AGENDIA ANNOUNCES DATA PRESENTED AT ASCO 2020 DEMONSTRATING IMPORTANCE OF FURTHER CLASSIFICATION OF BREAST CANCERS TO ENABLE PRECISE PROGNOSIS AND TREATMENT

Presentations outline how BluePrint® genomic testing enables further categorization of HER2-positive cancer and reclassification of ER+ tumors for patients’ benefit.

FLEX registry reinforces the clinical and real-world utility of MammaPrint® and BluePrint to improve stratification of breast cancer patients.

IRVINE, CALIF., U.S., and AMSTERDAM, NETHERLANDS – MAY 29, 2020 – Agendia, Inc., a world leader in precision oncology for breast cancer, announced that new data from ongoing clinical research on MammaPrint® and BluePrint® was debuted at the American Society of Clinical Oncology 2020 Virtual Scientific Program (ASCO) today. A total of five posters were presented on Agendia’s genomic profiling assays.

The highlighted data below further illustrate the efficacy of Agendia’s MammaPrint and BluePrint genomic testing to consistently stratify breast cancers, allowing for a highly personalized regimen throughout a patient’s treatment journey. The latest findings from Agendia deliver immediate, actionable information for doctors and patients early in the diagnosis and treatment planning process and build on research that will impact breast cancer treatment and outcomes in the future.

One scientific presentation, entitled “Adding precision to 2018 ASCO/CAP HER2 testing guidelines in breast cancer with genomic profiling,” evaluated the concordance between human epidermal growth factor receptor 2 (HER2) status as put forth by the 2018 ASCO/CAP guidelines and Agendia’s BluePrint genomic testing. In this real-world diagnostic data set, the 2018 guideline recommendations led to fewer HER2 equivocal tumors overall, confirming the positive impact of the revisions. Of note, BluePrint reclassified 69 percent of HER2-positive tumors and all HER2 equivocal tumors to non-HER2 molecular subtypes, indicating that these tumors may have suboptimal responses to HER2-directed therapy. This study found that molecular classification by BluePrint adds further precision in stratifying HER2-positive patients, offering the potential to predict responsiveness to HER2-targeted therapies.

“In this study, nearly 70 percent of HER2-positive diagnoses were reclassified to non-HER2, based on molecular subtyping. This is interesting and may have the potential at some point to affect treatment decisions and patient outcomes,” said Adam Brufsky, MD, PhD, and Professor of Medicine at the University of Pittsburgh School of Medicine. “Data continue to show the value of MammaPrint and BluePrint as diagnostic tools that allow physicians to make more informed decisions to address their patients’ disease.”

Also at ASCO, Agendia shared updates on the ongoing FLEX trial, the massive real-world clinical data set designed to drive the medical community forward in its approach to precision medicine. In addition to a designated FLEX study poster – “The FLEX Real World Data Platform Explores New Gene Expression Profiles and Investigator-Initiated Protocols in Early Stage Breast Cancer” – that gave general updates on the registry, Agendia also
highlighted FLEX and forward-looking studies, one of which has immediate implications for how a patient’s treatment may change based on comprehensive information uncovered by BluePrint.

The FLEX scientific presentation, entitled, “TNBC subtype and clinical estrogen receptor status of genomically basal breast tumors in Caucasian, African American, and Latin American patients,” evaluated the distribution of triple-negative breast cancer (TNBC) subtypes in genomically Basal-Type cancers from self-reported patient ethnicities (Caucasian, African American, and Latin American). The data show that Basal-Type tumors are heterogeneous and include all defined TNBC subtypes, independent of ethnicity.

In addition, the study evaluated the association of IHC-determined estrogen receptor status and Basal-Type tumors of each ethnicity. Analyses demonstrated that BluePrint reclassified a subset of estrogen receptor positive (ER+) tumors to molecular Basal-Type and that ER status was not significantly associated with a specific TNBC subtype or ethnicity. This highlights the clinical need to trace basal biology in ER+ patients to refine treatment for basal-like tumors.

“The reclassification of a subset of ER+ tumors identifies an urgent and actionable situation,” said Cathy Graham, MD, Assistant Professor of Surgery in the Division of Surgical Oncology at Emory University School of Medicine and Director, Breast Surgery at Emory St. Joseph's Hospital. “From a clinical perspective, when these patients are first diagnosed, they appear to have luminal breast cancer. But, when you are able to look at the underlying mechanism with comprehensive genomic testing, a large subset of these breast cancers is reclassified to Basal-Type, which is high risk. This knowledge allows us to execute a more personalized and precise treatment approach immediately.”

Two other forward-looking studies reinforce the future utility of better stratifying patients, and Agenda’s ability to provide a more sophisticated platform for discovery in gene signature research.

