Agendia Earns ISO Certification for Facilities in Amsterdam and Irvine

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IRVINE, CA and AMSTERDAM, THE NETHERLANDS, August 20, 2012 – Agendia, an innovative molecular cancer diagnostics company and leader in personalized medicine, today announced that it has been granted the International Organization for Standardization (ISO) 13485 certification for all activities at their facilities in Irvine and Amsterdam. Agendia has been a leader in maintaining the highest quality standards and operating in compliance with FDA GMP QSR, CLIA, CAP, OSHA, the CE Mark, as well as requirements for all 50 states in the United States.

Agendia's breast cancer Symphony suite consists of unique FFPE tissue tests that provide vital genomic information to support complex breast cancer treatment decisions. As the globally recognized quality control certification for medical devices and related services, receipt of ISO 13485 certification confirms that the execution of Agendia's Symphony diagnostic services, including MammaPrint®, BluePrint™, TargetPrint® and TheraPrint®, meet the highest internationally recognized quality standards. In addition, the certification affirms that the design and development of all of Agendia's current and future diagnostic services are of the highest quality.

"Agendia is committed to developing clinically useful diagnostic tests that provide clear and accurate results. Part of this commitment is ensuring that our products and facilities comply with the most rigorous quality standards," said David Macdonald, CEO of Agendia. "In addition to the FDA clearances for our products, ISO certification provides patients and physicians with the confidence that Agendia's diagnostic tests provide safe, effective, reliable and actionable information."

The ISO 13485 quality standard specifies requirements for a quality management system to demonstrate its ability to consistently meet customer and regulatory requirements. The primary objective of ISO 13485 is to harmonize regulatory requirements for quality management systems globally and includes an emphasis on process control and effectiveness for; design, development, manufacture, risk management, and distribution of related medical services.

About Agendia:
Agendia is a leading molecular diagnostic company that develops and markets genomic-based 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 100% definitive results for cancer patients. 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®, 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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