Agendia Announces New Data Assessing the Immune Active State in HR+/HER2- Early-Stage Breast Cancer at 2024 ASCO

FLEX data show MammaPrint High 2 tumors exhibited a heightened immune response compared to High 1 tumors.

IRVINE, CALIF., U.S., and AMSTERDAM, NETHERLANDS – May 31, 2024 – Agendia®, Inc. today announced it will present new data characterizing the immune biology of MammaPrint High Risk tumors in an oral session at the 2024 Annual American Society of Clinical Oncology (ASCO) Meeting, taking place in Chicago, IL. on June 3rd, 2024.

The study presented by Erin Cobain MD, Associate Professor in the Division of Hematology/Oncology at the University of Michigan Medical School, Ann Arbor and co-Principal Investigator of the SWOG S2206 Trial, titled **Elucidating the immune active state of HR+HER2- MammaPrint High 2 early breast cancer** [Cobain, E., et al.] characterizes the underlying immune biology that mediates immune therapy response in early stage hormone receptor-positive (HR+), Human Epidermal Growth Factor Receptor negative (HER2-) breast cancer, categorized as MammaPrint High Risk 2 (MP H2) in patients enrolled in the prospective, observational FLEX Study (NCT03053193). This study builds upon the findings from the I-SPY 2 Trial, which showed that patients with MP High-2, HR+HER2- tumors have improved response rates when immunotherapy is added to standard neoadjuvant chemotherapy.

Using whole transcriptome analysis, researchers evaluated relative frequency of immune cell types, expression level of genes involved in antigen processing and presentation, and expression of immune checkpoint genes PD-1 and PD-L1. Results of the analysis showed that MP High-2 tumors had a significantly higher frequency of antigen presenting cells (APCs) (including activated dendritic cells and macrophages, CD4+ memory T cells, CD8+ T cells, memory B cells and antibody producing plasma cells) relative to High-1 tumors, highlighting an increased immune active state in High-2 tumors. The increased antigen presentation and presence of APCs, which are critical in activating T- and B-cells, may explain why High-2 tumors display improved response rates to immunotherapy. The data from this study suggests that early stage HR+HER2- High-2 tumors might benefit from the addition of immunotherapy to their chemotherapy treatment regimens. These findings support the rationale for the ongoing SWOG S2206 (NCT06058377) Trial, which is utilizing MP High-2 as a biomarker to select patients for neoadjuvant chemo-immunotherapy treatment.

“There is a great need for biomarkers beyond PD-L1 and tumor mutational burden that may predict clinical benefit from immunotherapy-based treatments. The recent CheckMate 7FL and KEYNOTE-756 studies demonstrated that there is a subset of patients with HR+HER2- early breast cancer that will benefit from immunotherapy, as both trials demonstrated an improvement in likelihood of pathologic complete response rates for those patients receiving neoadjuvant chemo-immunotherapy compared to chemotherapy alone,” said Dr. Cobain. “However, we are aiming to take this a step further and refine the biomarkers that will allow for us to identify those patients most likely to benefit from this approach and avoid overtreatment. This is particularly important given the potential serious toxicities that can result from immunotherapy treatment.”

“This study highlights the importance of understanding how the classification of tumors may determine different response rates to treatment and how this will inform breast cancer care going forward. With the FLEX Study, we are now able to not only look at clinical outcomes but also analyze whole transcriptome data to better understand how women with breast cancer respond to different treatment regimens and use this information to customize breast cancer treatment,” said William Audeh, MD, MS, Chief Medical

Officer of Agendia. “The data we’re sharing at 2024 ASCO further validates MammaPrint utility in identifying not only the question of chemo vs. no chemo, but also illustrates the ability of MammaPrint to identify tumors with increased immune activation, supporting the rationale for using MammaPrint High 2 as a selective biomarker for immunotherapy in SWOG S2206.”

About Agendia

Agendia is a leading provider of innovative solutions in the field of precision oncology. With a focus on early-stage breast cancer, Agendia offers reliable biological insights that inform personalized treatment decisions for patients and their care teams. Their advanced genomic assays, MammaPrint® + BluePrint®, enable clinicians to quickly identify the most effective treatment plan, minimizing the risk of both under- and over-treatment.

Founded in 2003 in Amsterdam, Agendia is headquartered in Irvine, California with a state-of-the-art laboratory facility. Led by world-renowned scientists and oncologists, Agendia is committed to advancing genomic insights through ongoing research. This includes the notable FLEX Study– the world's largest whole transcriptome Real-World Evidence-based Breast Cancer database which aims to revolutionize precision in breast cancer management. With cutting-edge technology, research and innovation, Agendia strives to shape the future of precision oncology and make a significant impact in the fight against breast cancer.

About MammaPrint

MammaPrint is a gene expression profiling test that reveals the distinct underlying biology of an early-stage tumor to determine its risk of spreading. This FDA-cleared gene expression profiling test assess a woman’s risk of distant metastasis and provides critical answers that inform the future of woman’s treatment plans at the point of diagnosis, including the timing and benefit to chemotherapy and endocrine therapy. MammaPrint listens to the signals from 70 key genes in a woman’s tumor to stratify her risk within four distinct categories - ranging from UltraLow, Low, High-1, and High-2 – to fuel a right-sized care plan tailored to her biology and her life’s plans.

About BluePrint

BluePrint® is a gene expression profiling test that reveals the driving forces behind a tumor’s growth at the earliest stage possible in a woman’s breast cancer care journey to help optimize and personalize treatment planning. As the only molecular subtyping test available in the U.S., BluePrint® goes where pathology cannot, offers critical insights that providers may otherwise have not known to act on, and gives women the best chance to return to a life not defined by cancer. BluePrint® measures the activity of 80 key genes that are involved in a tumor's growth to classify a tumor as Luminal-type, HER2-type, or Basal-type, each of which warrant distinct treatment pathways. By revealing the distinct underlying biology of a woman's tumor, BluePrint® can catch often misclassified, yet highly aggressive, Basal tumors, so women can be prescribed the most appropriate treatment from the start.

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