Current Agreements

Dealdoc

Collaborative R&D agreement for biofluid sample preparation kits

Qiagen
Exosome Diagnostics

Jul 24 2013

Collaborative R&D agreement for biofluid sample preparation kits

Companies:	Qiagen Exosome Diagnostics
Announcement date:	Jul 24 2013
Amendment date:	Jan 13 2014
Deal value, US$m:	n/d

Details

Announcement date:	Jul 24 2013
Amendment date:	Jan 13 2014
Industry sectors:	Diagnostic Research tools
Asset type:	Technology
Therapy areas:	Oncology » Lung cancer » Non small cell lung cancer
Technology types:	Biomarkers Biomaterials Diagnostics Diagnostics » Molecular diagnostics Personalised medicine Research supplies
Deal components:	Collaborative R&D

Financials

Deal value, US$m:	n/d

Termsheet

13 January 2014

Exosome Diagnostics announced an expansion of its strategic collaboration with QIAGEN to develop non-invasive molecular diagnostics for use in detecting and monitoring actionable genetic mutations in lung cancer patients.

In contrast with current molecular diagnostics requiring tissue biopsy, the focus will be to enable detection of well-understood cancer biomarkers in plasma, reducing both cost and patient risk.

Financial terms of the collaboration were not disclosed.

The program will focus on detection of known mutations associated with non-small cell lung cancer (NSCLC) and other malignancies that have the potential to be paired with targeted therapies.

QIAGEN plans to submit the first diagnostic test developed under the collaboration to the Food and Drug Administration following clinical validation.

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24 July 2013

QIAGEN announced a partnership with Exosome Diagnostics to develop and commercialize high-performance sample preparation kits for the processing of nucleic acids from exosomes.

Combining the Exosome Diagnostics platform technology approach with select QIAGEN consumables and automation platforms has the potential to allow researchers, drug developers and doctors to take repeated, real-time genetic "snapshots" of disease from patients' blood, urine or cerebrospinal fluid without the need for tissue biopsy.

Press Release

13 January 2014

Exosome Diagnostics And QIAGEN Inc. (QGEN) Expand Collaboration To Develop Non-Invasive Biofluid Diagnostic For Lung Cancer

NEW YORK, Jan. 13, 2014 /PRNewswire/ -- Exosome Diagnostics today announced an expansion of its strategic collaboration with QIAGEN to develop non-invasive molecular diagnostics for use in detecting and monitoring actionable genetic mutations in lung cancer patients. In contrast with current molecular diagnostics requiring tissue biopsy, the focus will be to enable detection of well-understood cancer biomarkers in plasma, reducing both cost and patient risk. Financial terms of the collaboration were not disclosed. The program will focus on detection of known mutations associated with non-small cell lung cancer (NSCLC) and other malignancies that have the potential to be paired with targeted therapies. QIAGEN plans to submit the first diagnostic test developed under the collaboration to the Food and Drug Administration following clinical validation.

"The ability to perform molecular testing in blood represents an important advance in personalized medicine," said James McCullough, Chief Executive Officer of Exosome Diagnostics. "QIAGEN is the ideal partner to bring robust, regulated exosome technology products to the global clinical market place."

Exosome Diagnostics' proprietary technology is focused on rapid, robust isolation of clinically actionable genetic biomarkers from blood, urine and cerebrospinal fluid for diagnosis, monitoring and companion diagnostic applications. The Company's clinical in vitro diagnostic products are designed to operate on widely available sequencing and PCR instruments. Exosome Diagnostics intends to launch the first in a series of blood-based mutation diagnostics in its CLIA laboratory beginning in 2014.

Exosomes are the messenger packages in a fundamental biological communication system that transmits genetic instructions from cell to cell. The unique technology developed by Exosome Diagnostics allows non-invasive detection of key disease associated gene mutations and gene expressions in blood, urine and cerebrospinal fluid without the need for a surgical tissue biopsy.

About Exosome Diagnostics Exosome Diagnostics is a leading developer of biofluid-based molecular diagnostic tests for use in personalized medicine. Exosomes and other microvesicles are packaged and shed into all biofluids, including blood, urine and CSF, providing a stable source for intact, disease-specific nucleic acids. The company's proprietary exosome technology makes use of the presence and natural stability of RNA in exosomes to detect and measure levels of genes responsible for cancer and other diseases. The company is commercializing in vitro diagnostic tests for use in personalized medicine and real-time monitoring of disease. For more information, please visit www.exosomedx.com.

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24 July 2013

QIAGEN N.V. (QGEN) Partners With Exosome Diagnostics to Create High-Performance Biofluid Sample Preparation Kits for Personalized Healthcare Research

GERMANTOWN, Maryland, and HILDEN, Germany, July 23, 2013 --

Molecular testing of biofluids promises unprecedented access to gene mutations, gene expression signatures and expression levels without costly, invasive tissue biopsies

Developing Exosome Diagnostics technology for use with QIAGEN's nucleic acid-targeted consumables and automation - with initial product launches targeted in 2014

Standardized, easy-to-use exosome workflows will offer superior testing solutions from basic research to personalized healthcare on widely available PCR, pyrosequencing and next-generation sequencing technologies

QIAGEN N.V. (NASDAQ: QGEN; Frankfurt Prime Standard: QIA) today announced a partnership with Exosome Diagnostics Inc. to develop and commercialize high-performance sample preparation kits for the processing of nucleic acids from exosomes. Combining the Exosome Diagnostics platform technology approach with select QIAGEN consumables and automation platforms has the potential to allow researchers, drug developers and doctors to take repeated, real-time genetic "snapshots" of disease from patients' blood, urine or cerebrospinal fluid without the need for tissue biopsy. The companies are targeting initial product launches in the first half of 2014. Financial terms were not disclosed.

