July 31, 2014

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 Co-Founder and CSO Develops Method to Identify Women Who Will Benefit from Tamoxifen Therapy for Breast Cancer

New Study by Rene Bernards, Ph.D. Shows the Promise of Clinical Utility in Refining Cancer Treatment among Most Breast Cancer Patients

IRVINE, CA and AMSTERDAM – Innovative research by Rene Bernards, Ph.D., the co-founder of Agendia, Inc., has identified a gene signature that has potential to identify which patients will benefit from tamoxifen therapy.

Bernards' research appears in the journal *Cancer Research*, published by the American Association for Cancer Research. The new study drew upon data involving about 680 patients with estrogen receptor-positive breast cancer. About 70 percent of women with breast cancer have ER-positive cancer.

Although tamoxifen is effective in reducing the risk of cancer recurrence in most of these patients, not all of them respond well to tamoxifen -- and they may therefore be needlessly exposed to the potential risks and side effects of the treatment.

"It has previously been very difficult to identify patients whose tumors lack a proper response to tamoxifen," Bernards said. "About one-third of ER-positive patients experience a relapse after post-surgical treatment with tamoxifen. Median overall survival in these patients, even with further treatment, is around 30 to 45 months."

Tamoxifen is an endocrine therapy that is one of the most frequently used medications worldwide to

reducing recurrence risk, many of them experience menopausal-like side effects such as hot flashes, vaginal dryness and loss of libido. More serious but less common risks include endometrial cancer and blood clots. Roughly half of women who begin tamoxifen therapy do not complete the full course of treatment.

Breast cancer patient Lisa Hill remembers closing in on the finish line of five years with tamoxifen. “I was planning a party to celebrate the end of my aches, pains and weight gain,” Hill said, when her oncologist told her new studies showed women should stay on the drug for ten years.

“Dr. Bernards’ research draws upon next-generation technologies that have proven so valuable to specialists who want to offer their patients the very best treatment for breast cancer,” said Neil Barth, M.D., the Chief Medical Officer at Agendia. “This new line of research has the potential to expand clinicians’ ability to identify which treatments will be most beneficial. It may also enable them to suggest alternatives to tamoxifen treatment when it is not likely to be effective.”

In their study, Bernards and colleagues identified and tested a gene signature that is associated with the loss of function of a gene called USP9X. When USP9X loses function in breast cancer cells, they concluded, it results in tamoxifen resistance.

“We showed that this gene signature was able to identify tamoxifen-resistant patients in two large cohorts,” said Bernards. “We are now working to validate these promising results using data from a prospective randomized controlled trial, and we expect to complete this process by the end of the year. If this is successful, clinical implementation is a logical next step.”

Bernards co-founded Agendia, Inc., in 2003. He is head of Molecular Carcinogenesis at the Netherlands Cancer Institute at Antoni van Leeuwenhoek Hospital and a part-time professor at Utrecht University. His study was funded by the Dutch Cancer Society.

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 tests were 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. 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 other 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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