



Agendia Publishes Compelling First Independent Validation Study of Colon Cancer Recurrence Test “ColoPrint” in *Journal of Clinical Oncology*

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Second Independent Validation Study of ColoPrint Selected for Oral Presentation and Press Conference at ASCO GI in January 2011

IRVINE, CA, and AMSTERDAM, THE NETHERLANDS, December 15, 2010 – Agendia, a world leader in molecular cancer diagnostics, announced today that together with principal investigators from Spain, the UK, and the Netherlands, it has published the first independent validation study of its colon cancer recurrence test “ColoPrint” in the *Journal of Clinical Oncology*. The authors conclude that ColoPrint significantly improves prognostic accuracy over assessment solely based on pathologic factors and microsatellite instability in patients with stage II and III colorectal cancer. In combination with classical pathological criteria, ColoPrint facilitates the identification of stage II patients who may be safely managed without chemotherapy.

About the study

This study aimed to develop a robust gene expression classifier that can predict disease relapse in patients with early-stage colorectal cancer (CRC). ColoPrint was developed using an unbiased analysis of the entire human genome to identify recurrence-related genes. Frozen tumor tissue from 188 untreated patients with stage I to IV CRC was analyzed using Agilent 44K oligonucleotide arrays. A nearest mean classifier was developed using a cross-validation procedure and an optimal set of 18 genes was identified. The signature was validated on an independent set of 206 samples from patients with stage I, II, and III CRC.

In the subset of patients with stage II disease, ColoPrint correctly identified most patients (63%) as low risk. Low risk patients had a chance of 90.9% to remain relapse free for 5 years while high risk patients had only a 73.9% 5-year relapse-free survival (RFS). In stage II patients, ColoPrint was the strongest predictor for RFS in the univariate analysis (HR, 3.34; 95% CI, 1.24 to 9.00; P 0.017) and multivariate analysis. The classifier performed independently from the ASCO risk criteria when analyzed either individually or combined (HR, 3.66; 95% CI, 1.24 to 9.08; P 0.017). Furthermore, in the analysis of all samples and of samples from patients with stage III disease only, ColoPrint remained a strong independent prognostic factor.

The study’s lead author is Ramon Salazar, MD, from the Institut Catala` d’Oncologia-IDIBELL, L’Hospitalet de Llobregat, in Barcelona, Spain. The co-authors are from Agendia; the Netherlands Cancer Institute and Slotervaart Hospital in Amsterdam, the Netherlands; Leiden University Medical Center in Leiden, the Netherlands; and the University of Oxford, Radcliffe Infirmary, in Oxford, United Kingdom.

To access the article online go to: <http://jco.ascopubs.org/content/early/2010/11/15/JCO.2010.30.1077.full.pdf+html>

About ASCO GI (Jan 20-22, 2011, San Francisco, CA, US)

The results of a second independent validation study by principal investigators from the university hospital Klinikum *rechts der Isar*, in Munich, Germany, have been submitted to the upcoming Gastrointestinal Cancers Symposium organized by the American Society of Clinical Oncology (ASCO). The lead author of the study, Dr. Robert Rosenberg, has been invited to give an oral presentation at ASCO GI and, additionally, to present his data at a press conference for specialized media.

About ColoPrint®

ColoPrint® is a novel gene expression profile that identifies Stage II or III colorectal cancer patients who are either at low risk or at high risk of experiencing a disease relapse. In combination with clinical parameters, ColoPrint can provide clinicians with a reliable means to assist them in adjuvant treatment decision-making. The development of ColoPrint follows the successful development and widespread clinical use of MammaPrint, the first and only FDA-cleared breast cancer recurrence assay. ColoPrint and MammaPrint have been developed by Agendia.

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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