QIAGEN Completes Second U.S. Submission for Companion Diagnostic to Guide Treatment Decisions in Colorectal Cancer

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GERMANTOWN, Maryland and HILDEN, Germany, August 5, 2011 /PRNewswire/-- ? <ul class="discStyle" type="disc"> Food and Drug Administration will review therascreen® KRAS RGQ PCR Kit for use with Erbitux® (cetuximab), a metastatic colorectal cancer therapy PMA follows a recent submission for use with another EGFR inhibitor drug, also in patients with metastatic colorectal cancer QIAGEN achieves milestones in Personalized Healthcare with innovative companion diagnostics; FDA decisions expected in 2012 QIAGEN (NASDAQ: QGEN; Frankfurt, Prime Standard: QIA) today announced it has completed its second U.S. submission of the therascreen® KRAS RGQ PCR Kit for use as a companion diagnostic paired with Erbitux® (cetuximab), a leading drug for treatment of patients with metastatic colorectal cancer (mCRC). Erbitux is marketed in the United States by Bristol-Myers Squibb Company and Eli Lilly and Company. Merck KGaA has the right to market Erbitux outside the US and Canada. QIAGEN submitted a Premarket Approval (PMA) application to the FDA for use of its innovative assay in determining which patients can be expected to benefit from Erbitux in treatment of mCRC. The first submission of the KRAS assay, earlier in July, paired QIAGEN's molecular test with another drug for treatment of metastatic colorectal cancer. Both therapies are monoclonal antibody EGFR inhibitors expected to target a range of cancers. Last year's sales of Erbitux were US$820 million, representing an 18 percent increase over 2009. The therascreen KRAS assay reliably detects mutations of the KRAS gene, which are frequently found in human cancers. Because monoclonal antibody EGFR inhibitors are h
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