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Hologic Receives FDA Approvable Letter for Selenia Dimensions (3-D) Digital Mammography Tomosynthesis System

PR Newswire
BEDFORD

BEDFORD, Mass., Nov. 23, 2010 /PRNewswire-FirstCall/ -- Hologic, Inc. (Hologic or the Company) (Nasdaq: HOLX), a leading developer, manufacturer and supplier of premium diagnostics products, medical imaging systems and surgical products dedicated to serving the healthcare needs of women, announced today that Hologic has received an approvable letter from the U.S. Food and Drug Administration (FDA) for the Selenia Dimensions three-dimensional (3-D) digital mammography tomosynthesis system. Final approval of the Company's pre-market approval application for the system remains subject to satisfactory review and inspection of our manufacturing facility, methods and controls. The Company plans to work closely with the FDA to complete this final inspection.

"We are extremely pleased to have received the FDA's approvable letter, which represents an important step forward in the commercialization of our Selenia Dimensions tomosynthesis system," said Rob Cascella, President and Chief Executive Officer. "The Selenia Dimensions technology is designed to provide radiologists with enhanced screening and diagnostic capabilities through the incorporation of fast, high-quality 3-D imaging in combination with 2-D imaging. We believe this new technology will address many of the limitations present in stand-alone 2-D imaging and improve upon both sensitivity and specificity. We look forward to working with the FDA to complete the remaining steps in the approval process."

Hologic's Selenia Dimensions 3-D digital mammography system is a new method for breast cancer screening and diagnosis. Unlike prior-generation mammography systems which generate two-dimensional images, breast tomosynthesis produces three-dimensional images which are intended to reveal the inner architecture of the breast, free from the distortion typically caused by tissue shadowing or density.

Hologic's Selenia Dimensions 3-D system is available commercially in more than a dozen countries outside the United States, including countries in Europe, Latin America and Asia. In North America, commercial systems are installed in Canada and Mexico.

Press Conference

Hologic management will hold a press conference to discuss Selenia Dimensions technology on Monday, November 29th from 1:30 to 2:00 p.m. (Central Time) at the Radiological Society of North America (RSNA) meeting in Chicago. The RSNA News Conference room is located in the McCormick Place Lakeside Center, Level 2, in room E252. This press conference is for members of the press only. Those interested in attending the press conference will need to register through the RSNA newsroom onsite or contact Linda Brooks at (630) 590-7762 or lbrooks@rsna.org.

About Hologic, Inc.

Hologic, Inc. is a leading developer, manufacturer and supplier of premium diagnostics products, 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, breast magnetic resonance imaging, radiation treatment for early-stage breast cancer, cervical cancer screening, treatment for menorrhagia, permanent contraception, osteoporosis assessment, preterm birth risk assessment, mini C-arm for extremity imaging and molecular diagnostic products including HPV and reagents for a variety of DNA and RNA analysis applications. For more information, visit www.hologic.com.

Hologic, Dimensions and Selenia, and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries.

Forward Looking Disclaimer

This News Release contains forward-looking information that involves known and unknown risks and uncertainties, including statements about Hologic's Selenia Dimensions digital breast tomosynthesis system, including the anticipated benefits of that system and the FDA approval process for that system. The Company cannot assure that the system will achieve the anticipated benefits described herein, or that such benefits will be replicated in any particular manner with respect to an individual patient as the actual effect of the use of the system can only be determined on a case-by-case basis depending on the particular circumstances and patient in question. Among other things, newly introduced products may contain undetected errors or defects or otherwise not perform as anticipated. The anticipated FDA approval process can be modified at any time. Moreover, Hologic cannot predict the outcome of the FDA review, and there can be no assurance that the FDA will approve Hologic's Selenia Dimensions 3-D system on a timely basis, if at all. In addition, even

if approved, the FDA could impose conditions to such approval that would significantly limit the use or commercialization of the system. The risks and uncertainties included above are not exhaustive. Other factors that could adversely affect the Company's business and prospects are described in the Company's filings with the Securities and Exchange Commission. 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 the Company's expectations or any change in events, conditions or circumstances on which any such data or statements are based.

Contact:

Deborah Gordon
Vice President, Investor Relations
Hologic, Inc.
Deborah.gordon@hologic.com
(781) 999-7716

Olga Karagiannis
Corporate Marketing
Hologic, Inc.
Olga.karagiannis@hologic.com
(781) 761-7069

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