Immediate Release
Contact:
Mark Weller, 202.408.3933
Mark.Weller@snrdenton.com

ICUS Pleased by FDA Modification of Boxed Warnings on Additional Ultrasound Contrast Agents

WASHINGTON, DC -- The International Contrast Ultrasound Society (ICUS) today applauded the FDA's decision to modify the U.S. product label for OPTISON®, an ultrasound contrast agent used to improve the accuracy of radiation-free ultrasound scans. OPTISON® is marketed by GE Healthcare.

The label change was supported by a Citizen Petition filed by ICUS in October, citing newer scientific studies showing the superior safety profile of ultrasound contrast agents along with their favorable risk-benefit ratios. The Citizen Petition, which was granted in part by the FDA last week, also supported a prior modification of the label for DEFINITY®, an ultrasound contrast agent marketed by Lantheus Medical Imaging.

The FDA's actions are "an important step forward for patients and for our health care system," said Dr. Steven Feinstein, a cardiologist at Rush University Medical Center in Chicago and ICUS Co-President.

Ultrasound contrast agents are administered intravenously during a noninvasive ultrasound scan to improve image clarity. The procedure does not expose patients to ionizing radiation, and ultrasound contrast agents do not contain dye or increase a patient's risk of nephrotoxicity, according to Dr. Feinstein.

"Ultrasound contrast agents are exceedingly safe and completely radiation-free diagnostic imaging tools," he said. "By improving the reliability of a simple front-line ultrasound scan, ultrasound contrast agents also may reduce the need for redundant, expensive and potentially riskier downstream testing - thereby improving patient care while also reducing the overall cost of diagnostic imaging."

The FDA's decision also will spare many patients from the cumulative effects of ionizing radiation that are inherent in certain alternative forms of diagnostic imaging, including SPECT and CT, according to Dr. Michael Main, an expert in contrast ultrasound safety and Treasurer of ICUS. Dr. Main also is a cardiologist and director of the echocardiography laboratory at Saint Luke's Mid-America Heart Institute in Kansas City.

"The FDA decision should lead to increased use of contrast, better imaging studies, better diagnosis for patients, and saved lives," Dr. Main added.

Main said that although the FDA retained boxed warnings on both ultrasound contrast agents, newer safety data demonstrate a more favorable risk-benefit profile that ultimately may warrant additional label changes with removal of the boxed warnings.

"Still, the current label modification for OPTISON® represents significant progress based on sound scientific evidence and now more accurately reflects the risk benefit profile."

The OPTISON® label no longer requires 30 minutes of monitoring after drug administration and notes that serious cardiopulmonary reactions are uncommon.

ICUS has long held that, given the strong safety profile of ultrasound contrast agents, boxed warnings on these products are inconsistent with the FDA's own standards for use of boxed warnings and stand in direct opposition to the FDA's statutory responsibility to protect the health of the American public.

ICUS, which has members in 59 countries, represents cardiologists, radiologists, and other physicians and imaging professionals who use CEUS imaging.

ABOUT ICUS: ICUS is an international, multi-disciplinary, not-for-profit medical society that is exclusively dedicated to advancing the use of contrast enhanced ultrasound diagnostic imaging to improve patient care worldwide. Founded in September 2008, ICUS brings together physicians, scientists, and other ultrasound imaging professionals from over 55 countries. ICUS members represent diverse specialties such as cardiology, radiology, vascular imaging, gastro-intestinal imaging, oncology, OB-GYN, and hepatology. For more information about ICUS, please visit www.icus-society.org

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