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MammaPrint becomes the only molecular diagnostic recommended for early-stage node-positive breast cancer patients

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Guidelines affirm the importance of MammaPrint for node-positive patients and node-negative patients with high clinical risk

Agendia, a world leader in precision oncology has announced that its MammaPrint Breast Cancer Risk-of-Recurrence Test is the only molecular diagnostic indicated for use with patients who have breast cancer that has spread to their lymph nodes according to the updated Cancer Care Ontario Guidelines. The guidelines, which also recommend the test for select patients with node-negative breast cancer, are endorsed by the American Society of Clinical Oncology (ASCO).

The microarray technology-based MammaPrint, which has extensive clinical validation, uses the proprietary, 70-gene expression profile to classify patients with breast cancer as having a “low” or “high” risk of recurrence over a period of 10 years. Oncologists and breast surgeons use the information provided by MammaPrint to help guide overall treatment strategy for patients diagnosed with early stage breast cancer.

The guidelines by Cancer Care Ontario, a governmental agency of the province that is responsible for improving cancer services for residents across the territory, recommend MammaPrint for patients with ER/PR-positive, HER2-negative breast cancer who are also considered high clinical risk for recurrence. Patients can either be negative for lymph node involvement or positive with one to three lymph nodes positive for metastases. MammaPrint can help patients and their doctors determine whether adjuvant systemic chemotherapy should be part of their treatment regimen.

“We know that cancer often does not remain localized to a specific part of the body. It can easily spread, especially through the lymph nodes, but that does not always mean that the patient is going to benefit from adjuvant systemic chemotherapy,” said William Audeh, MD, Medical Oncologist and Agendia Chief Medical Officer. “Unfortunately, due to a lack of adherence to clinical guidelines, clinicians have used genomic assays that are not validated for patients with lymph node-positive breast cancer to help make decisions about the most beneficial treatment approach. We are pleased that the new guidelines now provide access to both centralized microarray and local next-generation sequencing platforms for Canadian patients and healthcare providers, and that the agency recognizes that MammaPrint is the only assay with enough evidence to be used in

such a high-risk group of patients.”

The guidelines were also published by ASCO and build upon 2016 recommendations for the use of MammaPrint.

Agendia is a privately-held, leading precision oncology 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. The company’s offerings include the MammaPrint Breast Cancer Risk-of-Recurrence Test, and the BluePrint Molecular Subtyping Test, both on microarray technology, whereas the new MammaPrint BluePrint Breast Cancer Recurrence and Molecular Subtyping Kit, is on NGS technology. The MammaPrint BluePrint next-generation sequencing-based kit is a CE-marked device currently available for use in cancer centers in select regions of the world.

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.

MammaPrint is an *in vitro* diagnostic medical device, performed as a testing service in a central laboratory, using the 70-gene expression profile of breast cancer tissue samples to assess a patient’s risk for distant metastasis within 5 years. The test is performed for breast cancer patients, with Stage I or Stage II disease, with tumor size ? 5.0 cm and lymph node negative. The device is FDA-cleared and CE-marked, enabling use in the European Union. MammaPrint is indicated for use by physicians as a prognostic marker only, along with other clinical-pathological factors. It is not intended to determine the outcome of disease, nor to suggest or infer an individual patient’s response to therapy. MammaPrint is the only test of its kind recommended for lymph node-negative and lymph node-positive patients by both the American Society of Clinical Oncology (ASCO) and National Comprehensive Cancer Network (NCCN). The test is also recommended by many other national and international clinical practice guidelines.