March 11, 2014

Contact:
Liz Dowling (Medical & Consumer Media)
Dowling & Dennis Public Relations
415-388-2794
Liz@DowlingDennis.net

Len Hall (Financial Media)
Allen & Caron Inc. 949-474-4300
len@allencaron.com

Agendia Test for Molecular Subtyping of Breast Cancer Shown to Better Identify Risk of Disease Recurrence

Scientific Poster and Symposium at Miami Breast Cancer Conference Demonstrate Value of MammaPrint and BluePrint Tests Compared to First-Generation Test

IRVINE, CA and AMSTERDAM – A scientific poster comparing Agendia's MammaPrint® and BluePrint® tests to the 21-gene test, found that for a large group of women with breast cancer, molecular subtyping with the Agendia tests provides more accurate information about the risk of disease recurrence.

The poster results are believed to be the first head-to-head comparison that explains discordance (lack of agreement) between different kinds of genomic tests for breast cancer. Many patients in the study who were classified by the first-generation 21-gene test as being at low risk of recurrence were discovered to in fact be at high risk of recurrence by MammaPrint. Of those patients classified as low risk by the first-generation test but high risk by the next-generation MammaPrint test, most of them were determined to be the Luminal B subtype by the Agendia molecular subtyping assay BluePrint. That category conveys a significantly higher risk of disease recurrence that is not identified by the first-generation test.

Additionally, by adding information about the molecular subtype of the cancer, it was also shown that a proportion of IHC hormone receptor positive patients demonstrated either a predominant Her-2-type or basal-like molecular signature that may partially explain why some patients fail to benefit from endocrine therapy.

The research poster was authored by Steven C. Shivers, Ph.D., Charles E. Cox, M.D., at the University of South Florida (USF), and others. It was presented at the recently concluded Miami Breast Cancer Conference, held March 6-9. The conference also featured a lunchtime symposium that discussed favorable new research about MammaPrint and BluePrint.

"Molecular subtyping can help oncologists and surgeons personalize and improve each patient's individual treatment for breast cancer," said Peter Blumencranz, M.D. a poster co-author. "In this research, we saw that a substantial number of breast cancer patients, who had been identified as being low risk by the earlier genomic test, were in fact at high risk of recurrence. We learned this by using molecular subtyping to stratify these patients, determining that most of them were of the Luminal B subtype and therefore at higher risk of

recurrence." Dr. Blumencranz is the Medical Director of Comprehensive Breast Program and Cancer Services for Morton Plant Mease Health Care, and Medical Director of Moffitt–Morton Plant Mease Cancer Care.

Molecular subtyping classifies breast cancer tumors into one of four genetically distinct categories, or subtypes: Luminal A, Luminal B, Basal (a subset of triple negative), and HER2-type. Each subtype responds to certain kinds of treatments and not others. Some subtypes are also associated with a higher risk of disease recurrence, which can also affect treatment choices. In particular, women at high risk of recurrence are usually counseled to receive chemotherapy. Women at low risk can choose to forgo chemotherapy and its potentially damaging side effects and still expect a good outcome.

For the scientific poster, researchers examined tumor samples from a study population of 148 patients. The greatest discordance between MammaPrint and the 21-gene test about recurrence risk was found among 33% of the patients. Those patients were stratified by the latter test as being at low risk of recurrence, but MammaPrint identified them as being at a high risk of recurrence.

In an attempt to explain this discrepancy, BluePrint was used to determine the molecular subtype of the tumors with discordant results. The overwhelming number of patients, classified as low risk by the 21-gene assay but as high risk by MammaPrint, turned out to have the Luminal B subtype, which confers a high risk of recurrence.

"This new scientific poster has important implications for clinical practice," said Agendia's Chief Medical Officer, oncologist Neil Barth, M.D. "When breast cancer patients and their physicians are trying to decide whether chemotherapy would be beneficial, it is crucial that they know the molecular subtype of the cancer. The MammaPrint and BluePrint tests together provide this additional information about tumor biology, while the older, first-generation test does not, and may in fact supply inaccurate information about a patient's risk of recurrence."

The lunchtime symposium at the Miami conference was titled "Molecular Subtypes: Clinical Implications for Breast Cancer Patients in Your Practice." The featured speaker was Massimo Cristofanilli, M.D., a noted oncologist, who described recent research at his institution and several other noted cancer centers.

Researchers reported that molecular subtyping with MammaPrint and BluePrint was more effective than traditional, clinical pathology methods for identifying women who will not benefit from chemotherapy after breast cancer surgery. These women may therefore safely forego chemotherapy and its side effects.

They concluded that oncologists who relied exclusively on clinical pathology subtyping with IHC/FISH would have misclassified a substantial number of these patients, potentially leading to overtreatment with chemotherapy in some cases and undertreatment in others. The research was first presented at the 2013 San Antonio Breast Cancer Symposium (SABCS).

MammaPrint uncovers more treatable biology, providing invaluable clinical information about an individual woman's breast cancer and whether she is likely to experience a recurrence of the disease. The test delivers definitive High Risk or Low Risk information about the risk of recurrence, with no ambiguous "intermediate" results. It is the only assay providing risk recurrence information that is based on prospective trials including peer-reviewed patient outcome data (the RASTER study).

The first FDA-cleared test of its kind, MammaPrint is performed as part of Agendia's Symphony® test panel, which also includes BluePrint, the most widely available test providing molecular subtyping of individual breast cancers. The Agendia tests have substantial insurance coverage encompassing an estimated 182 million lives and including coverage by Medicare and regional and national insurers.

The scientific poster presented at MBCC was titled "Molecular subtypes of cases discordant between risk classification assays in patients with ER+, N0-N1 breast cancer."

About Agendia:

Agendia is a leading molecular diagnostic company that develops and markets FFPE-based genomic diagnostic products, which help support physicians with their complex treatment decisions. Agendia's breast cancer Symphony suite was developed using unbiased gene selection, analyzing the complete human genome. Symphony includes MammaPrint, the first FDA-cleared IVDMIA breast cancer recurrence assay, as well as BluePrint, a molecular subtyping assay, and TargetPrint®, an ER/PR/HER2 expression assay. MammaPrint is the only breast cancer recurrence assay backed by peer-reviewed, prospective outcome data proven to uncover more treatable biology. Together, these tests help physicians determine a patient's individual risk for metastasis, which patients will benefit from chemo, hormonal, or combination therapy, and which patients do not require these treatments and can instead be treated with other, less arduous and less costly methods.

In addition to the Symphony suite of tests, Agendia has a rich pipeline of 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 and is a critical partner in the ISPY-2 and MINDACT trials. For more information, visit www.agendia.com.

-- END –