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FDA Pre-Market Approval Announced for Hologic 3D Digital Mammography

Hologic, Inc., a developer, manufacturer and supplier of premium diagnostics products, medical imaging systems and surgical products dedicated to serving the healthcare needs of women, announced that the Radiological Devices Panel (Panel) of the U.S. Food and Drug Administration (FDA) today unanimously voted that Hologic's Pre-Market Approval (PMA) demonstrated both the effectiveness and safety of the Company's Selenia Dimensions three-dimensional (3D) digital mammography tomosynthesis system, "Selenia Dimensions 3D." In addition, the Panel voted in favor that the benefits of this new technology outweigh the risks.

Following today's FDA Panel meeting, which was held in Gaithersburg, Maryland, Hologic will work with the FDA on next steps for approval of its 3D digital mammography system. While the Panel's favorable vote is advisory in nature, the FDA will consider it in its final review of Hologic's PMA application for the Selenia Dimensions tomosynthesis system.

"Our Selenia Dimensions 3-D technology marks tremendous progress in the early diagnosis of breast cancer," said Jay A. Stein, Co-Founder and Chief Technical Officer. "The system is designed to increase accuracy when screening women for the presence of cancerous tissue, and to enable a more precise characterisation of suspicious lesions. I speak for all of Hologic in voicing great satisfaction that the FDA Panel has weighed in so positively in favor of this valuable new tool in the battle to limit breast cancer mortality."

Hologic's Selenia Dimensions 3D digital mammography tomosynthesis system is a new method for breast cancer screening and diagnosis. Unlike current mammography systems, which generate a two-dimensional (2D) image, breast tomosynthesis produces a three-dimensional image. We believe our multicenter clinical study has demonstrated that compared to 2D digital mammography alone, 3D digital tomosynthesis used in combination with 2D digital mammography has the potential to reduce recall rates and improve cancer detection.

Hologic's Selenia Dimensions 3D digital mammography tomosynthesis system is presently commercially available outside the United States, including countries in Europe, Latin America and Asia. In North America, commercial systems are installed in Canada and Mexico. In the United States, Selenia Dimensions is currently available as a two dimensional only system that can be upgraded to do breast tomosynthesis (3D) imaging when and if the product is approved by the FDA.

"We are extremely pleased with the outcome of today's FDA Panel meeting," said Rob Cascella, President and Chief Executive Officer. "Hologic has worked diligently on the development of breast tomosynthesis to overcome the primary limitation of the existing 3D imaging technology, which is that the superimposition of normal breast anatomy may mask a breast cancer. Our Selenia Dimensions platform represents the next phase in breast cancer detection - fast, high-quality 2D and 3D digital tomosynthesis imaging of the breast. We look forward to working with the FDA to help complete the review process and bring this important new tool to radiologists to help save more women's lives."

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