Pfizer Logo

QIAGEN and Pfizer partner to develop companion diagnostic for novel compound in global clinical trials for lung Cancer

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- **Diagnostic-therapeutic combination aims to improve standard of care for patients with non-small cell lung cancer (NSCLC)**
- **Molecular test for KRAS gene mutations holds potential to help determine whether there is a subset of patients who are more likely to benefit from Pfizer's investigational anticancer compound**
- **Collaboration in lung cancer follows QIAGEN's two FDA submissions of KRAS mutation-based companion diagnostics in metastatic colorectal cancer treatment**
- **Partnership builds on QIAGEN's leadership in Personalized Healthcare, with more than 15 co-developments and 20 companion diagnostics**

Germantown, Md., and Hilden, Germany, August 16, 2011 - QIAGEN (NASDAQ: QGEN; Frankfurt, Prime Standard: QIA) today announced it has entered into a partnership with Pfizer Inc. (NYSE: PFE) for the development of a companion molecular diagnostic test for use with an investigational Pfizer compound in global clinical development for treatment of non-small cell lung cancer (NSCLC). Financial terms of the agreement were not disclosed.

Pfizer's investigational compound, dacomitinib (PF-00299804), is an oral inhibitor of HER-1 (EGFR), HER-2 and HER-4 tyrosine kinases. The HER (human epidermal growth factor receptor) signaling pathway plays a role in the complex process of cell growth and metastasis, making it a target for anti-cancer drugs.

QIAGEN's proposed companion diagnostic will be based on its proprietary KRAS assay technology, which reliably detects mutations of the KRAS gene that are frequently found in human cancers. Because EGFR inhibitors are generally effective in patients without these KRAS mutations, the QIAGEN assay can be useful in identifying patients most appropriate for EGFR-inhibitor therapies. QIAGEN recently submitted the application for Premarket Approval (PMA) for KRAS companion diagnostics to the FDA for use with two other, separate drugs targeting metastatic colorectal cancers. The Pfizer drug companion diagnostic test is being specifically developed for use in lung cancer tissue. It uses the same core assay component as the therascreen KRAS RGQ kit for colorectal cancers but varies in the workflow to allow for lung tissue-specific sample technology in a fully automated workflow.

QIAGEN and Pfizer will engage in collaborative efforts to develop the KRAS companion diagnostic for use with dacomitinib (PF-00299804). The global partnership covers clinical trials and submissions for a PMA application in the United States and the CE mark in Europe, as well as applicable regulatory approvals in other regions.

"We are pleased to collaborate with Pfizer seeking to advance personalized healthcare with a new potential tool in the fight against non-small cell lung cancer, a major killer around the world," commented Dr. Stephen Little, Vice President Personalized Healthcare at QIAGEN. "This partnership unites QIAGEN's capabilities in companion diagnostics with Pfizer's scientific excellence and global presence to develop an innovative diagnostic-therapeutic combination with the potential to improve the standard of care for NSCLC patients."

Lung cancer is the most common cancer globally in incidence and mortality. About 1.1 million new cases are reported each year in males, with 0.95 million deaths, and 0.51 million new cases per year are reported in females, with 0.43 million deaths. Worldwide, approximately 85% of all lung cancers are classified as non-small cell lung cancer, with a five-year survival rate of only about 15%.

"QIAGEN has invested deeply in Personalized Healthcare as the global leader in partnering with pharmaceutical companies to create companion diagnostics. Using genomic information to guide each patient's treatment is transforming the practice of medicine," Dr. Little added. "In addition to more than 20 tests we already offer commercially, QIAGEN is co-developing companion diagnostics in more than 15 Pharma partnerships, a dynamic growth driver for our business."

Following clinical development of the KRAS companion diagnostic for NSCLC, QIAGEN expects to submit a premarket approval application supplement (PMAS) to FDA for full automation of the workflow to allow pathologists easy access and processing of lung tissue samples.

About QIAGEN
QIAGEN N.V., a Netherlands holding company, is the leading global provider of sample and assay technologies. Sample technologies are used to isolate and process DNA, RNA and proteins from biological samples such as blood or tissue. Assay technologies are used to make such isolated bio-molecules visible. QIAGEN has developed and markets more than 500 sample and assay products as well as automated solutions for such consumables. The company provides its products to molecular diagnostics laboratories, academic researchers, pharmaceutical and biotechnology companies, and applied testing customers for purposes such as forensics, animal or food testing and pharmaceutical process control. QIAGEN's assay technologies include one of the broadest panels of molecular diagnostic tests available worldwide. This panel includes the digene HPV Test, which is regarded as a "gold standard" in testing for high-risk types of human papillomavirus (HPV), the primary cause of cervical cancer, as well as a broad suite of solutions for infectious disease testing and companion diagnostics. QIAGEN employs nearly 3,600 people in over 35 locations worldwide. Further information about QIAGEN can be found at http://www.qiagen.com/. Certain of the statements contained in this news release may be considered forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, and Section 21E of the U.S. Securities Exchange Act of 1934, as amended. To the extent that any of the statements contained herein relating to QIAGEN's products, markets, strategy or operating results, including without limitation its expected operating results, are forward-looking, such statements are based on current expectations and assumptions that involve a number of uncertainties and risks. Such uncertainties and risks include, but are not limited to, risks associated with management of growth and international operations (including the effects of currency fluctuations, regulatory processes and dependence on logistics), variability of operating results and allocations between business segments, the commercial development of markets for our products in applied testing, personalized healthcare, clinical research, proteomics, women's health/HPV testing and nucleic acid-based molecular diagnostics; changing relationships with customers, suppliers and strategic partners; competition; rapid or unexpected changes in technologies; fluctuations in demand for QIAGEN's products (including fluctuations due to general economic conditions, the level and timing of customers' funding, budgets and other factors); our ability to obtain regulatory approval of our products; difficulties in successfully adapting QIAGEN's products to integrated solutions and producing such products; the ability of QIAGEN to identify and develop new products and to differentiate and protect our products from competitors' products; market acceptance of QIAGEN's new products and the integration of acquired technologies and businesses. For

further information, please refer to the discussions in reports that QIAGEN has filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC).