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Agendia B.V.

Agendia Receives New York State Laboratory Permit and Laboratory Accreditation by College of American Pathologists

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Huntington Beach, California and Amsterdam (ots/PRNewswire)

-- Agendia, a world leader in molecular cancer diagnostics, announced today that it has received the Clinical Laboratory Permit from the New York State Department of Health. The New York State permit allows the company to receive commercial samples of MammaPrint, its FDA-cleared breast cancer recurrence test.

With this latest permit, Agendia has now obtained all major U.S. clinical laboratory licenses. In addition, the College of American Pathologists (CAP) has accredited Agendia's CLIA regulated laboratory in Huntington Beach, CA.

"The New York State permit is often recognized as one of the most difficult to obtain. Together with our CAP accreditation, CLIA compliance, and FDA-clearance for MammaPrint, we give patients and physicians the confidence they need while making important treatment decisions," said Dr. Bernhard Sixt, Agendia's Chief Executive Officer. "The growing clinical importance of complex genomic testing means that our laboratories need to meet the highest standards of quality for patients and health care professionals."

About MammaPrint(R)

MammaPrint is the first and only breast cancer recurrence test cleared by the U.S. Food and Drug Administration (FDA). FDA clearance under the in vitro diagnostic multivariate index assay (IVDMIA) guidelines requires clinical and analytical validation and reporting systems to ensure patient safety issues are addressed. Highly accurate, MammaPrint identifies patients with early metastasis risk - patients who are likely to develop metastases within five years following surgery. Several authoritative studies have shown that chemotherapy particularly reduces early metastasis risk. In planning treatment, the MammaPrint test results provide doctors with a clear rationale to assess the benefit of chemotherapy in addition to other clinical information and pathology tests.

All MammaPrint tests are conducted in Agendia's CAP-accredited and CLIA compliant service laboratories. Breast cancer recurrence assays currently marketed by other manufacturers have not been subject to the rigorous FDA clearance process.

About Agendia

Agendia is at the forefront of the personalized medicine revolution, striving to bring more effective, individualized treatments within reach of patients. Building on a cutting-edge genomics platform for tumor gene expression profiling, the company's tests help physicians more accurately tailor cancer treatments. Agendia markets four products, with several new genomic tests under development. In addition, Agendia collaborates with pharmaceutical companies to develop highly effective personalized drugs in the area of oncology. Agendia is based in Huntington Beach, California, and in Amsterdam, The Netherlands.

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