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Molecular Subtyping with Agendia Tests Can Provide Better Guidance for Breast Cancer Treatment, New Research Reports

Presentations to American Society of Breast Surgeons Detail Clinical Insights from MammaPrint and BluePrint Genomic Tests

IRVINE, CA and AMSTERDAM – New evidence showing that the MammaPrint® and BluePrint® tests provide insights into how to treat breast cancer was presented at the annual conference of the American Society of Breast Surgeons (ASBrS).

Molecular subtyping with MammaPrint and BluePrint offers a more precise prognosis and clinically useful guidance about neoadjuvant (presurgical) chemotherapy and neoadjuvant endocrine therapy, according to a podium presentation by Pat Whitworth, M.D., a surgical oncologist at Nashville Breast Center and Saint Thomas Midtown Hospital, in Nashville. A separate scientific poster presented by Katharine Yao, M.D, et al. concludes MammaPrint could help distinguish between patients who would benefit from more comprehensive radiation treatment, and those who may be safely treated with more targeted radiation.

"The BluePrint test takes a much more nuanced look at breast cancer biology than is available from conventional IHC-FISH pathology tests," Dr. Whitworth said. "These results look like a breakthrough for BluePrint, because it provides clinically useful guidance that amplifies the insights from other standard measures."

Dr. Whitworth said the BluePrint test more accurately classifies an individual woman's breast cancer, compared to conventional IHC-FISH pathology tests. Armed with that information, oncologists and surgeons can better determine the best neoadjuvant treatment depending on the individual patient's molecular subtype.

The 426 patients in the prospective trial reported by Dr. Whitworth were from 50 different centers. "One of the significant aspects of this study is that it gathers real-world outcomes from a broad base of community and academic practices," he said. Patients in the study are part of the ongoing Neoadjuvant Breast Registry Symphony Trial study (NBRST).

Researchers looked at how IHC-FISH and MammaPrint-BluePrint classified each patient's subtype. They then examined how patients responded to neoadjuvant chemotherapy or endocrine treatment, to see whether IHC-FISH or MammaPrint-BluePrint was better at predicting response to neoadjuvant therapy. Overall, BluePrint reclassified 22% of tumors in the study.

The demonstrated benefits of MammaPrint-BluePrint can in turn help guide oncologists and surgeons in the future, as they consider whether to propose neoadjuvant treatment and what kind of treatment (typically chemotherapy or endocrine therapy) to recommend.

Genomic tests such as MammaPrint and BluePrint are part of the revolution in personalized medicine. Genomic tests examine the activity of groups of genes within a cancer tumor, to provide a more comprehensive view of the cancer and treatment options. The MammaPrint test predicts how likely it is that a woman's breast cancer will recur. BluePrint then identifies the molecular subtype of her cancer and predicts tumor response to targeted therapies before and after surgery. The four molecular subtypes are known as Luminal A, Luminal B, Basal-type and HER2-type.

In the separate poster, Dr. Yao and colleagues reported that MammaPrint accurately predicts an individual patient's risk of local-regional recurrence in stage 1 through 2b breast cancer upon original diagnosis. The poster also said MammaPrint "could help define patients that would benefit from more comprehensive treatment (nodal irradiation, tumor bed boost) or that may be safely treated with a targeted approach (partial breast irradiation or IORT)."

Yao and colleagues at NorthShore University Health System (Chicago) and Fox Chase Cancer Center and Thomas Jefferson University Hospital (Philadelphia) analyzed the recurrence rate in 374 patient tumor samples. Their data had a median follow-up of 8.3 years.

The American Society of Breast Surgeons annual meeting was held in Las Vegas on April 30-May 4, 2014.

Resources for further reference

- RASTER prospective outcome study and press release
- MammaPrint valid up to 25 years: study and press release
- Molecular subtyping study

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 Symphony breast cancer suite was developed using an unbiased gene selection by analyzing the complete human genome. This includes MammaPrint, 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 backed by peer-reviewed, prospective outcome data. These 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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