

U-SYSTEMS ANNOUNCES COMPLETION OF PIVOTAL STUDY SUPPORTING FDA SUBMISSION FOR ULTRASOUND BREAST CANCER SCREENING INDICATION

ROC Reader Study conducted by University of Chicago

SUNNYVALE, Calif. - U-Systems, the leader in automated breast ultrasound today announced the completion of a pivotal ROC Reader Study for automated breast ultrasound cancer screening. Conducted by University of Chicago, an acclaimed pioneer in women's health research, the multi-reader, multi-case (MRMC) ROC Reader Study was carried-out to evaluate the sensitivity of somo•v™ Automated Breast Ultrasound (ABUS) together with a screening mammogram in detecting breast cancer in women with dense breast tissue.

“For most women, mammography remains the gold standard for the early detection of breast cancer, but multiple studies have demonstrated that it is not enough for women with dense breast tissue,” said study principal investigator Maryellen Giger, Ph.D., Professor of Radiology at the University of Chicago. “The primary objective of this reader study was to determine the impact of ABUS on Reader (interpreting physician) performance when used in combination with mammography as a screening modality for asymptomatic women with dense breast tissue. This study brings us one step closer to earlier detection of breast cancer using ultrasound as an adjunctive screening tool.”

“The reader study data will provide the scientific and statistical foundation to validate the efficacy of our ABUS technology and will be used as the basis for our Pre-Market Application (PMA) submission to the U.S. Food & Drug Administration,” said Ron Ho, president and CEO of U-Systems.

Successful completion of this key milestone keeps U-Systems on schedule for an FDA submission in which the company will seek a new indication for the use of somo•v ABUS for use in screening women with dense breast tissue. The somo•v is currently FDA 510(k)-cleared for adjunctive diagnostic use with mammography.

The Reader Study cases were collected under the SOMO•INSIGHT Clinical Study, which is the largest prospective clinical trial ever undertaken by an ultrasound company. The SOMO•INSIGHT Clinical Study was designed to evaluate whether digital mammography in combination with somo•v ABUS is more sensitive than a routine screening mammogram alone in detecting breast cancer in women with dense breast tissue. To date, more than 12,000 women have participated in the study which is actively recruiting up to 20,000 women at multiple breast imaging centers nationwide. To date, the study has identified a significant number of mammographically negative breast cancers that were subsequently detected by ABUS

“While ultrasound is a proven tool throughout the diagnosis and treatment of breast cancer, it has not typically been used during the screening process. However, for women with dense breast tissue several large studies have shown that supplementing mammograms with ultrasound can increase detection from 48 to 97 percent,” added Ho. “New approaches to improve early detection in women with dense breasts are clearly needed. We have dedicated significant time and resources to establishing a solid scientific basis for the use of ABUS as a cancer screening tool for women with dense breast tissue.”

A growing body of research demonstrates a strong link between breast density and increased cancer risk; up to 4-6 times in one study (Boyd, et al. New England Journal of Medicine 2007;356:227-36M). The study, published in the New England Journal of Medicine, showed 35 percent of breast cancer goes undetected by mammography in women with dense breasts as density masks the appearance of tumors. Since both dense breast tissue and cancer appear white on a mammogram, it is difficult to detect cancer when there is increased dense breast tissue. As breast density increases, the accuracy of the mammogram decreases.

About the University of Chicago Medical Center

The University of Chicago Hospitals and Health System, of Chicago, Il., has been at the forefront of medicine for decades – quietly delivering extraordinary care to patients who come from all parts of the world. The Health System was selected by U.S. News & World Report as one of the best hospitals in the United States. Additional information can be found at www.uchospitals.edu.

About U-Systems

U-Systems is the leader in developing automated breast ultrasound systems and the sponsor of the SOMO•INSIGHT multi-center study that will enroll up to 20,000 women at clinical study sites in the United States to determine the sensitivity of mammography and sono•v Automated Breast Ultrasound Systems (ABUS) together, compared to mammography alone for women with greater than fifty percent dense breast tissue. The U-Systems sono•v Automated Breast Ultrasound System (ABUS) is currently cleared under 510(k), indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of a patient's breast when used with an automatic scanning linear array transducer. The device is not intended to be used as a replacement for screening mammography. For more information, please visit our website at <http://www.u-systems.com>.

#

MEDIA CONTACT:

Chris K. Joseph or Diana Soltesz
510/435-4031 or 818/592-6747
chris@ckjcomm.com or diana@dsmmmedia.com