Subject to successful performances of these new solutions, QIAGEN's exclusive agreement with Exosome Diagnostics will cover co-development, manufacturing and commercialization of a full product line for the life science and translational medicine markets. First

applications of Exosome Diagnostics' technology are being developed with QIAGEN's microRNA isolation solutions and are designed to run on QIAGEN automated instrument platforms. The product portfolio is also expected to create the basis for development and commercialization of clinical in-vitro diagnostic products for a range of non-invasive personalized healthcare solutions.

Exosomes are one of many different subpopulations of microvesicles that can be isolated from biofluids such as blood, urine and cerebrospinal fluid and from which high-quality RNA and DNA can be extracted and purified for analysis. Exosomes are shed by cells under both normal and pathological conditions. They are a key part of the body's complex communication system that transfers genetic instructions from cell to cell through all biofluids. Exosomes carry nucleic acids and proteins from their host cells and are widely considered to be essential for biomarker discovery for personalized healthcare diagnostics. Tumor cells, for instance, release exosomes which contain tumor-specific RNAs that can be isolated easier from biofluids such as blood and urine than from biopsies. Exosome Diagnostics' proprietary technology makes use of the presence and stability of nucleic acids in exosomes to detect and measure levels of genes implicated in cancer, neurodegenerative, metabolic, infectious and other diseases.

"QIAGEN is a global leader in personalized healthcare solutions, and Exosome Diagnostics is a leading developer in biofluid-based molecular testing. Together we expect to create the 'gold standard' in this emerging field of exosome-based testing, advancing research and improving healthcare," said Dirk Loeffert, Vice President Global Product Development Life Sciences of QIAGEN. "We believe QIAGEN can bring to market the first comprehensive line of products to help researchers and pharmaceutical companies explore and monitor disease status using fresh or frozen biofluids, addressing the critical challenge of access to samples. We also intend to co-develop exosome-based workflows for routine use in personalized healthcare, a revolutionary improvement compared to today's widespread dependence on tissue biopsies, offering the ability to create a new dimension of utility for our molecular testing assay portfolio. This approach holds promise to significantly improve medical care as physicians may be able to use real-time molecular information to change the care pathway and bring about disease management."

James McCullough, Chief Executive Officer of Exosome Diagnostics, said: "Our partnership with QIAGEN brings unprecedented access to key genetic information directly from a patient's biofluid sample for academic, biomedical research and pharmaceutical drug programs around the world. We expect this partnership, focused on development of a broad range of products, will help accelerate commercialization of the next generation of minimally invasive, clinical-grade diagnostics for personalized healthcare."

QIAGEN's exosome technology-driven kits will offer distinct advantages including the ability to work with scalable patient sample volumes, from as little as 200µL; RNA capture from frozen, bio-banked fluids; the use of plasma, urine and cerebrospinal fluid with no special stabilization or handling required; and streamlined clinical laboratory workflow for analysis on PCR, pyrosequencing and next-generation sequencing (NGS) instruments. Previously, such analysis would have depended on the use of tissue and/or cells, potentially requiring invasive procedures for patients.

As part of an active biological packaging and distribution mechanism for RNA and DNA, exosomes and their nucleic acid contents are being investigated for their implications and utility in a broad range of diseases including cancer, central nervous system disorders such as Alzheimer's and Parkinson's diseases, cardiovascular disease, maternal/fetal medicine, and chronic kidney disease. The natural stability of the exosome compartment allows collection of clinical samples without special tubes or preservatives. As a result, researchers can perform analysis and biomarker discovery on high-quality RNA from both fresh and frozen plasma, serum, urine and cerebrospinal fluid samples. This is of particular interest for analysis of RNA-based biomarkers such as ALK or RET.

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 March 31, 2013, QIAGEN employed approximately 4,000 people in more than 35 locations worldwide. Further information can be found at http://www.QIAGEN.com/.

About Exosome Diagnostics

Exosome Diagnostics is a leading developer of biofluid-based molecular diagnostic tests for use in personalized medicine. Exosomes are packaged and shed into all biofluids, including blood, urine and CSF, providing a stable source for intact, cell-specific nucleic acids. The Company's proprietary exosome technology makes use of the presence and natural stability of RNA in exosomes to detect and measure levels of genes responsible for cancer and other diseases. The Company is commercializing in vitro diagnostic tests for use in companion diagnostic applications and real-time monitoring of disease. For more information, please visit http://www.exosomedx.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).

Filing Data

Not available.

Contract

Not available.