GERMANTOWN, Maryland, and HILDEN, Germany, October 21, 2013 /PRNewswire/ --

- **Collaboration to expand label of QIAGEN's FDA-approved *therascreen*® EGFR RGQ PCR Kit and creates framework for long term development and commercialization partnership**

- **Companion diagnostic will run on QIAGEN's efficient Rotor-Gene Q MDx platform**

- **QIAGEN adds to growing portfolio of companion diagnostics in co-development with world's leading pharmaceutical and biotechnology companies**

QIAGEN N.V. (NASDAQ: QGEN ; Frankfurt Prime Standard: QIA) today announced a partnership with Clovis Oncology (NASDAQ: CLVS) to co-develop and co-commercialize a companion diagnostic test to guide the use of CO-1686, a novel Clovis Oncology product candidate currently in clinical development. The Clovis drug candidate will initially target an unmet clinical need in patients with epidermal growth factor receptor (EGFR) driven non-small cell lung cancer (NSCLC) for whom current EGFR-inhibiting drugs no longer control disease.

The diagnostic will build on QIAGEN's *therascreen*® EGFR RGQ PCR Kit, which was approved by the U.S. Food and Drug Administration (FDA) in
July 2013

as a companion diagnostic for use in the treatment of metastatic NSCLC in patients whose tumors have certain EGFR mutations. Analytical performance of the *therascreen*
EGFR
test has been established for 21
EGFR
mutations, including the most prevalent resistance mutation, T790M. The test supports efficient laboratory workflow with real-time PCR technology on the FDA approved Rotor-Gene Q MDx, which is part of the QIAsymphony family of laboratory solutions.

The development plan for the companion diagnostic complements Clovis Oncology's accelerated plan for CO-1686 development by potentially allowing a supplemental premarket approval (PMA) filing for the diagnostic. Subject to regulatory approvals, QIAGEN will be responsible for the global development and commercialization of the companion diagnostic, and Clovis will be responsible for the global development and commercialization of CO-1686. The partners also created the framework for possible future collaborations, thereby adding another master agreement to QIAGEN's growing pipeline of collaborations with some of the world's leading pharmaceutical and biotechnology companies. Further terms of the agreement were not disclosed.

"We are pleased to partner with Clovis Oncology in developing a companion diagnostic based on QIAGEN's *therascreen* technology and to expand the label of our approved *therascreen* EGFR kit. Together, we can accelerate the development of this important drug candidate and deliver a solution to an unmet medical need," said
Peer Schatz
, QIAGEN's Chief Executive Officer. "Our
therascreen
EGFR kit, approved by the FDA based on extensive analytical and clinical data, is the most comprehensive test and offers unique features such as detection of actionable mutations in separate tubes. QIAGEN is a preferred partner in personalized medicine because of our ability to deliver reproducible results, the efficient workflow of our platforms, and our track record in development and regulatory approvals."

"We are pleased to collaborate with QIAGEN for the development of a companion diagnostic for our lead compound CO-1686," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "QIAGEN's *therascreen* is a validated test and already FDA approved to detect both activating EGFR mutations and the resistance mutation T790M. Working with QIAGEN will help support our accelerated clinical development plan for CO-1686."

The Rotor-Gene Q MDx platform, which has been adopted by most major U.S. laboratories and many labs around the world, runs a growing menu of molecular tests. Rotor-Gene Q MDx is approved in the U.S. for use with QIAGEN's *therascreen*® KRAS RGQ PCR Kit for colorectal cancer patients and *therascreen* EGFR test for metastatic NSCLC patients - important Personalized Healthcare products.

QIAGEN continues to expand its pipeline of Personalized Healthcare technologies and intends to submit more tests around the world for regulatory approvals to run on the Rotor-Gene Q MDx. The company already markets Personalized Healthcare tests covering over 30 biomarkers in Europe, Asia/Pacific and Japan. In addition, QIAGEN has more than 15 projects to co-develop and market companion diagnostics with leading pharmaceutical and biotech companies such as Amgen, AstraZeneca, Bayer, Bristol-Myers Squibb, Eli Lilly and Company, and Pfizer. QIAGEN is developing numerous companion diagnostics, plus a range of other molecular tests, as part of a broad menu of reliable, cost-effective molecular diagnostics.

About QIAGEN

QIAGEN N.V., a Netherlands holding company, is the leading global provider of Sample & Assay Technologies that are used to transform biological materials into valuable molecular information. Sample technologies are used to isolate and process DNA, RNA and proteins from biological samples such as blood or tissue. Assay technologies are then used to make these isolated biomolecules visible and ready for interpretation. QIAGEN markets more than 500 products around the world, selling both consumable kits and automation systems to customers through four customer classes: Molecular Diagnostics (human healthcare), Applied Testing (forensics, veterinary testing and food safety), Pharma (pharmaceutical and biotechnology companies) and Academia (life sciences research). As of June 30, 2013 , QIAGEN employed approximately 4,050 people in over 35 locations worldwide. Further information 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 customer classes, 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, the consummation of acquisitions, 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).

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