



## **MEDIA STATEMENT**

### **Statement from GE Healthcare on Settlement with Professor Henrik Thomsen**

CHALFONT ST. GILES, UK, FEBRUARY 17, 2010-- Terms of settlement have been agreed in libel proceedings brought in London by GE Healthcare against Henrik Thomsen, Professor of Radiology at Herlev hospital, Copenhagen.

The proceedings related to a presentation Professor Thomsen gave at a "Management in Radiology" conference in Oxford in October 2007, and statements made in an article published in his name in "Imaging Management", a specialist magazine for managers in the field of radiology, in February 2008.

Professor Thomsen said today:

"My purpose was to share with fellow clinicians and healthcare professionals my experience in managing a serious problem at our hospital where we found 20 patients suffering from NSF.\* The cause was unknown, but in early 2006, it was clear to us that all of our nephrology patients with NSF had only one factor in common; they had all been exposed to Omniscan. In March 2006, after a recently published research paper reported the possibility of a link between NSF and a gadolinium based contrast agent, I discovered the agent used there was also Omniscan. After we switched contrast agent at my hospital we saw no new cases of NSF.

It was not my intention to suggest on the basis of the evidence then available to me that GE Healthcare had marketed Omniscan knowing that it might cause NSF. My comments were based on statements made by acknowledged experts in the development of gadolinium-based contrast agents, in particular the late Dr. Hanns-Joachim Weinmann, at the ISMRM (International Society for Magnetic Resonance in Imaging) symposium in Berlin in May 2007, which indicated that it had been known for many years that there was a specific risk arising from the formulation of gadodiamide.

I stand by my publicly expressed opinion, based on my experience and research on published papers that there is an association between the chemical formulation of gadolinium-based contrast agents and NSF."

Dr. Lynne Gailey, executive vice-president for communications at GE Healthcare said:

"It was not the intention of GE Healthcare by bringing proceedings for libel against Professor Thomsen to stifle academic debate. GE Healthcare objected to statements made by Professor Thomsen which it interpreted as suggesting that it had known from the outset that Omniscan caused NSF. GE Healthcare accepts, however, that Professor Thomsen's concerns were expressed



in good faith. GE Healthcare regrets that these proceedings were necessary to reach the common understanding described in this statement.

GE Healthcare has co-operated fully and actively with global healthcare authorities and promoted a robust evaluation of the safety of gadolinium-based contrast agents in Europe, the United States and elsewhere based on evidence and science. GE Healthcare welcomes the continuation of a principled dialogue about the safety of gadolinium-based contrast agents.”

**\*NOTE**

Nephrogenic Systemic Fibrosis (NSF) is an extremely rare, but debilitating, painful and, in a small percentage of cases, potentially deadly disease, which was first identified in 1997. Its cause is not fully understood but the consensus of medical opinion is that it is associated with the administration of gadolinium-based contrast agents in severely renally impaired patients. Contrast agents are injected into patients prior to MRI scans in order to obtain enhanced images.

**About Omniscan:**

**WARNING: Not for Intrathecal Use and Nephrogenic Systemic Fibrosis (NSF)**

**Not for Intrathecal Use. Inadvertant intrathecal use of OMNISCAN has caused convulsions, coma, sensory and motor neurologic deficits.**

**Nephrogenic Systemic Fibrosis (NSF). Gadolinium-based contrast agents increase the risk for nephrogenic systemic fibrosis in patients with acute or chronic severe renal insufficiency (glomerular filtration rate <30mL/min/1.73m<sup>2</sup>), or acute renal insufficiency of any severity due to the hepato-renal syndrome or in the perioperative liver transplantation period. In these patients, avoid use of gadolinium-based contrast agents unless the diagnostic information is essential and not available with non-contrast enhanced magnetic resonance imaging. NSF may result in fatal or debilitating systemic fibrosis affecting the skin, muscle and internal organs. Screen all patients for renal dysfunction by obtaining a history and/or laboratory tests. When administering a gadolinium-based contrast agent, do not exceed the recommended dose and allow a sufficient period of time for elimination of the agent from the body prior to any readministration.**

The most frequent adverse events observed during OMNISCAN clinical trials in 1,369 patients, at doses between 0.025 mmol/kg and 0.3 mmol/kg, were headache, dizziness, and nausea. The majority of these adverse events were of mild to moderate intensity. The possibility of a reaction, including serious, life-threatening, fatal, anaphylactoid, or cardiovascular reactions, or other idiosyncratic reaction, should always be considered, especially in those patients with a known clinical hypersensitivity. Refer to the boxed warning section of the Prescribing Information for acute or chronic severe renal insufficiency since OMNISCAN is cleared from the body by glomerular filtration. Patients with a history of allergy or drug reaction should be observed for several hours after administration.