Agendia to Provide Testimony at Public Meeting on FDA Oversight of Laboratory-Developed Tests

World Leader in Cancer Diagnostics Joins Nation's Top Safety Agency in Calling for Risk-Based Oversight of Genomic Testing

IRVINE, CA, and AMSTERDAM, THE NETHERLANDS, July 15, 2010 – Agendia, a world leader in molecular cancer diagnostics, announced today that company CEO Dr. Bernhard Sixt will provide testimony at a public meeting on July 20 in Washington D.C. on the federal regulation of laboratory developed tests (LDTs). Jointly organized by the Food and Drug Administration (FDA) and Center for Devices and Radiological Health (CDRH), the Public Meeting on Oversight of Laboratory Developed Tests will be a forum for key stakeholders, including laboratory professionals, clinicians, patients and industry leaders to discuss and define the issues surrounding LDT regulation which pose the greatest risk to the public health. Dr. Sixt will present in Session II, "Oversight of LDTs: Clinical Laboratory Challenges."

Since the implementation of the 1976 Medical Device Amendments, the FDA has exercised enforcement discretion over LDTs, but has not pursued active regulation of the category. However, in recent years these tests have become increasingly complex and high risk in nature, and are playing an important role in clinical decision-making. As a result, the FDA has decided that LDTs which have not been properly validated put patients at risk, and that a risk-based application of oversight for the category is appropriate.

Agendia joins the FDA among other leading organizations, including Genentech, the College of American Pathologists, and the Genetics & Public Policy Center at Johns Hopkins University, in calling for a tiered risk-based approach to the regulation of LDTs. As the nation's leading authority for patient safety, Agendia believes that only the FDA can regulate the LDT category in a uniform and unbiased manner to ensure that all claims are validated, data is accurate and post-market surveillance is in place. Moreover, Agendia believes that holding the LDT category to the rigors of FDA scrutiny will inspire greater confidence among investors to enter this emerging market, foster a level playing field among molecular diagnostics companies and encourage the best technology to come to the fore in personalized medicine.

As the developer of the first and only FDA-cleared breast cancer recurrence test, MammaPrint, Agendia has led by example in the molecular diagnostics industry by embarking on a path of regulatory compliance. Agendia believes that patients and physicians deserve to be fully informed about the benefits and risks of medical diagnostics, and that all companies developing these devices should be held accountable for the claims and safety of their tests.

The FDA will collect and review all comments and information presented at this public meeting towards the development of a draft oversight framework for public comment. The meeting will be held on July 19 (8:00 a.m. to 5:00 p.m.) and July 20 (8:00 a.m. to 5:30 p.m.) at The Marriott Inn and Conference Center, University of Maryland University College.

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