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Published Study Validates Agendia's MammaPrint Test for Long-Term Prediction of Breast Cancer Outcome

Researchers Conclude Molecular Test Is Able to Differentiate High and Low Recurrence Risk up to 25 Years after Diagnosis, Further Validating NEJM Study

IRVINE, CA and AMSTERDAM, THE NETHERLANDS – A newly published study concludes that the MammaPrint® breast cancer test can accurately stratify a woman's breast cancer risk for up to 25 years after she is first diagnosed with the disease.

U.S. and Dutch researchers reported the longest-term follow-up study of its kind that confirms the durable accuracy of a unique genomic test for early-stage breast cancer. They concluded the 70-gene MammaPrint test has the statistically significant ability to predict, for up to a quarter-century, whether a newly diagnosed breast cancer patient is at low risk or high risk of a breast cancer recurrence. Their new findings, which expand upon foundational data about the MammaPrint test that was first published in the *New England Journal of Medicine* (NEJM) in 2002, appear in the peer-reviewed journal *Breast Cancer Research and Treatment.*

The study authors looked at two key measures regarding the set of 295 patients who were the subject of the earlier NEJM study: distant metastasis-free survival (DMFS) and overall survival. The accuracy of MammaPrint results held true for both DMFS and overall survival, regardless of whether patients had node-negative or node-positive cancer. The data was generated from a group of consecutively treated women who were originally diagnosed between 1984 and 1995 and were less than 53 years of age at diagnosis. Median follow-up on these patients was 18.5 years – far longer than has previously been reported for a test of this kind – with a range of 15 to 25 years.

"These findings address a significant concern for physicians who treat patients according to the results of gene signatures like the 70-gene test, as to the long-term consequences of their treatment," said Stefan Glück, M.D., Ph.D. "This study provides the first conclusive evidence that a genomic test can accurately stratify patients' recurrence risk for many years after their breast cancer is first discovered." Dr. Glück is a medical oncologist with

a specific focus on breast cancer and the Sylvester Professor in the Department of Medicine, Division of Hematology/Oncology, Sylvester Comprehensive Cancer Center at the University of Miami, Leonard M. Miller School of Medicine Miami, FL.

MammaPrint is the fastest-growing risk-recurrence assay for breast cancer and uniquely provides definitive High Risk or Low Risk information without ambiguous "intermediate" results. The test is the first FDA-cleared assay of its kind and the only one that is backed by peer-reviewed, prospective outcome data (e.g., the RASTER study). MammaPrint is performed as part of the Symphony® test panel, which also includes the BluePrint® assay, the most widely available test providing molecular subtyping of individual breast cancers.

"This remarkable long-term study demonstrates the ability of the 70-gene signature to accurately differentiate higher-risk from lower-risk women with regard to risk of recurrence and overall survival, at a time in their lives when breast cancer can have its most devastating impact on fertility, productivity, and capacity to fulfill childrearing responsibilities," said Agendia's Chief Medical Officer, oncologist Neil Barth, M.D. "The data show MammaPrint retains its accuracy to classify the intrinsic long-term biology of a patient's cancer. This accuracy persists regardless of changes that have occurred over time such as earlier patient diagnosis, expanded treatment options and improved efficacy of therapy. The study provides oncologists and their patients with an extra measure of confidence that the results of the test will remain accurate for many years forward."

About Agendia:

Agendia is a leading molecular diagnostic company that develops and markets FFPE-based genomic diagnostic products, which help support physicians with their complex treatment decisions. Agendia's breast cancer Symphony suite was developed by analyzing the complete human genome and identifying the most relevant genes to ensure definitive (no "intermediate') results. Symphony includes MammaPrint, the first FDA-cleared IVDMIA breast cancer recurrence assay and the only one backed by prospective outcome data, as well as BluePrint, a molecular subtyping assay, and TargetPrint®, an ER/PR/HER2 expression assay. Together, these tests help physicians determine a patient's individual risk for metastasis, which patients will benefit from chemo, hormonal, or combination therapy, and which patients do not require these treatments and can instead be treated with other, less arduous and less costly methods. The Agendia tests have substantial insurance coverage encompassing an estimated 170 million lives and including coverage by Medicare and regional and national insurers.

In addition to the Symphony suite of tests, Agendia has a rich pipeline of 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 and is a critical partner in the ISPY-2 and MINDACT trials. For more information, visit www.agendia.com.

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