- In the first, entitled, “High Risk breast cancer genes at 8q22-24 and their role in over 5,000 patients evaluated with the MammaPrint risk of recurrence assay,” FLEX researchers looked at the 8q22-24 chromosomal region, known to be associated with breast cancer. The study results provided further evidence that aberrations in this region are associated with higher-risk disease. Within the MammaPrint signature, the genes CCNE2, MTDH, and TSPYL5 have similar expression patterns and when overexpressed, represent a unique subgroup of high-risk tumors. These findings and further research on the 8q22-24 region may help to better stratify high-risk patients through ongoing clinical trials evaluating response and resistance to targeted therapies.

- The second, entitled, “12-chemokine gene expression score in breast cancer patients treated with neoadjuvant chemotherapy,” builds on existing research related to gene expression as a predictive biomarker for immune responses in breast cancer patients. The study found that chemokine gene expression, which indicates the presence of immune cells, was associated with pathologic complete response (pCR), MammaPrint High Risk index, and BluePrint subtypes. This research suggests that chemokine score may be further stratified by using MammaPrint and BluePrint in order to identify patients who may be more likely to benefit from neoadjuvant chemotherapy. This work also suggests that future studies may evaluate the potential utility for chemokine score and MammaPrint in predicting responses to immunotherapy in breast cancer patients.
“The research we are showcasing at this year’s ASCO Annual Meeting underscores our commitment to patients and physicians,” said William Audeh, MD, Chief Medical Officer at Agendia. “With our growing arsenal of data collected through prospective clinical trials such as FLEX, I-SPY2 and MINDACT, we are able to help patients now while information-gathering for future breast cancer treatment strategy.”

Agendia is proud to present these findings at the ASCO 2020 Annual Meeting, which underscore the company’s commitment to innovation and discovery through extraordinary, patient-focused research.

About Agendia

Agendia is a precision oncology company committed to improving clinical outcomes and informing the journey for patients with early-stage breast cancer. The company currently offers two commercially available genomic profiling tests, processed through its state-of-the-art facility in Irvine, California. Agendia also provides a next-generation sequencing kit for use by local laboratories outside of the United States.

MammaPrint®, the 70-gene breast cancer recurrence assay, is the first FDA-cleared risk-of-recurrence test backed by peer-reviewed, prospective outcome data and included in both national and international treatment guidelines. BluePrint®, the 80-gene molecular subtyping assay, is a commercially available test that evaluates the underlying biology of a tumor to determine what is driving its growth. Together, MammaPrint and BluePrint provide a comprehensive genomic profile to help physicians make more informed decisions in the pre- and post-operative treatment settings. By developing evidence-based, novel genomic tests, Agendia aims to support the evolving clinical needs of breast cancer patients and their physicians.

Agendia’s assays can be ordered on core biopsies or surgical specimens with results provided in as little as 5-7 days to inform pre- and post-operative treatment decisions. For more information on Agendia’s assays and ongoing trials, please visit www.agendia.com.

About the FLEX Registry

Three years ago, Agendia launched a clinical trial for patients in the US, known as the FLEX Registry. It is a large-scale, prospective, observational breast cancer study that links whole transcriptome profiling, including MammaPrint and BluePrint, with complete clinical data. FLEX generates a comprehensive patient database with the potential to identify new gene associations with prognostic and/or predictive value in breast cancer.

View FLEX Registry details here.

About the I-SPY2 Study

The I-SPY2 trial looks at whether adding experimental agents to standard neoadjuvant medications increases the probability of pathologic complete response (pCR) beyond standard neoadjuvant chemotherapy for each biomarker signature established at trial entry. So far, findings support the use of residual cancer burden (RCB) as a prognostic indicator for three-year outcomes in patients pre-selected as high risk for recurrence, and the importance of MammaPrint in identifying these patients.
I-SPY2 breaks from the traditional randomized trial design, employing an ‘adaptive’ model that allows multiple treatments (up to six different agents) to be studied in parallel. This master framework also allows new agents to enter and leave the study without having to halt enrollment or resubmit the entire clinical trial protocol for regulatory review.

View the I-SPY2 trial site here.

About the MINDACT Trial

MammaPrint is supported by the highest level of clinical evidence (level 1A) from MINDACT, a landmark independent trial published in the New England Journal of Medicine in 2016.

MINDACT stands for Microarray In Node-Negative and 1-3 node-positive Disease may Avoid ChemoTherapy. It was a phase III, prospective, randomized, clinical study for a breast cancer recurrence test sponsored by the European Organization for Research and Treatment of Cancer (EORTC-10041/BIG3-04).

View the whole trial here.

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