Press Release

Agendia's MammaPrint® breast cancer prognosis test cleared by U.S. Food and Drug Administration (FDA).

-- MammaPrint® is the first multi-gene expression test to receive market clearance by the FDA --

Amsterdam, The Netherlands [Tuesday 6 February 2007]

Agendia's MammaPrint® breast cancer prognosis test is the world's first In Vitro Diagnostic Multivariate Index Assay (IVDMIA) to acquire market clearance from the U.S. Food and Drug Administration (FDA). Clearance of Agendia's 'de novo 510K' application for MammaPrint® provides the legal basis for offering this service in the United States. Agendia had previously received clearance from European authorities to market MammaPrint® in Europe and substantial progress has already been made there in market acceptance and reimbursement.

Dr. Bernhard Sixt, Chief Executive Officer at Agendia notes: "The FDA's focus on the emerging field of molecular diagnostics underscores the growing importance of personalized medicine. Agendia is very pleased that its MammaPrint®, as the frontrunner in this area, is the first to receive clearance by the FDA. This is not only an acknowledgement of Agendia's efforts to provide state of the art technology for the benefit of cancer patients, but also sends a clear message to the medical community that our MammaPrint® test is reliable and clinically useful. In Europe Agendia's service has already demonstrated its technical robustness and reliability, adding significant clinical value for physicians and breast cancer patients. We are exploring ways to make this product available in the US. We are also confident that the present FDA clearance of MammaPrint® will help to increase acceptance of this type of technology in clinical decision making for cancer in Europe".

Guido Brink, Director Regulatory Affairs at Agendia comments: "For the last 18 months, we have been working diligently with the FDA to answer the many clinical and technical questions posed by the FDA. And on September 6th 2006, the FDA announced that it planned to assert its authority to regulate this new category of multi-variate diagnostic tests designed to individualize the medical treatment of patients. Agendia's commitment to comply with the highest quality standards, as reflected in our ISO 17025 accreditation, was a critical asset towards achieving FDA clearance. At present, MammaPrint® is the first cleared IVDMIA which can be marketed in the US in compliance with these new FDA guidelines."

About MammaPrint®

MammaPrint® is a DNA micro array-based *in vitro* diagnostic laboratory service that measures the activity of 70 genes, providing information about the likelihood of tumour recurrence. The MammaPrint® test measures the level of expression of each of these genes in a sample of a woman's surgically-removed breast cancer tumour and then uses a specific formula or algorithm to produce a score that determines whether the patient is deemed low risk or high risk for spread of the cancer to another site. The result may help a doctor in planning appropriate follow-up for a patient when used with other clinical information and laboratory tests.

About Agendia

Agendia, located in Amsterdam, the Netherlands, is a world leader in gene expression analysis-based diagnostics with three products on the market. The company focuses on the development and commercialization of diagnostic tests using tumor gene expression profiling.

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Agendia was the first company to commercialize a prognostic test - MammaPrint® - that predicts the risk of breast cancer recurrence. Agendia maintains close ties with several leading academic centers to develop state of the art diagnostic tests for cancer. Agendia also offers its expertise to pharma companies focusing on development of highly effective personalized drugs in the area of oncology.

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FDA Clears Breast Cancer Specific Molecular Prognostic Test

The U.S. Food and Drug Administration (FDA) today cleared for marketing a test that determines the likelihood of breast cancer returning within five to 10 years after a woman's initial cancer. It is the first cleared molecular test that profiles genetic activity.

The MammaPrint test uses the latest in molecular technology to predict whether existing cancer will metastasize (spread to other parts of a patient's body). The test relies on microarray analysis, a powerful tool for simultaneously studying the patterns of behavior of large numbers of genes in biological specimens.

The recurrence of cancer is partly dependent on the activation and suppression of certain genes located in the tumor. Prognostic tests like the MammaPrint can measure the activity of these genes, and thus help physicians understand their patients' odds of the cancer spreading.

MammaPrint was developed by Agendia, a laboratory located in Amsterdam, Netherlands, where the product has been on the market since 2005.

"Clearance of the MammaPrint test marks a step forward in the initiative to bring molecular-based medicine into current practice," said Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs. "MammaPrint results will provide patients and physicians with more information about the prospects for the outcome of the disease. This information will support treatment decisions.

Agendia compared the genetic profiles of a large number of women suffering from breast cancer and identified a set of 70 genes whose activity confers information about the likelihood of tumor recurrence. The MammaPrint test measures the level of activity of each of these genes in a sample of a woman's surgically removed breast cancer tumor, then uses a specific formula, known as an algorithm, to produce a score that determines whether the patient is deemed low risk or high risk for spread of the cancer to another site. The result may help a doctor in planning appropriate follow-up for a patient when used with other clinical information and laboratory tests.

The MammaPrint is the first cleared in vitro diagnostic multivariate index assay (IVDMIA) device. Several months ago, FDA issued a draft guidance document concerning the need for these complex molecular tests to meet pre-market review and post-market device requirements even when the tests are developed and used by a single laboratory. Although FDA regulates diagnostic tests sold to laboratories, hospitals and physicians, it uses discretion when regulating tests developed and performed by single laboratories.

On February 8, FDA will hold a public meeting to discuss its draft guidance document describing its regulatory approach to this type of test.

"There have been rapid advances in microarrays and other pioneering diagnostics, and a corresponding increase in the use and impact of these complex tests. This has prompted FDA to take a closer look at the potential risks as well as the benefits associated with such tests when they are developed and used in laboratories," remarked Steven Gutman, M.D., Director, Office of In Vitro Diagnostic Device Evaluation. "This test clearance takes into account the development of these innovative technologies and ensures public health by carefully evaluating their performance."

Prior to clearance, FDA requested evidence that the MammaPrint had been properly validated for its intended use. Agendia submitted data from a study using tumor samples and clinical data from 302 patients at five European centers. These studies confirmed that the test was useful in predicting time to distant metastasis in women who are under age 61 and in the two earliest stages of the disease (Stage I and Stage II) and who have tumor size equal to or less than five centimeters and no evidence that the cancer has spread to nearby lymph nodes (lymph node negative). FDA plans to publish a special controls guidance document within the next 60 days describing types of data that should support claims for genetic profiling for breast cancer prognosis.

According to the American Cancer Society, an estimated 178,480 new cases of invasive breast cancer will be diagnosed among women in the United States this year and over 40,000 women are expected to die from the disease.

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