Agendia Announces First Patient Enrolled in PROOFS Registry Trial to Determine Optimal Treatment and Ability to Forgo Chemotherapy for Premenopausal Women with Early HR+ Breast Cancer
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IRVINE, Calif. & AMSTERDAM & MÖNCHENGLADBACH, Germany--(BUSINESS WIRE)--Agendia, Inc., a leader in gene expression profiling for early-stage breast cancer, today announced the first patient has been enrolled in the PROOFS Registry trial. In partnership with the West German Study Group (WSG), the study aims to determine whether premenopausal women with early HR+ breast cancer, originally defined as clinically high-risk and classified as MammaPrint Low Risk, can avoid chemotherapy, and maintain strong outcomes by opting instead for temporary ovarian function suppression (OFS) in combination with endocrine therapy. By determining the drivers behind a young woman's response to chemotherapy, the trial's results could empower young women with the ability to safely forgo chemotherapy toxicities and preserve their fertility and quality of life.

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Breast cancer uses estrogen to grow, and chemotherapy suppresses the ovaries' production of estrogen to cut off the cancer's fuel source. While MINDACT study data found a small 3-5% chemotherapy benefit in premenopausal women with MammaPrint Low Risk tumors, the authors later concluded it is likely due to the chemotherapy-induced ovarian function suppression (OFS), rather than the effect of chemotherapy on the cancer itself. The PROOFS Registry trial intends to show this perceived benefit is merely a side effect of chemotherapy-induced OFS, deeming chemotherapy unnecessary and replaceable by temporarily suppressing the ovaries. Every young woman with early-stage breast cancer deserves the right to make truly informed treatment decisions tailored to her unique biology.

"Several studies have shown chemotherapy can have an irreversible impact on fertility, therefore the right treatment decision is critical in a woman's potential family planning," said PD Dr. Oleg Gluz, Scientific Director of the WSG and leader of the Breast Center Niederrhein, Ev. Hospital Bethesda, Mönchengladbach and PD at the University of Cologne. "This study could potentially show that young women with breast cancer could be treated with endocrine therapy and OFS without compromising outcomes and without the risk of permanently affecting their fertility – all based on insights from her tumor's unique gene expression profile."

"While chemotherapy is often assumed to be necessary for all young women with hormone receptor positive breast cancer, we have been able to harness the power of gene expression profiling to understand the biology of each breast cancer beyond the effects of age and standard pathology, and better define the true benefit of treatment. These insights could allow some young women with breast cancer to forgo chemotherapy and avoid unnecessary toxicity," said William

Audeh, MD, Chief Medical Officer at Agendia. “If their small chemotherapy benefit indeed stems from OFS as the PROOF Registry trial seeks to prove, more young women can forgo the potentially serious and sometimes life-threatening effects of chemotherapy. We’re proud to partner with WSG on this important step to advance personalized treatment planning, reduce overtreatment, and help more women with breast cancer maintain their quality of life.”

The PROOFS Registry trial intends to enroll 1,500 patients via 100 sites in Germany by January 2025. Right now, it is critical young women with early breast cancer be afforded the opportunity for shared decision-making when weighing the small perceived chemotherapy benefit against its impact on their future fertility and quality of life. By the close of the PROOFS Registry study, providers may be in a position to confidently recommend OFS as an alternative to toxic chemotherapy and preserve a woman’s fertility while maintaining the best chance at survival. Together with WSG, Agendia continues to enable more personalized treatments in breast cancer care.