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Agendia Test for Molecular Subtyping of Breast Cancer Is a Better Guide to Pre-Surgical Treatment, Study Finds

Presentation at ASCO Breast Cancer Symposium Shows BluePrint Test Is More Accurate than Conventional Subtyping

IRVINE, CA and AMSTERDAM – In findings that could eventually change the way breast cancer is treated, a study reports that the BluePrint genomic test provides more accurate information about the molecular subtype of breast cancer than does conventional IHC-FISH pathology testing. The results were reported at the recent American Society of Clinical Oncology (ASCO) 2014 Breast Cancer Symposium (#BCS14), held Sept. 4-6 in San Francisco.

The prospective observational study of 515 patients showed that the 80-gene BluePrint test reclassified 22% of tumors overall – meaning that it more accurately identified breast cancer subtypes than did the IHC-FISH tests. Based on these results, researchers concluded that the BluePrint assay may be superior to IHC-FISH testing for guiding physicians' decisions about how to treat their patients' early-stage breast cancers before surgery.

"This genomic test gives us a better picture of which patients will and won't respond to preoperative therapy, and also helps suggest the best course for therapy," said Pat Whitworth, M.D., a Nashville surgical oncologist and lead study author. "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 molecular subtype rather than just IHC-FISH pathology results."

More information and updated data from this ongoing study will also be presented at the European Society for Medical Oncology (ESMO) 2014 Congress in a poster discussion. ESMO 2014 will be held Sept. 26-30 in Madrid.

An earlier iteration of the study encompassing 426 patients was recently published by the *Annals of Surgical Oncology,* as part of the ongoing Neoadjuvant Breast Registry Symphony Trial (#NBRST, pronounced "N-breast"), with details available here. The researchers' findings will also be published in the October print edition of the *Annals of Surgical Oncology*,

The BluePrint test is performed in conjunction with Agendia's 70-gene MammaPrint test. MammaPrint provides the foundational risk classification of High Risk or Low Risk about breast cancer recurrence, without the ambiguity of intermediate results. Additional therapy-predictive information is then conferred by the 80-gene BluePrint assay, which identifies the molecular subtype.

"This study is telling us that we now have a better tool to measure the dominant biological drivers of each individual breast cancer," said Neil Barth, MD., an oncologist and Agendia's Chief Medical Officer.

In addition to Dr. Whitworth's Nashville Breast Center, the multi-site study drew patients from a broad base of community and academic practices, including hospitals in Washington, D.C., Dallas, Virginia, Pennsylvania and Georgia.

Resources for further reference

- Independent comparison validates molecular subtyping (includes video)
- RASTER prospective outcome study and press release
- MammaPrint valid up to 25 years: study and press release

About Agendia:

Agendia is a 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 tests were developed using an unbiased gene selection by analyzing the complete human genome. MammaPrint is the only breast cancer recurrence assay backed by peer-reviewed, prospective outcome data. Agendia's tests can help physicians assess a patient's individual risk for metastasis, which patients may benefit from chemo, hormonal or combination therapy, and which patients may not require these treatments and can instead be treated with other, less arduous and less 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 and is a critical partner in the ISPY-2 and the MINDACT trials. For more information, visit www.agendia.com.

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