For Immediate Release

Agendia Successfully Completes Bi-Annual FDA Inspection

IRVINE, CA and AMSTERDAM, THE NETHERLANDS, October 3, 2011 – Agendia, an innovative molecular cancer diagnostics company, today announced that the company successfully completed a recent, routine inspection of its Irvine, California-based laboratories by the US Food and Drug Administration (FDA). Agendia received FDA 510(k) clearance for its MammaPrint® breast cancer recurrence test in early 2007. It remains the first and only test of its kind to receive FDA clearance, which, in addition to validiation of the product's safety and efficacy, periodically subjects the company's laboratories to the scrutiny of FDA inspectors to ensure continuous compliance with regulations.

"Agendia was founded on the principle of providing safe and effective products to improve patients' quality of life, and we have gone to great lengths to ensure that MammaPrint meets this high standard," said Dr. Bernhard Sixt, CEO and co-founder of Agendia. "Ensuring the safety of MammaPrint doesn't just stop at the approval process. We must ensure that MammaPrint continues to comply with regulations throughout the life of the test. This is why we sought FDA clearance and why we believe the industry, as a whole, should be regulated in the same manner. I am immensely proud that FDA has once again validated Agendia's MammaPrint test and take even greater pride to offer the only breast cancer recurrence test that has been subjected to such painstaking FDA oversight."

FDA inspectors thoroughly examined Agendia's facilities, evaluating the company's compliance with FDA's Good Manufacturing Practice Regulations (GMP), which require manufacturers of drugs, medical devices and FDA cleared laboratory tests to ensure product safety and effectiveness. GMP regulations compel companies, such as Agendia, to employ strong manufacturing practices that minimize or eliminate the risk of contamination, laboratory mixups and errors. FDA inspectors assessed Agendia's laboratory operations from top to bottom, including recordkeeping, personnel, sanitation and cleanliness, equipment, process validation and complaint handling. This meticulous inspection ensures the reliability and safety of Agendia's MammaPrint test, and protects patients.

About Agendia:
Agendia is a leading global commercial molecular diagnostic company that develops and markets genomic-based diagnostic products that improve the quality of life for cancer patients and simplifies complex treatment decisions for their physicians. Agendia's Symphony™ suite of breast cancer products is based on the analysis of hundreds of genes in a patient's breast and provides unprecedented biological insight to address complex treatment decisions. Symphony includes MammaPrint, the first and only FDA-cleared IVDMIA breast cancer recurrence assay, as well as BluePrint, a molecular subtyping assay, TargetPrint®, an ER/PR/HER2 expression assay, and TheraPrint®, a therapy selection assay. Together, these tests help physicians determine a patient's individual risk for metastasis, which patients will benefit from chemo or hormonal therapy, and which patients do not require these treatments and can instead be treated with other less arduous and costly methods.

In addition to the Symphony suite of tests, Agendia has a rich pipeline of genomic products in development based on its world-class genomic platform. The company also collaborates with pharmaceutical companies to develop companion diagnostic tests in the area of oncology and is a critical partner in the ISPY-2 and MINDACT trials.

Agendia was founded in 2003 as a spin-off of the Netherlands Cancer Institute and is based in Irvine, California, United States, and Amsterdam, the Netherlands. For more information, please visit www.agendia.com.

For further information, please contact:

Ricochet Public Relations
Valerie Carter
Tel: +1 202 316 0143
E-mail: Agendia@RicochetPR.com