

## QIAGEN Unit And Pfizer Enter Into An Agreement To Develop A Companion Diagnostic For Brain Tumor Patients

Thursday, February 04, 2010 - 05:30am

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) and DxS (a wholly owned subsidiary of QIAGEN N.V.) (NASDAQ: QGEN; Frankfurt, Prime Standard: QIA) today announced that they have entered into an agreement to develop a companion diagnostic test kit for PF-04948568 (CDX-110), an immunotherapy vaccine in development for the treatment of glioblastoma multiforme (GBM). Financial terms of the diagnostic agreement have not been disclosed.

On April 16, 2008, Pfizer and Celldex Therapeutics, Inc. entered into an agreement to grant Pfizer an exclusive worldwide license to PF-04948568 (CDX-110) which is currently in Phase 2 clinical development for the treatment of newly diagnosed GBM.

Glioblastoma multiforme is the most common malignant primary brain tumor in adults and occurs in around 25,000 patients worldwide each year. Pfizer's investigational drug PF-04948568 (CDX-110) is a peptide vaccine which targets the tumor-specific Epidermal Growth Factor Receptor variant III (EGFRvIII), a mutated form of the epidermal growth factor receptor that is only present in cancer cells and occurs in 25-40 percent of GBM tumors. The QIAGEN assay is designed to identify those patients whose tumors express the EGFRvIII mutation, allowing for the possibility of more targeted and personalized treatment.

The EGFRvIII companion diagnostic will be developed and manufactured at QIAGEN'S Center of Excellence for Companion Diagnostics in Manchester, UK. The diagnostic will be a real-time PCR assay used to detect EGFRvIII RNA in tumor tissue. The assay is designed to offer a simple workflow, which supports its clinical utility in routine mutation testing.

Commenting on this announcement, Dr. Stephen Little, Vice President Personalized Healthcare, for QIAGEN, said, "We are very pleased to have signed this agreement with Pfizer, as it is another important step toward the realization of personalized medicine. QIAGEN is aligned to deliver companion diagnostics to our pharmaceutical partners and this deal is further evidence of our commitment to develop our scientific and operational capabilities to help select the right patient for the right medicine."

"We look forward to collaborating with QIAGEN's DxS unit in the development of this important diagnostic tool that could potentially help physicians better define the most appropriate treatment for patients who suffer from glioblastoma multiforme," said Garry Nicholson, president and general manager of Pfizer's Oncology Business Unit.

## **About Pfizer Oncology**

Pfizer Oncology is committed to the discovery, investigation and development of innovative treatment options to improve the outlook for cancer patients worldwide. Our strong pipeline, one of the most robust in the industry, is studied with precise focus on identifying and translating the best scientific breakthroughs into clinical application for patients across a wide range of cancers, including breast, lung, prostate, sarcoma, melanoma, and various hematologic cancers. Pfizer Oncology Pfizer Oncology has more than 32 biologics and small molecules in clinical development and more than 200 clinical trials underway.

By working collaboratively with academic institutions, individual researchers, cooperative research groups, governments, and licensing partners, Pfizer Oncology strives to cure or control cancer with breakthrough medicines, to deliver the right drug for the right patient at the right time.

About Pfizer Inc: Working together for a healthier world™

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com.

## **About QIAGEN**

QIAGEN N.V., a Netherlands holding company and the leading global provider of sample and assay technologies. The Company's products are sold to molecular diagnostics laboratories, academic researchers, pharmaceutical and biotechnology companies, and applied testing customers and include one of the broadest panels of molecular diagnostic tests for prevention, profiling and personalized healthcare available worldwide.

About QIAGEN and Personalized Healthcare: QIAGEN is a leading company providing molecular diagnostics to aid doctors and drug companies in selecting therapies for patients. Working in partnership with pharmaceutical companies, QIAGEN and it's wholly owned subsidiary, DxS supports the development and sales of targeted cancer therapies by providing biomarkers and companion diagnostics. The Company has a continually expanding portfolio, most notably including the TheraScreen® and Pyromark assay lines.. The TheraScreen® range of CE-marked clinical diagnostic kits can identify genetic tumor mutations that are useful in the determination of whether a patient may respond to specific cancer therapies, thus enabling doctors to provide the most beneficial treatment. The portfolio includes two clinical diagnostic kits, K-RAS and EGFR.\* The TheraScreen: K-RAS Mutation kit is a companion diagnostic for Vectibix® (Amgen) and Erbitux® (Merck KGaA), two drugs used for the treatment of colorectal cancer. In addition, QIAGEN has created a portfolio of personalized healthcare assays for the PyroMark real time full sequence resolution platform.

For more information on QIAGEN and personalized medicine: www.giagen.com.

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of February 4, 2010. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information that involves substantial risks and uncertainties about a product candidate, PF-04948568 (CDX-110), including its potential benefits, as well as an agreement between Pfizer and Qiagen to develop a diagnostic test kit to help select patients who might benefit from such product candidate. Such risks and uncertainties include, among other things, the uncertainties inherent in drug research and development and in the development of diagnostic test kits; decisions by regulatory authorities regarding whether and when to approve such diagnostic test kit and any drug applications that may be filed for such product candidate, as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such product candidate; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and in its reports on Form 10-Q and Form 8-K.

## QIAGEN SAFE HARBOR STATEMENT

Statements contained in this release that are not historical facts are forward-looking statements, including statements about our products, markets, strategy and operating results. Such statements are based on current expectations that involve risks and uncertainties including, but not limited to, those associated with: management of growth and international operations (including currency fluctuations and logistics), variability of our operating results, commercial development of our markets (including applied testing, clinical and academic research, proteomics, women's health/HPV testing, molecular diagnostics, personalized healthcare and companion diagnostics), our relationships with customers, suppliers and strategic partners, competition, changes in technology, fluctuations in demand, regulatory requirements, identifying, developing and producing integrated products differentiated from our competitors' products, market acceptance of our products, and integration of acquired technologies and businesses. For further information, refer to our filings with the SEC, including our latest Form 20-F. Information in this release is as of the date of the release, and we undertake no duty to update this information unless required by law.

\* In the United States, both test kits are available for research use only. They have not been cleared or approved by authorities including the United States Food and Drug Administration or any other regulatory agency in the United States for human diagnostic or other clinical use, and is not intended and should not be used for human diagnostic or any other clinical purposes.

Pfizer Inc. Media: Samantha Cummis, 212-733-6924 or Investor Relations: Suzanne Harnett, 212-733-8009 or QIAGEN GmbH Public Relations: Dr. Thomas Theuringer, +49 2103 29 11826 or QIAGEN N.V. Investor Relations: Dr. Solveigh Mähler, +49 2103 29 11710 or QIAGEN North America Investor Relations: Albert F. Fleury, +1-301-944-7028