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Hologic Receives FDA 510(k) Clearance of Quantra™ 2.2 Breast Density Assessment Software

--Latest addition to market-leading portfolio of innovative breast and skeletal health solutions to be featured at RSNA 2017--

MARLBOROUGH, Mass., Nov. 24, 2017 /PRNewswire/ -- Hologic, Inc. (Nasdaq: HOLX) announced today that it has received 510(k) clearance from the United States Food and Drug Administration (FDA) for its Quantra™ 2.2 Breast Density Assessment Software, which enables clinicians to provide women with consistent breast density assessments during routine breast cancer screenings.

The software is one of several groundbreaking products that will be available for demonstration in Hologic's booth (#4705) at the 103rd Scientific Assembly and Annual Meeting of the Radiological Society of North America (RSNA) at McCormick Place in Chicago from Nov. 26 to 30.

Through a proprietary algorithm powered by machine learning, Quantra software analyzes mammography images for distribution and texture of breast tissue, delivering clinicians patient-specific breast density assessment. Quantra software categorizes breasts into four categories of density, in alignment with the ACR BI-RADS® Atlas 5th Edition.[1,2]

Nearly half of women between the ages of 40 and 74 have dense breasts, which can make it difficult to detect breast cancer during annual screenings and lead to additional imaging, resulting in increased patient anxiety and unnecessary facility costs.[3,4] Perhaps most importantly, women with very dense breasts are four to five times more likely to develop breast cancer than women with less dense breasts.[5,6] Breast density is only identifiable on a mammogram or other screening modality, and has historically been determined by the radiologist who reads the image. With Quantra software, clinicians can feel confident they are providing their patients with an unbiased breast density assessment that removes the potential for visual subjectivity.

"As the global leader in breast cancer screening technology, we relentlessly pursue the development of clinically superior products that address the unmet and changing needs of our customers and their patients, especially when it comes to breast density," said Pete Valenti, Hologic's Division President, Breast and Skeletal Health Solutions. "Quantra software is yet another example of our dedication and we are proud to feature it – along with a number of other new, breakthrough products – for the world's leading radiologists at RSNA this week."

Earlier this year, Hologic's Genius™ 3D Mammography™ exam became the only mammogram approved by the FDA as superior to standard 2D mammography for routine breast cancer screening for women with dense breasts.[7] The updated labeling was based on clinical studies proving that the exam improves invasive breast cancer detection while reducing unnecessary recalls among women of all breast densities. The expanded labeling provides clarity for physicians who previously were unsure how to screen patients with dense breasts.

Quantra software is available for use with Hologic® 3D Mammography™ systems, including the new 3Dimensions™ mammography system, which is designed to be the fastest, highest resolution breast tomosynthesis system ever, with the Intelligent™ 2D imaging technology.[8,9] On display at RSNA for the first time, the 3Dimensions system offers a variety of features designed to provide higher quality 3D™ images for radiologists, enhanced workflow for technologists, and a more comfortable

mammography experience, with low-dose options, for patients.[9]

In addition to the 3Dimensions system, RSNA attendees can experience Hologic's comprehensive portfolio of breast and skeletal health products designed to deliver improved patient satisfaction, better clinician workflow and facility cost savings. They can also visit Hologic's "New Product Theater," where representatives from the Company's screening, interventional and skeletal teams will present every hour during exhibition times. Presentations will feature new products including the 3Dimensions system, Brevera® breast biopsy system with CorLumina® imaging technology, and Fluoroscan® InSight™ FD Mini C-Arm extremities imaging system, all of which will be showcased on the exhibit floor.

Throughout the show, Hologic will host a number of interactive workshops and educational symposia, two of which will address the impact that breast tomosynthesis and breast density assessment software can have on clinicians and women with dense breasts. Additional workshops will focus on topics including contrast-enhanced 2D mammography, advancements in 3D™ Mammography, and 3D™ image-guided biopsy solutions. For more information or to RSVP, please visit HologicRSNA.com or stop by Hologic's Booth #4705.

RSNA is an international society of radiologists, medical physicists and other medical professionals with 55,000 members from more than 140 countries. The RSNA Annual Meeting is expected to attract more than 60,000 attendees.

The Genius™ 3D Mammography™ exam (also known as the Genius ™ exam) is only available on a Hologic® 3D Mammography™ system. It consists of a 2D and 3D™ image set, where the 2D image can be either an acquired 2D image or a 2D image generated from the 3D™ image set. There are more than 4,000 Hologic 3D Mammography™ systems in use in the U.S. alone, so women have convenient access to the Genius exam. To learn more about the Genius exam, visit http://www.Genius3DNearMe.com.

The Quantra™ software requires the Hologic® Cenova Server and minimal technical specs. Hologic Cenova and Quantra™ products are only available on Hologic® mammography systems.

About Hologic, Inc.

Hologic, Inc. is an innovative medical technology company primarily focused on improving women's health and well-being through early detection and treatment. For more information on Hologic, visit www.hologic.com.

Forward-Looking Statements

This news release may contain forward-looking information that involves risks and uncertainties, including statements about the use of Hologic products. There can be no assurance these products will achieve the 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 products can only be determined on a case-by-case basis. In addition, there can be no assurance that these products will be commercially successful or achieve any expected level of sales. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements presented herein to reflect any change in expectations or any change in events, conditions or circumstances on

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This information is not intended as a product solicitation or promotion where such activities are prohibited. For specific information on what products are available for sale in a particular country, please contact a local Hologic sales representative or write to womenshealth@hologic.com.

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[1] FDA 510(k) K163623

[2] Understanding Quantra™ (Version 2.2) User Manual

[3] Ho JM, Jafferjee N, Covarrubias GM, Ghesani M, Handler B. Dense breasts: a review of reporting legislation and available supplemental screening options. AJR Am J Roentgenol. 203(2):449-56, 2014.

[4] Sprague BL, Gangnon RE, Burt V, et al. Prevalence of mammographically dense breasts in the United States. J Natl Cancer Inst. 106(10), 2014.

[5] Boyd NF, Guo H, Martin LJ, et al. Mammographic density and the risk and detection of breast cancer. N Engl J Med. 356(3):227-36, 2007.

[6] Yaghjyan L, Colditz GA, Collins LC, et al. Mammographic breast density and subsequent risk of breast cancer in postmenopausal women according to tumor characteristics. J Natl Cancer Inst. 103(15):1179-89, 2011.

[7] U.S. Food & Drug Administration Premarket Approval (PMA). FDA.gov https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P080003S005 accessed June 5, 2017.

[8] Data on file

[9] Upon FDA approval and/or commercial availability.

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