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Agendia's Breast Cancer Test MammaPrint(R) Identifies New Subset of Low Risk HER2+ Patients

Huntington Beach, California and Amsterdam (ots/PRNewswire)

- Recent Study Reveals Substantial Group of Traditionally Miscategorized HER2+ Patients

Dr. Michael Knauer from the Netherlands Cancer Institute today announced data uncovering a substantial group of traditionally miscategorized low risk HER2+ patients. Agendia's highly accurate breast cancer tumor recurrence test, MammaPrint(R), was used to differentiate between patients at high and low risk for recurrence.

HER2+ patients are commonly identified as high risk, yet MammaPrint was able to identify a low risk subgroup of HER2+ patients, who subsequently experienced a 10 year disease-free survival of close to 90 percent even in the absence of (neo)adjuvant trastuzumab (Herceptin(R)) and chemotherapy. Additionally, in a subgroup of highly endocrine responsive HER2/NEU positive patients, MammaPrint(R) low risk patients had no relapse.

The results were presented by Dr. Michael Knauer during the 2008 San Antonio Breast Cancer Symposium (SABCS). In the study population of 169 HER2+ patients MammaPrint(R) classified 16 percent of patients as having a good prognosis signature with a 10-year distant disease-free survival (DDFS) of 89 percent, compared to 84 percent of patients classified as having a poor prognosis signature with a DDFS of 64 percent.

MammaPrint(R)'s robustness is underscored by the 70 gene panel unique to the test and a resulting gene profile that covers all molecular pathways associated with breast cancer. HER2/NEU-overexpression is observed in 15-20 percent of invasive breast cancers and is widely considered to be a negative prognostic factor. As a result, current treatment guidelines classify all HER2-positive breast cancer patients at high risk of relapse, and recommend trastuzumab and chemotherapy.

MammaPrint(R) accurately identified a subgroup of patients with a good clinical outcome in HER2+ early breast cancer. These patients will be further studied in the ongoing MINDACT-trial (Microarray for Node-negative and 1-3 positive node Disease may Avoid ChemoTherapy) to determine the prospects of withholding chemotherapy and/or trastuzumab in HER2+, MammaPrint(R) low risk patients.

About MammaPrint(R)

MammaPrint(R) is the first 'in vitro diagnostic multivariate index assay' (IVDMIA) cleared by the U.S. Food and Drug Administration (FDA). FDA clearance requires clinical and analytical validation and reporting systems to ensure patient safety issues are addressed. Highly accurate, MammaPrint(R) identifies patients with early metastasis--those 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(R) test result provides a doctor with a clear rationale to assess the benefit of adjuvant chemotherapy in addition to other clinical information and pathology tests.

All MammaPrint(R) tests are conducted in Agendia's CLIA-certified service laboratory. All other breast cancer recurrence assays currently marketed 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 aim to help physicians more accurately tailor cancer treatments. The company 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. For more information please visit http://www.agendia.com.

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