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New England Journal of Medicine Study Shows Hologic Computer-Aided Detection Could Improve Rate of Cancer Detection in Screening Mammography

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U.K. Study Suggests that Where Single Reading is Standard Practice, R2 CAD has the Potential to Improve Cancer-Detection Rates to the Level Achieved by Double Reading

BEDFORD, Mass., Oct. 2, 2008 [/PRNewswire-FirstCall/](#) -- Hologic, Inc. (NASDAQ: HOLX), a leading developer, manufacturer and supplier of premium diagnostics, medical imaging systems and surgical products dedicated to serving the healthcare needs of women, today announced the positive results of a study to be published October 16, 2008 in the New England Journal of Medicine involving its R2 Computer-Aided Detection (CAD) system¹. The study was published in the on-line version of the Journal yesterday (<http://content.nejm.org/cgi/content/full/NEJMoa0803545>). In this prospective, multi-center clinical trial, researchers compared the cancer detection rate for single reading of screening mammograms with CAD input versus double reading without CAD support.

Interpretation by two readers (double reading) rather than one reader is known to improve the cancer detection rate. The study's authors stated that "Where single reading is standard practice, computer-aided detection has the potential to improve cancer detection to the level achieved by double reading."

In the study, lead author Dr. Fiona Gilbert and her colleagues in the United Kingdom analyzed the screening results from 31,057 women undergoing routine screening by film mammography and found that a single reader with Hologic's R2 CAD system produced comparable cancer detection rates (87.2%) to double reading (87.7%) without CAD. Although single reading with CAD produced a higher recall rate (3.9%) than double reading (3.4%), they concluded that despite this difference, "Single reading with computer-aided detection could be an alternative to double reading and could improve the rate of detection of cancer from screening mammograms read by a single reader."

"Double reading is a method for increasing cancer detection commonly used in European screening programs. However, it is used by few practices in the United States because it is time-consuming and because of a shortage of radiologists focused on breast imaging," said Ronald A. Castellino, MD, FACR, Chief Medical Officer for Hologic. "These results indicate that in the United States, where single reading of mammograms is most common, Hologic's R2 CAD system can provide an improvement in cancer detection rates comparable to those achieved with double reading. This important study, combined with prior published research studies, further supports the use of the R2 CAD system to increase cancer detection."²

The strengths of this study are that it was a multicenter, prospective trial involving more than 30,000 women and that the high volume readers (reading more than 5,000 mammograms per year) were unaware of their reading assignments.

About Hologic, Inc.

Hologic, Inc. is a leading developer, manufacturer and supplier of premium diagnostics, medical imaging systems and surgical products dedicated to serving the healthcare needs of women. Hologic's core business units are focused on breast health, diagnostics, GYN surgical, and skeletal health. Hologic provides a comprehensive suite of technologies with products for mammography and breast biopsy, radiation treatment for early-stage breast cancer, cervical cancer screening, treatment for menorrhagia, osteoporosis assessment, preterm birth risk assessment, mini C-arm for extremity imaging, and molecular diagnostic products including reagents for a variety of DNA and RNA analysis applications.

Forward Looking Statement Disclaimer

This News Release may contain forward-looking information that involves risks and uncertainties, including statements about the effect of the use of Computed-Aided Detection, or CAD, technology (as utilized in Hologic's R2 ImageChecker CAD system) in mammography screening. There can be no assurance that the effects demonstrated in the study described herein will be replicated in any particular manner with respect to an individual patient as the actual effect of the use of CAD technology in mammography screenings can only be determined on a case-by-case basis depending on the particular circumstances of the exam and patient in question. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to the data or statements presented herein to reflect any change in Hologic's expectations or any change in events, conditions or circumstances on which any such data or statements are based. Certain factors that could adversely affect Hologic's business and prospects are described in Hologic's filings with the Securities and Exchange Commission.

¹ Fiona J. Gilbert, F.R.C.R., Susan M. Astley, Ph.D., Maureen G. C. Gillan, Ph.D., Olorunsolo F. Agbaje, Ph.D., Matthew G. Wallis, F.R.C.R., and Stephen Duffy, M.Sc. for the CADET II Group, "Single Reading with Computer-Aided Detection for Screening mammography", The New England Journal of Medicine, 359: 16, Oct. 16, 2008, pp. 1675-1684.

2 A bibliography of published peer-reviewed studies is posted on the Hologic web site <http://www.hologic.com/wh/pdf/2008-02-19-R2-CAD-Bibliography.pdf>

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