



PRESS RELEASE

Agendia's MammaPrint® Recommended by ASCO Breast Cancer Guideline in Focused Update Based on Landmark MINDACT Trial Data

- ASCO® recommends MammaPrint® for clinical high risk, hormone receptor-positive, HER2-negative breast cancer, to inform decisions on withholding chemotherapy
- ASCO recommends MammaPrint as currently the only genomic test to be used to guide treatment decisions for 1-3 lymph node positive early-stage breast cancer patients
- Revised ASCO Guidelines mark the fourth positive international guideline update for MammaPrint in 2017, recognizing the highest level of clinical evidence provided by MINDACT

IRVINE, CA and AMSTERDAM – 10 July 2017 - Agendia, Inc., a world leader in personalized medicine and molecular cancer diagnostics, announces that the American Society of Clinical Oncology (ASCO®) has today published revised early-stage breast cancer guidelines in the *Journal of Clinical Oncology*, titled *The Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy for Women with Early Stage Invasive Breast Cancer: American Society of Clinical Oncology Practice Guideline*.¹

This focused update is dedicated exclusively to Agendia's MammaPrint® 70-Gene Breast Cancer Risk-of-Recurrence Test and was triggered by the practice-changing data from the randomized, prospective, phase III MINDACT trial which was published in August 2016.²

In a significant update to the 2016 guidelines, the ASCO panel identified MammaPrint as currently the only genomic test to be considered to inform treatment decisions in women with estrogen receptor-positive or progesterone receptor-positive, HER2-negative breast cancer with lymph node negative, or one to three positive lymph nodes who are at a high clinical risk of recurrence. For these patients, MammaPrint is now recommended by the ASCO Guidelines to inform decisions on withholding adjuvant (post-surgery) systemic chemotherapy due to its ability to identify patients with a good prognosis with limited chemotherapy benefit.

This is the first time that ASCO has recommended a genomic test to inform treatment decisions in withholding chemotherapy for lymph node positive patients, for whom lymph node involvement often causes them to be classified at high clinical risk and requiring chemotherapy. It is noted that such patients "should be informed that a benefit of chemotherapy cannot be excluded, particularly in patients with greater than one involved lymph node."

Dr. William Audeh, Chief Medical Officer at Agendia said:

"This is a significant update to the ASCO guideline and testament to the clinical utility of the MammaPrint test as demonstrated in the MINDACT trial. MammaPrint is the only breast cancer genomic test that has been validated in a truly clinically high risk (luminal B) cohort of patients, providing physicians and their patients with unique genomic information to help personalize how their treatment is managed. The ASCO panel stated that reduction of overtreatment is an important goal, and confirmed the utility of MammaPrint in achieving this.



“This is the second guideline update for MammaPrint in three weeks. Based on MINDACT, both ASCO and the St. Gallen panel have now endorsed this test for both lymph-node negative and lymph node positive patients. Indeed, each of the four guidelines which included a review of the published findings of this unique trial so far this year have added or expanded their recommendation of MammaPrint,” said Dr. Audeh.

Mark R. Straley, Chief Executive Officer at Agendia said:

“I am very pleased to see MammaPrint recommended by the updated ASCO guidelines. This will enable a whole new group of lymph-node positive patients to benefit from genomic testing, and not have their complex treatment decisions based entirely on clinical factors alone. At Agendia we are dedicated to improving the quality of life for early-stage breast cancer patients. ASCO’s recommendation is a powerful force in helping to extend the benefits of MammaPrint to reach many more women.”

MammaPrint is currently the only genomic breast cancer risk-of-recurrence test backed by level 1A prospective, randomized evidence to support the de-escalation of chemotherapy in patients who are classified as clinically high risk. As stated in the ASCO guidelines, “the reduction of overtreatment in patients with early-stage breast cancer is an important goal [...] such a reduction would likely have the greatest societal and individual impact in patients with ER/PgR–positive disease.”

The ASCO guidance on the use of biomarkers in early-stage breast cancer supports the position of the recently-published biennial 2017 St. Gallen International Breast Cancer Guidelines that there is “no role for gene testing in clinical pathological low risk cases”³, which are mostly node-negative, lower grade and smaller tumors (high estrogen receptor-positive, grade 1-2 and less than or equal to 2 cm).

MammaPrint was recognized as being supported by the highest level of clinical evidence by both the German Gynecological Oncology Group (AGO) and the European Group on Tumor Markers (EGTM) in March 2017. The test is also recommended for use in other important oncology practice guidelines including those of the European Society for Medical Oncology (ESMO), and several national guidelines in Europe.

You can access *The Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy for Women with Early Stage Invasive Breast Cancer: American Society of Clinical Oncology Practice Guideline* from the Journal of Clinical Oncology here: <http://ascopubs.org/doi/full/10.1200/JCO.2017.74.0472>

¹ [Krop I, Ismaila N, Andre F et al. Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy for Women With Early-Stage Invasive Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline Focused Update. DOI: 10.1200/JCO.2017.74.0472 Journal of Clinical Oncology - published online before print July 10, 2017](#)

² [Cardoso F, van't Veer LJ, Bogaerts J et al. 70-Gene Signature as an Aid to Treatment Decisions in Early-Stage Breast Cancer. N Engl J Med 2016; 375: 717-29.](#)

³ [Curigliano G, Burnstein H, Winer E et al. De-escalating and Escalating Treatments for Early Stage Breast Cancer: The St. Gallen International Expert Consensus Conference on the Primary Therapy of Early Breast Cancer 2017. Ann Oncol 2017 mdx308.](#)



About MINDACT

The Microarray In Node-negative and 1 to 3 positive lymph node Disease may Avoid ChemoTherapy (MINDACT) trial (EORTC 10041/BIG 3-04) is an independent, prospective, randomized, phase III, controlled clinical trial that investigated the clinical utility of MammaPrint, when used in conjunction with standard clinical pathological criteria, for the selection of patients unlikely to benefit from adjuvant chemotherapy.

From 2007 to 2011, 6,693 women who had undergone surgery for early-stage breast cancer enrolled in the trial, across 112 centers in nine countries. The results were published in the prestigious New England Journal of Medicine in August 2016.

About MammaPrint

MammaPrint is an *in vitro* diagnostic test, performed in a central laboratory, using the gene expression profile of breast cancer tissue samples to assess a patients' risk for distant metastasis. MammaPrint is cleared by the US FDA and carries the CE Mark which certifies that the test complies with the quality standards set by the European *In Vitro Diagnostic Directive*, enabling the use of the test in the European Union. MammaPrint is indicated for use by physicians as a prognostic marker only, along with other clinical-pathological factors. The test is not intended to determine the outcome of disease, nor to suggest or infer an individual patient's response to therapy.

About Agendia

Agendia is a privately held, leading molecular diagnostics company that develops and markets genomic diagnostic products, which help support physicians with their complex treatment decisions. Agendia's breast cancer tests were developed using an unbiased gene selection by analyzing the complete human genome. Our offerings include MammaPrint®, a 70-Gene Breast Cancer Risk-of-Recurrence test, and Blueprint®, a Molecular Subtyping Assay that provides deeper insight leading to more clinically actionable breast cancer biology.

In addition, Agendia has a pipeline of other genomic products in development. The company collaborates with pharmaceutical companies, leading cancer centers and academic groups to develop companion diagnostic tests in the area of oncology.

For more information on Agendia or the MammaPrint and Blueprint tests, you can visit Agendia's patient site at www.KnowYourBreastCancer.com or the corporate site at www.agendia.com.

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