



## **Agendia & Collaborators Publish Key MammaPrint Paper in *Nature Cell Biology* Study Once More Underpins the Clinical Value of FDA-cleared Breast Cancer Recurrence Assay**

IRVINE, CA, and AMSTERDAM, THE NETHERLANDS, December 20, 2010 – Agendia, a world leader in molecular cancer diagnostics, announced today that together with several groups of scientific collaborators it has identified a major role for *TSPYL5*, one of its MammaPrint breast cancer prognosis genes, in the genesis of breast cancer. The study entitled: “*TSPYL5* suppresses p53 levels and function by physical interaction with USP7”, was published today in *Nature Cell Biology*, one of the foremost scientific journals.

The study provides further proof of the superiority of the unbiased whole genome discovery process on which MammaPrint is based. The 70 genes that constitute the MammaPrint signature were arrived at after comparison of full genome gene expression profiles of a large number of breast tumors. In 2002, when the first landmark papers on MammaPrint were published in the *New England Medical Journal* and *Nature*, the individual function of nearly half of the 70 genes was unknown, including the *TSPYL5* gene. Despite this, it was clear that MammaPrint offered the strongest prognostic evidence of any molecular diagnostic assay for breast cancer recurrence and is able to identify chemotherapy-sensitive metastasis risk with 94% accuracy. The discovery process commonly used today by developers of molecular diagnostic assays relies on the so-called candidate gene approach, in which genes are selected based what is known from the scientific literature and expert opinion at the specific date of development. By its nature this approach has important limitations, since it ignores the wealth of information in the human genome, such as the *TSPYL5* gene, that, even if unexplained, still plays a pivotal role in disease processes.

The paper in *Nature Cell Biology* describes for the first time the function of the *TSPYL5* gene, and specifically its crucial interaction with p53, one of the best-described tumor suppressor genes. By suppressing p53, *TSPYL5* seems to disarm one of the key genes responsible for combating tumor development, and the authors show that *TSPYL5* is an independent poor prognosis marker in breast cancer. The *TSPYL5* gene and another previously unknown MammaPrint gene, *metadherin* (*MTDH*), which was also recently found to mediate metastasis and chemoresistance, are not included in other breast cancer recurrence assays and in hindsight provide a scientific rationale for MammaPrint’s unprecedented clinical utility.

To access the paper, please go to: <http://www.nature.com/ncb/journal/vaop/ncurrent/abs/ncb2142.html>

### **About MammaPrint®**

MammaPrint is the first and only breast cancer recurrence test cleared by the U.S. Food and Drug Administration (FDA). FDA clearance requires clinical and analytical validation and reporting systems to ensure patient safety issues are addressed. Highly accurate, MammaPrint identifies patients with early metastasis risk — patients who are likely to develop metastases within five years following surgery. Several authoritative studies have shown that chemotherapy particularly reduces early metastasis risk. In planning treatment, the MammaPrint test results provide doctors with a clear rationale to assess the benefit of chemotherapy in addition to other clinical information and pathology tests. All MammaPrint tests are conducted in Agendia’s CAP-accredited and CLIA compliant service laboratories.

### **About Agendia**

Agendia is at the forefront of the personalized medicine revolution, striving to bring more effective, individualized treatments within reach of patients. Building on a cutting-edge genomics platform for tumor gene expression profiling, the company’s tests help physicians more accurately tailor cancer treatments. Agendia markets four products, with several new genomic tests under development. In addition, Agendia collaborates with pharmaceutical companies to develop highly effective personalized drugs in the area of oncology. Agendia is based in Irvine, California, and in Amsterdam, the Netherlands.

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