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Agendia Receives New FDA Clearance for MammaPrint FFPE Breast Cancer Test

FDA Decision Covers Use of MammaPrint in FFPE for the 70-Gene Breast Cancer Recurrence Assay

IRVINE, CA and AMSTERDAM, THE NETHERLANDS – Agendia, a leading molecular diagnostics company that develops and markets genomic diagnostic products, announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the company's MammaPrint® breast cancer recurrence test in FFPE (formalin-fixed paraffin embedded) tissue.

The MammaPrint FFPE test utilizes the same 70 genes and proprietary algorithm as the previously cleared MammaPrint Fresh, the first multi-gene medical device to ever receive a 510(k) FDA clearance. Due to the larger panel of genes than any other commercially available test, both tests provide an unambiguous result of "Low vs. High risk'" for recurrence of a patient's breast cancer. This capability surpasses all other commercially available tests because it applies across all age groups, and is not restricted by estrogen or HER 2 receptor status. This additional insight about the

cancer's biology enables physicians to appropriately choose the best treatment for their patients.

"MammaPrint FFPE changes the conversation between physicians and patients at that critical point where treatment decisions are being made," said Jan Egberts M.D., CEO of Agendia. "The test result eliminates the ambiguity of the 'Intermediate result' seen in other test platforms, and in concert with other factors, facilitates a decision by both patients and physicians about the relative benefit of chemotherapy and endocrine therapy."

The MammaPrint FFPE 510(k) clearance not only confirmed the robust accuracy, repeatability and reproducibility of the original 70 gene signature, but it also confirmed the clinical performance of the signature using the results of the first ever five-year clinical outcome study (RASTER) in which MammaPrint results were utilized by physicians to decide post-surgical management. In that real-world study, patients were treated according to the best standard of care. Patients with a "Low Risk" MammaPrint score had a 97.7 % probability of being cancer free at five years, while those with a "High Risk" score had an 88.5% probability of being cancer free. In a univariate analysis against other clinical pathologic factors, MammaPrint's prognostic value is highly statistically significant (P=0.002)

"Originally cleared in 2007, Agendia was the first company, to have FDA clearance for its breast cancer genomic test," said Egberts. "This sixth FDA clearance further reinforces our positive relationship with the FDA and our leadership in the molecular diagnostic field."

In July of 2014, the FDA publicly announced that it intends to publish a risk-based oversight framework for LDTs:

"Ensuring that doctors and patients have access to safe, accurate and reliable diagnostic tests to help guide treatment decisions is a priority for the FDA," said FDA Commissioner Margaret A. Hamburg, M.D. *"Inaccurate test results could cause patients to seek unnecessary treatment or delay and sometimes forgo treatment altogether. Today's action demonstrates the agency's commitment to personalized medicine, which depends on accurate and reliable tests to get the right treatment to the right patient."*

"We actively support the FDA's objective that doctors and patients should have access to safe, accurate and reliable diagnostic tests and we support the FDA in taking a strong stance to regulate Laboratory Developed Tests (LDT's). The absence of FDA enforcement over high-risk non-FDA cleared LTDs raises concern about the reliability, reproducibility and efficacy of these non-approved tests," Egberts added. "Our longstanding working relationship with the FDA has been a favorable experience. We are hopeful that once this enforcement is operationalized, it will eliminate the unfair

commercial advantage currently enjoyed by vendors whose claims have not been subject to the rigorous FDA review and approval process."

"In the minds of clinicians, this decision will ease the process to choose MammaPrint from among other commercially available tests," said Dr. Massimo Cristofanilli, a medical oncologist and Director of the Jefferson Breast Center and Clinical Program at Sidney Kimmel Cancer Center at Thomas Jefferson University. "Doctors and patients typically rely on a number of factors when selecting a clinical test. The FDA clearance provides reassurance that tests have been sufficiently reviewed and validated and are clinically indicated and useful."

With this FDA clearance, Agendia has taken its next step in a continuing tradition of scientific excellence and clinical and social responsibility to patients worldwide. MammaPrint has substantial insurance coverage, including by Medicare and regional and national insurers, encompassing an estimated 200 million lives in the U.S.

Resources for further reference

- RASTER prospective outcome study and press release
- Independent comparison validates molecular subtyping (includes video)
- MammaPrint valid up to 25 years press release

About Agendia:

Agendia is a privately held, leading molecular diagnostics company that develops and markets FFPE-based genomic diagnostic products, which help support physicians with their complex treatment decisions. Agendia's breast cancer suite was developed using an unbiased gene selection by analyzing the complete human genome. Our offerings include the FDA-cleared MammaPrint FFPE as well as BluePrint®, a molecular subtyping assay that provides deeper insight leading to more clinically actionable biology, and TargetPrint®, an ER/PR/HER2 expression assay. MammaPrint is the only breast cancer recurrence assay supported by peer-reviewed, published, prospective outcome data. These tests can help physicians assess a patient's individual risk for metastasis – that is, which patients are more sensitive to chemo, hormonal, or combination therapy, and which patients may not require these treatments and which patients may be treated with other, less arduous and costly methods.

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. It is also a critical partner in the ISPY-2 and the MINDACT trials. For more information, visit www.agendia.com.

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