Head-to-Head Study Shows GE Healthcare's Visipaque™ (iodixanol) More Comfortable During Abdominal CT Scans

Princeton, NJ – November 27, 2013 – GE Healthcare today announced results from a new study, which showed that patients receiving Visipaque™ (iodixanol 320mg I/ml) were less likely to experience discomfort, characterized by heat or cold sensation or pain upon injection, than patients receiving Isovue® (iopamidol 370 mg I/ml). As with other iodinated contrast agents, Visipaque is often associated with sensations of discomfort, heat or pain. The data were published online in Acta Radiologica.1

“Patient discomfort from iodinated contrast media administration, including pain and heat sensation, continues to be a common concern for patients during or immediately following injection because of potential for body movement and image degradation,” said Frederick L. Weiland, MD, lead author of the study and Radiologist at Sutter Roseville Hospital, Roseville, CA. “These data may provide evidence for clinical practice that the physiochemical properties of Visipaque might help minimize patient discomfort.”

About the Study
This prospective, randomized, double-blind, and parallel group study evaluated and compared contrast-induced patient discomfort and overall safety following contrast administration in 299 patients receiving either Visipaque 320mg I/mL or Isovue 370mg I/mL at 9 centers in the United States and Europe.

In patients undergoing contrast-enhanced computed tomography (CECT) imaging of the abdomen/pelvis using IV administration as part of their routine medical care, the study found administration of iso-osmolar Visipaque 320 mg I/mL resulted in less frequent and less severe patient discomfort than did low-osmolar iopamidol 370 mg I/mL, with heat being the major contributor. Specifically:

• Patients receiving Visipaque experienced significantly less moderate/severe discomfort (35.1% vs. 67.3%; p<0.0001) or heat (29.8% vs. 63.9%; p<0.0001), and severe discomfort (2.6% vs. 16.3%; p<0.0004) or heat (2.6% vs. 15%; p=0.0008) than patients receiving Isovue.

• 21.2% of Visipaque patients had no discomfort from contrast administration whereas 7.5% of Isovue patients had no discomfort from contrast administration (p=0.0008).

“Patient discomfort immediately following iodinated contrast agent injection continues to be a concern because of potential for body movement and image degradation” said Prof. Hans-Christoph Becker, Department of Clinical Radiology, Ludwig-Maximilians-University Munich, Germany. “Results from this study showed that Visipaque use resulted in significantly less patient discomfort when compared to Isovue, primarily driven by heat sensation.”

The overall image quality was graded as excellent for 95.4% of patients in the Visipaque group and 89.9% of patients in the Isovue group, though the difference did not reach statistical significance (p=0.0508). Other than patient discomfort there was no statistical difference between the two agents in adverse events reported in this trial. Patients receiving iodixanol, but not iopamidol, reported skin reactions, but the difference was not statistically significant.
“This study, using our iodinated contrast agent, Visipaque, is significant and further proof of our commitment to our continued research in contrast media to improve patient care,” said Jan Makela, General Manager, Core Imaging, GE Healthcare Life Sciences. “The study results provide relevant information to both referring physicians and imaging specialists on the frequency and severity of patient discomfort following administration of different contrast agents, which may help them inform patients and choose appropriate contrast media.”

**Safety Disclaimer**
Serious, life-threatening and fatal reactions, mostly of cardiovascular origin, have been associated with the administration of iodine-containing contrast media, including Visipaque. Most deaths occur during injection or five to ten minutes later. Rare reports of anaphylaxis have been documented during post-market surveillance. As with other contrast agents, Visipaque is often associated with sensations of discomfort, warmth or pain. The reported incidence of adverse reactions to contrast media in patients with a history of allergy is twice that of the general population. Patients with a history of a previous reaction to a contrast agent are three times more susceptible than other patients.

**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.

For our latest news, please visit [http://newsroom.gehealthcare.com](http://newsroom.gehealthcare.com)

**Contact**
GE Healthcare
Scott Lerman
609-514-6346 (office)
609-937-9253 (mobile)
[scott.lerman@ge.com](mailto:scott.lerman@ge.com)

**Important Risk and Safety Information about Visipaque (Iodixanol) Injection**

**BOXED WARNING:** NOT FOR INTRATHECAL USE: Serious adverse reactions have been reported due to the inadvertent intrathecal administration of iodinated contrast media (CM) not indicated for such use including: death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema. Assure that Visipaque product is not administered intrathecally.

