March 4, 2015

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Agendia's BluePrint Molecular Subtyping Assay Highlighted at the 32nd Annual Miami Breast Cancer Conference

Results of the NBRST Trial Using Agendia's BluePrint 80-Gene Molecular Subtyping Assay Presented

IRVINE, CA and AMSTERDAM, THE NETHERLANDS – Agendia, a leading molecular diagnostics company that develops and markets genomic diagnostic products, said new data from an ongoing study indicates the BluePrint® functional molecular subtyping assay more accurately identifies molecular subgroups and may be a better guide for neoadjuvant treatment than standard, local IHC/FISH assays.

The study was selected by organizers of the Miami Breast Cancer Conference and was presented from the podium on Friday, Feb. 27 by Pat Whitworth, M.D., a Nashville surgical oncologist and principal investigator in the trial. The presentation was titled, *Can We Expand the Pool of Patients Who May Respond to Trastuzumab? Results of the NBRST Trial Using an 80-Gene Functional Assay*.

The aim of the prospective NBRST study is to compare functional molecular subtyping by BluePrint/MammaPrint® to conventional local IHC/FISH subtyping to predict chemosensitivity as defined by pathologic complete response (pCR). “BluePrint gives us a more accurate picture of which patients may or may not respond to neoadjuvant chemotherapy by reclassifying up to 22% of tumors and also helps suggest the best course for therapy,” said Whitworth. “One implication of the study findings is that we will eventually end up evaluating and treating many breast cancer patients differently than we do now, because we will rely on their functional molecular subtype rather than just IHC-FISH pathology results.”

Interim results on the first 426 patients of the study were published in October 2014 by the *Annals of Surgical Oncology.* This analysis found the pCR rate by functional molecular subtype-classified HER2-type patients was 53% and was significantly superior to the 38% pCR rate in IHC/FISH HER2+ patients (p=0.047). Details available here.

Agendia’s BluePrint 80-gene Molecular Subtyping Assay is the most widely available test providing the functional molecular subtype of a woman’s breast cancer. BluePrint is performed on formalin-fixed paraffin-embedded (FFPE) tissue and is part of Agendia’s suite of breast cancer assays that also includes the MammaPrint 70-gene Risk of Recurrence assay, which recently received FDA 510(k) clearance for use in FFPE tissue samples. MammaPrint was the first breast cancer risk of recurrence multi-gene assay to receive FDA 510(k) clearance. With the most recent clearance, Agendia now has six FDA clearances in its breast cancer portfolio.

Physicians and their patients typically rely on a number of factors when selecting the best course of therapy. “Agendia’s suite of breast cancer recurrence assays fundamentally changes that conversation at that critical point where treatment decisions are being made,” said Jan Egberts M.D., CEO of Agendia. “While MammaPrint test results eliminate the ambiguity of the ‘Intermediate result’ seen in up to 39% of other tests, molecular subtyping by BluePrint provides greater insight into the biology of the tumor that just isn’t available from most of the other breast cancer recurrence assays on the market.”

MammaPrint has substantial insurance coverage, including Medicare, regional, and national insurers, encompassing an estimated 200 million lives in the U.S.

The 32nd annual Miami Breast Cancer Conference took place Feb. 27–March 1, 2015 at the Fontainebleau Hotel in Miami Beach, FL.

Resources for further reference

- MammaPrint FFPE receives FDA 510(k) clearance press release
- RASTER prospective outcome study and press release

- Independent comparison validates molecular subtyping (includes video)
- MammaPrint valid up to 25 years press release

About Agendia:

Agendia is a privately held, leading molecular diagnostics company that develops and markets FFPE-based genomic diagnostic products, which help support physicians with their complex treatment decisions. Agendia's breast cancer suite was developed using an unbiased gene selection by analyzing the complete human genome. Our offerings include the FDA-cleared MammaPrint FFPE as well as BluePrint, a molecular subtyping assay that provides deeper insight leading to more clinically actionable biology, and TargetPrint®, an ER/PR/HER2 expression assay. MammaPrint is the only breast cancer recurrence assay supported by peer-reviewed, published, prospective outcome data. These tests can help physicians assess a patient's individual risk for metastasis – that is, which patients are more sensitive to chemo, hormonal, or combination therapy, and which patients may not require these treatments and which patients may be treated with other, less arduous and costly methods.

In addition, Agendia has a pipeline of other 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. It is also a critical partner in the ISPY-2 and the MINDACT trials. For more information, visit www.agendia.com.

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