30 minutes of administration. Healthcare professionals should assess all patients for the presence of any condition that precludes Optison administration and always have resuscitation equipment and trained personnel readily available.

"GE Healthcare is committed to providing safe, innovative, and effective medical products that aid in the detection of cardiovascular diseases, and today's filing is further evidence of that commitment," said Stephen Lightfoot, General Manager, Core Imaging, GE Healthcare Medical Diagnostics. "While we cannot predict a timeline for regulatory authority approval, we look forward to servicing the US cardiology community directly in 2013."

Optison remains an important diagnostic option for patients with suboptimal echocardiograms. Additionally, Optison offers a unique, convenient value to clinicians and patients: It is stable at room temperature for up to 24 hours and takes less than 60 seconds to prepare, allowing for quick access to contrast in hospital settings like the cardiac lab or emergency room.

Optison vials do not contain preservative and are for single patient use only. Healthcare professionals should follow labeled instructions for product handling and use and discard unused product properly.

The most frequently reported adverse reactions following clinical trial use of Optison were headache, nausea and/or vomiting, warm sensation or flushing, and dizziness. Cardiac arrests and other serious but non-fatal adverse reactions were uncommonly reported post-marketing. Most of these uncommon reactions included cardiopulmonary symptoms and signs such as cardiac or respiratory

arrest, hypotension, supraventricular and ventricular arrhythmias, respiratory distress, or decreased oxygenation. Reports also identified neurologic reactions (loss of consciousness or convulsions) as well as anaphylactoid reactions.

Important Risk and Safety Information About Optison™ (Perflutren Protein-Type A Microspheres Injectable Suspension, USP)

BOXED WARNING: SERIOUS CARDIOPULMONARY REACTIONS: Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following perflutren-containing microsphere administration. Most serious reactions occur within 30 minutes of administration. Assess all patients for the presence of any condition that precludes Optison administration. Always have resuscitation equipment and trained personnel readily available.

INDICATIONS: Optison is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricle and to improve the delineation of the left ventricular endocardial borders. **CONTRAINDICATIONS:** Do not administer Optison to patients with known or suspected: (1) Right-to-left, bi-directional, or transient right-to-left cardiac shunts, or (2) Hypersensitivity to perflutren, blood, blood products, or albumin. Do not administer Optison by intra-arterial injection. **WARNINGS: Anaphylactoid Reactions:** In postmarketing use, uncommon but serious anaphylactoid reactions were observed during or shortly following perflutren-containing microsphere administration, including in patients with no prior exposure to perflutren-containing microsphere products. **High Ultrasound Mechanical Index:** High ultrasound mechanical index values may cause microsphere cavitation or rupture and lead to ventricular arrhythmias. Additionally, end-systolic triggering with high mechanical indices has been reported to cause ventricular arrhythmias. The safety of Optison at mechanical indices greater than 0.8 and the safety of Optison with the use of end-systolic triggering have not been evaluated. **PRECAUTIONS: General:** Optison contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral disease and Creutzfeldt-Jakob disease (CJD), no cases of which have ever been identified for albumin. **Pregnancy:** Adequate or well-controlled studies were not conducted in pregnant women. Optison should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Optison is administered to a nursing woman. **Pediatric Use:** Safety and efficacy have not been established in pediatric patients, or in patients with congenital heart disease. **ADVERSE REACTIONS:** The most frequently reported adverse reactions following clinical trial use of Optison were headache, nausea and/or vomiting, warm sensation or flushing, and dizziness. **Postmarketing Experience:** Cardiac arrests, and other serious, but non-fatal adverse reactions, were uncommonly reported. Most of these uncommon reactions included cardiopulmonary symptoms and signs such as cardiac or respiratory arrest, hypotension, supraventricular and ventricular arrhythmias, respiratory distress, or decreased oxygenation. Reports also identified neurologic reactions (loss of consciousness or convulsions) as well as anaphylactoid reactions.

Prior to Optison administration, please read the Full Prescribing Information.

About GE Healthcare
GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care. Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services help our customers to deliver better care to more people around the world at a lower cost. In addition, we partner with

healthcare leaders, striving to leverage the global policy change necessary to implement a successful shift to sustainable healthcare systems.

Our "healthymagination" vision for the future invites the world to join us on our journey as we continuously develop innovations focused on reducing costs, increasing access and improving quality and efficiency around the world. Headquartered in the United Kingdom, GE Healthcare is a $17 billion unit of General Electric Company (NYSE: GE). Worldwide, GE Healthcare employs more than 46,000 people committed to serving healthcare professionals and their patients in more than 100 countries. For more information about GE Healthcare, visit our web site at www.gehealthcare.com.

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