

Newly Published Results Reveal a Significant Proportion of Early-Stage HR+ Breast Cancer Survivors May Be Over- or Undertreated Without Breast Cancer Index Genomic Testing

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Results From a Large-Scale Prospective Study Investigating Long-Term Anti-Estrogen Therapy Recommendations
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MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Hologic, Inc. (Nasdaq: HOLX) and its subsidiary, Biotheranostics, Inc., today announced newly published study results revealing that use of the Breast Cancer Index® (BCI) test led to physicians changing their long-term anti-estrogen treatment recommendations for 40% of patients with early-stage hormone receptor-positive (HR+) breast cancer.¹ The results, which suggest that many women may be over- or undertreated without the incorporation of BCI, reflect real-world data from the largest prospective study assessing the impact of the BCI test on treatment decisions. The study was published in the March issue of the JNCCN — Journal of the National Comprehensive Cancer Network.

Previous studies have demonstrated that while some women with early-stage HR+ breast cancer may reduce their risk of recurrence with longer anti-estrogen therapy (10 vs. 5 years), most women do not benefit.²⁻⁷ The BCI test is the only genomic test recognized by multiple national oncology guidelines to predict which women are likely to benefit from continuing anti-estrogen therapy beyond five years, helping optimize the duration of treatment.

The key results from the JNCCN-published study underscore the value of BCI in helping to avoid:

- Overtreatment: Of the physician treatment decisions that changed, 63% changed from a YES to a NO recommendation for extended anti-estrogen therapy. This finding suggests a critical role of BCI in helping identify women whose treatment may be discontinued after the first five years to avoid potential side effects

and toxicities associated with longer anti-estrogen therapy.

- **Undertreatment:** The remaining 37% of changes in treatment decisions by physicians were from a NO to a YES recommendation for extended anti-estrogen therapy. This result highlights an equally important use of BCI: to identify women who may benefit from longer treatment to help avoid a potentially life-threatening metastatic recurrence when extended therapy may not have been previously recommended based on clinical and pathologic risk features alone.

“These results further reinforce the impact of the Breast Cancer Index test in clinical practice. For many physicians, the test results changed their recommendations for prescribing or not prescribing extended anti-estrogen therapy for patients based on the predictive benefit,” said Tara Sanft, M.D., the study’s primary author, Associate Professor of Medicine at Yale School of Medicine and Chief Patient Experience Officer at Smilow Cancer Hospital. “As clinicians, we always strive to give our patients the best clinical advice possible. The Breast Cancer Index helps us prevent over- and undertreatment for extended anti-estrogen therapy and is an incredibly helpful tool, giving us more confidence in our treatment decisions for breast cancer patients.”

Patients and physicians included in this study are participants in the BCI Registry Study. The BCI Registry Study is a prospective, large-scale, multi-center study that investigates long-term clinical outcomes, decision impact and medication adherence in patients with early-stage HR+ breast cancer receiving BCI testing as part of routine clinical care. The study concluded with the enrollment of over 3,000 patients who will continue to be followed until 10 years from diagnosis. The current publication reports results assessing the impact of BCI on clinical decision-making regarding extended anti-estrogen therapy in the first 1,000 patients enrolled in the BCI Registry Study.

Cancer patients look to their oncology care teams as experts for guidance in recommending the most appropriate treatment plan tailored to their individual health and needs. Ultimately, the newly published findings reveal that when incorporated into routine clinical care, BCI has the potential to provide clinicians with greater confidence in their treatment recommendations, with 39% of providers saying they felt more confident in their recommendation for extended anti-estrogen therapy following BCI testing. Additionally, BCI testing led to 41% of patients feeling more comfortable with their treatment decisions and 45% changing their preference regarding an additional five years of anti-estrogen therapy.

“For over 35 years, Hologic has been developing diagnostic solutions that are rooted in science and backed by robust clinical data. Alongside our portfolio of Breast and Skeletal Health Solutions, I’m proud of how Hologic’s Diagnostic Solutions division, through Biotheranostics, continues to transform the breast cancer care continuum for women and providers,” said Jennifer Schneiders, Ph.D., President of Diagnostic Solutions at Hologic. “As more research is published, I’m thrilled to see the continued, impressive utility of the Breast Cancer Index test. As seen in the results of this study, for women with early-stage hormone receptor-positive breast cancer, this test has the potential to reinforce the importance of the medication they are taking — or to allow them to discontinue



treatment without fear of reoccurrence.”

About the Breast Cancer Index Test

The Breast Cancer Index test is a molecular, gene expression-based test uniquely positioned to provide information to help physicians individualize treatment decisions for patients with early-stage HR+ breast cancer. This breakthrough test helps oncologists and patients navigate the difficult trade-offs between taking steps to prevent recurrence of their disease and facing significant side effects and safety challenges related to unnecessary treatment. The Breast Cancer Index test has guideline designation from the American Joint Committee on Cancer (AJCC) for cancer staging based on molecular profile. The American Society of Clinical Oncology (ASCO), the European Group on Tumor Markers (EGTM) and the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) acknowledge the Breast Cancer Index test as a biomarker to inform the extended endocrine treatment decision; and ASCO, EGTM and St. Gallen acknowledge the Breast Cancer Index test as a biomarker to inform the chemotherapy decision.⁸ BCI is the only validated, commercially available test that predicts the benefit from extended endocrine therapy.

The Breast Cancer Index test is intended for routine clinical use and treatment decisions based on results are the responsibility of the physician. It is a laboratory developed test (LDT) performed in a single CLIA-certified and CAP-accredited diagnostic laboratory. For more information, visit www.breastcancerindex.com.

About Hologic, Inc.

Hologic, Inc. is a global medical technology innovator focused on improving the health and well-being of women, their families and communities through early detection and treatment. Its advancements include invention of the world's first commercial 3D mammography system to find breast cancer earlier; leadership in testing for cervical cancer, sexually transmitted infections and respiratory illnesses; and minimally invasive surgical technologies for uterine fibroids and abnormal uterine bleeding.

The company also champions women through the **Hologic Global Women's Health Index**, which provides a science-backed data framework for improving women's well-being.

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,



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8Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.4.2023.© National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed December 15, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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