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

Matt Clawson (Financial Media)
Pure Communications
949-370-8500
Matt@PureCommunications.com

Agendia Breast Cancer Test for Molecular Subtyping Improves Match of Therapy to Patient, Study Finds

Presentation at ESMO Meeting Shows Value of BluePrint Test to Help Determine Best Presurgical Treatment

IRVINE, CA and AMSTERDAM – New data from an ongoing study indicates the BluePrint genomic test provides information about the molecular subtype of breast cancer that adds value beyond what can be learned from conventional IHC-FISH pathology testing. The results were reported at the recent European Society for Medical Oncology (#ESMO14) 2014 Congress.

The prospective observational study of 515 patients concluded that Agendia's 80-gene BluePrint assay reclassified 22% of tumors overall and more accurately identified breast cancer subtypes than did IHC-FISH tests. Researchers said the BluePrint assay may serve as a better guide for 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 poster co-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."

The study was selected for poster discussion at ESMO, and the results were discussed by Dr. Suzette Delaloge, a medical oncologist at the Institut de Cancérologie Gustave Roussy, in Villejuif, France. She explained the results and termed the findings very interesting.

Agendia's 70-gene genomic 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 BluePrint, which identifies the molecular subtype.

An earlier iteration of the study that was featured in the poster at ESMO 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 ESMO conference also included a scientific poster on a study from Spain that prospectively documented the ability of tests such as Agendia's MammaPrint to safely exempt some breast cancer patients from chemotherapy. The poster confirmed the power of the MammaPrint test to change physicians' recommendations about the best way to treat breast cancer after surgery.

In the Spanish study, the MammaPrint test was performed on tumor tissue from 150 node-negative, ER-positive patients who were served by community-based practices in Valencia, Spain. Researchers reported MammaPrint changed the initial treatment recommendation in 63.4% of relevant patients. The overall conclusions about MammaPrint are similar to those in a prospective, outcome-based study that appeared in the International Journal of Cancer (RASTER study).

The poster noted that use of an assay such as MammaPrint can be valuable in reducing the total number of patients receiving chemotherapy after breast cancer surgery, "thus preventing major toxicity and inconvenience to patients and saving costs." Eduardo Martinez de Duenas, M.D., was lead author on the poster. Among the co-authors was Antonio Llombart, M.D.

A separate program moderated at the ESMO meeting by Dr. Llombart highlighted both the process of evaluating breast cancer risk of recurrence and the significance of functional molecular subtypes. Dr. Llombart is head of the Medical Oncology Department of the Hospital Arnau de Vilanova, in Valencia, Spain and is also Chairman of SOLTI and Coordinator of the SOLTI Scientific Committee. SOLTI is a non-profit cooperative research group that performs clinical trials of excellence in oncology.

The ESMO 2014 meeting, held 26-30 September, drew 19,000-plus participants from 120 countries, a 23% increase in participants from the last such ESMO meeting.

Resources for further reference

- Independent comparison validates molecular subtyping (includes video)
- RASTER prospective outcome study
- 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

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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