**INDICATIONS:** Intrarterial (IA): Visipaque Injection (270 mgI/mL) is indicated for IA digital subtraction angiography. Visipaque Injection (320 mgI/mL) is indicated for angiocardiology (left ventriculography and selective coronary arteriography), peripheral arteriography, visceral arteriography, and cerebral arteriography. Intravenous (IV): Visipaque Injection (270 mgI/mL and 320 mgI/mL) is indicated for computed tomography (CT)
of the head and body, excretory urography. Visipaque Injection (270 mgI/mL) also is indicated for peripheral venography. **CONTRAINDICATIONS:** Visipaque Injection is not indicated for intrathecal use. In pediatric patients prolonged fasting and administration of a laxative before Visipaque injection are contraindicated. **WARNINGS:** Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke have been reported during angiographic procedures with CM. Serious or rare fatal reactions have been associated with the administration of iodine-containing CM. Use caution in patients with severely impaired renal function (either alone or combined with hepatic or cardiac disease), severe thyrotoxicosis, myelomatosis, or anuria, especially if administering large doses. Intravascular iodinated CM are potentially hazardous in patients with multiple myeloma or other paraproteineanous diseases, who are prone to disease induced renal insufficiency and/or renal failure. Thyroid storm has been reported following intravascular use of iodinated CM in patients with hyperthyroidism or an autonomously functioning thyroid nodule. Use extreme caution administering CM to patients known, or suspected of having, pheochromocytoma. CM may promote sickling in individuals homozygous for sickle cell disease. **PRECAUTIONS: General:** CM are associated with risk and increased radiation exposure. **Dehydration, Renal Insufficiency, Congestive Heart failure (CHF):** Pre-study dehydration is dangerous and may contribute to acute renal failure in patients with advanced vascular disease, congestive heart disease, diabetic patients, and others such as those on medications that alter renal function and the elderly with age-related renal impairment. Patients should be adequately hydrated prior to and after intravascular iodinated CM. Dose adjustments in renal impairment have not been studied. Iodinated CM may cross the blood-brain barrier (BBB). In patients where the BBB is known or suspected of disruption, or in patients with normal BBB and associated renal impairment, caution must be exercised in the use of iodinated CM. Patients with CHF receiving concurrent diuretic therapy may have relative intravascular volume depletion, which may affect the renal response to the CM osmotic load. **Renal Insufficiency:** In patients with significantly impaired renal function, the total clearance of iodixanol is reduced and the plasma half-life is prolonged. In a study of 16 adult patients scheduled for renal transplant, the plasma half-life was 23 hours (normal = 2 hours). Dose adjustments in patients with renal impairment have not been studied. Visipaque does not bind to plasma or serum protein and can be dialyzed. **Immunologic Reactions:** Always consider the possibility of a reaction, including serious, life-threatening, fatal, anaphylactoid or CV reactions. **Anesthesia:** A higher incidence of adverse reactions has been reported in patients receiving general anesthesia. **Venography:** Exercise extreme caution during CM injection to avoid extravasation, especially in patients with severe arterial or venous disease. **CT:** The use of CM may obscure some lesions seen on previous unenhanced scans. **Pediatric use:** Pediatric patients at high risk of adverse reactions during and after administration of CM include those with asthma, hypersensitivity to other medications and/or allergens, cyanotic and acyanotic heart disease, CHF, or a serum creatinine > 1.5 mg/dL. Patients with immature renal function or dehydration may be at increased risk due to prolonged elimination of iodinated CM. The injection rates in small vascular beds, and the relationship of the administered volume or concentration of iodinated CM in small neonates, infants and small pediatric patients, have not been established. In pediatric patients <1 year old, the relative safety of the volumes injected, the optimal concentrations, and the potential need for dose adjustment because of prolonged elimination half-lives have not been systematically studied. In pediatric patients studied, adverse events were associated with decreasing age and IA procedures. **Geriatric use:** While no overall differences in safety or effectiveness were observed between patients >65 years old greater sensitivity of some older individuals cannot be ruled out. As Visipaque is substantially excreted by the kidney, the risk of toxic reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function. **Nursing mothers:** It is not known whether Visipaque is excreted in human milk, however, many injectable CM are excreted unchanged in human milk. Consideration should be given to temporarily discontinue nursing. **ADVERSE REACTIONS:** Serious, life-threatening and fatal reactions, mostly of cardiovascular (CV) origin, have been associated with the administration of iodine-containing CM, including Visipaque Injection. Most deaths occur during injection or five to ten minutes later. Rare reports of anaphylaxis have been documented during post-market surveillance. As with other CM, Visipaque is often associated with sensations of discomfort, warmth or pain. The reported incidence of adverse reactions to CM in patients with a history of allergy is twice that of the general population. Patients with a history of a previous reaction to CM are three times more susceptible than other patients. **DRUG
INTERACTIONS: Renal toxicity has been reported in a few patients with liver dysfunction who were given an oral cholecystographic agent followed by intravascular CM. Other drugs should not be mixed with Visipaque.

OVERDOSAGE: The adverse effects of overdose of CM may be life threatening affecting mainly the pulmonary and CV systems.

Prior to use read the Full Prescribing Information for Visipaque.

*Isovue® is a registered trademark of Bracco Diagnostics