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

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IRVINE, California, and AMSTERDAM, July 15, 2010 /PRNewswire/ -- 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
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