Multiple International Breast Cancer Guidelines Confirm Use of Agendia Tests for Prognostic, Predictive Information in Cancer Treatment Decisions

Important Role of Molecular Subtyping in Determining the Need for Chemotherapy also Cited

IRVINE, CA, and AMSTERDAM, THE NETHERLANDS, September 9, 2013 – Agendia, a leader in molecular cancer diagnostics, today announced that multiple established international breast cancer treatment guidelines confirmed that Agendia's MammaPrint® tests, the leading product in Agendia's Symphony suite of breast cancer tests, significantly augment prognostic and predictive information in making key cancer treatment decisions. The updated clinical practice guidelines, published in the August edition of *Annals of Oncology*, were provided by the European Society of Medical Oncology (ESMO), the Japanese Society of Medical Oncology (JSMO) and the St. Gallen International Breast Cancer Conference Expert Panel.

MammaPrint was the first, and remains the only, breast cancer In Vitro Diagnostic Multivariate Index Assay (IVDMIA) to have received FDA clearances based on the FDA's rigorous de-novo 510K process. MammaPrint, as a prognostic stratification tool, has a 98.9% accuracy in classifying patients as 'Low Risk' or 'High Risk' and technical reproducibility of 98.5%. A number of pivotal clinical studies have highlighted the value of this next generation assay in providing a higher level of precision in treatment decisions for early breast cancer.

"We are seeing a progressive recognition of our technologies by the panels of international experts and their guidelines," said Agendia CEO David Macdonald. "It is very rewarding to see that multiple thought leaders and industry guidelines throughout the world now include our MammaPrint test. We are working with all of our physician partners in adopting this clinical advantage for their patients. Third party payors are seeing the clinical and economic benefit of using a more precise instrument for their insured lives."

Specifically, the ESMO and JSMO guidelines included:

- For staging and risk assessment, "gene expression profiles such as MammaPrint (Agendia)…may be used to gain additional prognostic and or predictive information to complement pathology assessment and to predict response to adjuvant chemotherapy."
- For adjuvant systemic treatment, "in case of uncertainty regarding indications for adjuvant chemotherapy (after consideration of other tests), gene expression assays, such as MammaPrint…may be used where available to determine the individual recurrence risk and predict the benefit from chemotherapy."

In addition, the St. Gallen guidelines strongly endorsed the need for intrinsic subtyping of patients as an accurate means of determining which patients need to undergo chemotherapy. The only commercially available genomic assay in the U.S. that can perform comprehensive molecular subtyping is Agendia's Symphony™ suite of breast cancer tests.

The St. Gallen panel was "strongly of the opinion that intrinsic subtypes should influence whether or not chemotherapy was used…" The panel guidelines also noted that "in those areas of the world where multi-gene

molecular assays are readily available, many clinicians prefer to base chemotherapy decisions for patients with luminal disease on these genomic results…"

"The guidance to physicians on the importance of subtyping, and how that affects treatment decisions, is one of the most significant messages that came out of the St. Gallen conference," said Neil Barth, M.D., Agendia's Chief Medical Officer. "Our Symphony suite of breast cancer tests offers treating physicians critical information not only about which patients may safely forgo chemotherapy versus those who truly benefit from chemotherapy, but also more accurately identify the specific genomic pathways that can be optimally targeted."

Ten clinical validation studies over the last several years have affirmed the contribution to clinical care for patients who were provided with the opportunity to have their tumors tested at Agendia. These studies have spanned neoadjuvant to adjuvant and prospective to retrospective studies. Notable mention in the St. Gallen guidelines publication was given to the recently published RASTER study, where 97% of patients who were identified as 'Low Risk' by MammaPrint and chose not to have chemotherapy were disease free at five years. RASTER remains the only published prospective study for breast cancer recurrence tests with patient outcome data.

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 using unbiased gene selection, analyzing the complete human genome, ensuring clinically actionable definitive results for cancer patients. Symphony™ includes MammaPrint®, a breast cancer recurrence assay and the first and only IVDMIA breast cancer recurrence assay to have received 510K clearances from the FDA. It also includes BluePrint, a molecular subtyping assay, TargetPrint®, an ER/PR/HER2 expression assay, and TheraPrint®, an alternative therapy selection 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.

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, please visit www.agendia.com.

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