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Agendia B.V.

Agendia to Play Pivotal Role in I-SPY-2 Trial for Breast Cancer

17.03.2010 - 17:01 Uhr, Agendia B.V.

HUNTINGTON BEACH, California and AMSTERDAM, March 17, 2010

(ots/PRNewswire) -- Agendia, a world leader in molecular cancer diagnostics, announced today it will participate in the highly anticipated I-SPY 2 TRIAL for breast cancer, set to launch at the first of nearly twenty research sites. I-SPY 2 is an exciting and groundbreaking new clinical trial model that will help scientists quickly and efficiently test the most promising drugs in development for women with higher risk, rapidly growing breast cancers-- women for whom an improvement over standard treatment could dramatically change the odds of survival. I-SPY is an initiative of the Biomarkers Consortium, a unique public-private partnership that includes the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and major pharmaceutical companies, led by the Foundation for the National Institutes of Health (FNIH).

"Cancer tumor profiling in the neoadjuvant setting is critical to the success of the I-SPY 2 trial. Agendia is uniquely positioned to be a part of the Biomarker Consortium in this landmark study, and proud to be working side by side with a large number of visionary therapeutic companies and research centers," said Bernhard Sixt, Chief Executive Officer of Agendia. "Agendia's MammaPrint test has proven value for breast cancer recurrence in the neoadjuvant and adjuvant settings, Agendia's TargetPrint provides objective, quantitative information about the expression of ER, PR and Her-2neu, while our DiscoverPrint measures the expression of the whole genome. In concert they will form an integral part of the clinically relevant discoveries the Consortium aims to make."

Scientists from the National Cancer Institute (NCI), FDA, and nearly 20 major cancer research centers across the United States have united to develop and conduct this unprecedented large-scale scientific collaboration to test novel breast cancer drugs in the neoadjuvant clinical trial setting. Results will be made broadly available to the cancer research and development community in order to foster this integrated approach to improve clinical trial success and the efficacy of cancer therapeutics.

The adaptive design of the I-SPY 2 trial promises to integrate and advance multiple biomarker types into a new generation of predictive signatures. This approach has the potential to both streamline Phase III trial designs and yield a new generation of personalized diagnostic tools with regulatory acceptance and approval. Information from Agendia's whole genome expression profiling, essentially "snapshots" of tumor biopsies before and after administration of the neoadjuvant therapies under investigation, combined with data from the other trial participants, promises to accelerate trials, reduce patient enrollment numbers, and generate huge savings for commercial, research and governmental institutions.

I-SPY 2 has been officially launched at a press conference earlier today at the National Press Club in Washington, DC. The archived webcast of the event, including both general and scientific Q&A sessions following the speakers' remarks, can be accessed at

<http://www.visualwebcaster.com/I-SPY2-Launch>

For the official announcement of the launch of I-SPY 2 and more information on The Biomarker Consortium, please go to: <http://www.biomarkerconsortium.org>

For background information on the I-SPY 2 trial, please go to <http://ispy2.org>

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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