GE Healthcare Receives Approval for Its Own Manufacturing of Optison™
(Perflutren Protein-Type A Microspheres Injectable Suspension, USP)

Optison Remains an Important Diagnostic Option for Patients With Suboptimal Echocardiograms

PRINCETON, NJ — November 18, 2013 — GE Healthcare announced today that it has received approval from the U.S. Food and Drug Administration (FDA) to allow the company to manufacture Optison™ (Perflutren Protein-Type A Microspheres Injectable Suspension, USP) in-house. 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. As a result of the FDA's action, GE Healthcare will provide a supply of Optison to the US and European markets from its manufacturing facility in Oslo, Norway, becoming the only contrast media manufacturer to supply its own stock to 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.

"Adding our own manufacturing site for Optison has multiple benefits for physicians and patients, including an ability to increase capacity to meet market demands and help to ensure consistent supply to the contrast media market," said Jan Makela, GM, Core Imaging, GE Healthcare Life Sciences. "GE Healthcare is committed to providing safe, reliable, innovative, and effective diagnostic products that aid in the detection of cardiovascular diseases. To that end, we have developed a multimillion dollar manufacturing facility in Oslo, making us the only contrast media manufacturer to supply its own product to the US market."

"In part because of interrupted supply, ultrasound contrast media usage has yet to reach its full potential, so we are quite pleased that GE Healthcare has made this commitment and investment to independently manufacture Optison within its own facility," said Benjamin F. Byrd, III, MD, FASE, President, American Society of Echocardiography. "Optison remains an important diagnostic option for patients who present with suboptimal echocardiograms. The Society believes that use of contrast in echocardiography studies can enhance the image and thus reduce the need for additional testing, helping to lower healthcare costs and provide better patient care."

Optison offers a unique, convenient value to clinicians and patients: It is stable at room temperature for up to 24 hours and is quick to prepare, allowing for quick access to contrast in hospital settings like the cardiac lab or emergency room.

Optison vials do not contain preservatives 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. **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.

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 to meet the demand for increased access, enhanced quality and more affordable healthcare around the world. GE (NYSE: GE) works on things that matter - great people and technologies taking on tough challenges. From medical imaging, software & IT, patient monitoring and diagnostics to drug discovery, biopharmaceutical manufacturing technologies and performance improvement solutions, GE Healthcare helps medical professionals deliver great healthcare to their patients.

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