Therawis Diagnostics

Therawis Diagnostics' licensing and development partner QIAGEN launches predictive *therascreen* PITX2 test in Europe to guide treatment in high-risk breast cancer

Novel DNA methylation assay provides insights for individualized chemotherapy selection

Munich, Germany, February 7, 2018 – Therawis Diagnostics GmbH today announced that its development partner QIAGEN N.V. has launched its novel *therascreen* PITX2 RGQ PCR Kit in Europe. The first clinically validated DNA methylation assay that helps to predict the response of high-risk breast cancer patients to anthracycline-based chemotherapy was co-developed in collaboration with Therawis Diagnostics. The CE-IVD marked assay is QIAGEN's first epigenetic test in breast cancer, as well as the latest addition to QIAGEN's broad portfolio of *therascreen* tests delivering individualized genetic insights to guide medical decisions in lung, colorectal and other cancers.

More than 460,000 women in Europe are newly diagnosed with breast cancer each year, with about 50% characterized as high-risk for disease recurrence. Anthracycline-based chemotherapy is the standard of care, yet not all patients benefit equally – and side effects can be as severe as congestive heart failure and leukemia. The *therascreen* PITX2 assay provides physicians and their patients a novel, independent criterion to augment clinical information used in selection of the most suitable therapy in high-risk breast cancer.

"We are very pleased to introduce this important test for Personalized Healthcare in assessing the best treatment approach for high-risk breast cancer patients. This reliable, clinically validated assay measures PITX2 DNA methylation to differentiate between patients who are more likely – or less likely – to show beneficial response to anthracyclines," said Thierry Bernard, Senior Vice President, Molecular Diagnostics Business Area, for QIAGEN. "The simple workflow of the *therascreen* PITX2 assay provides automated processing from Sample to Insight in less than 48 hours. The test can easily be adopted by customers already running other *therascreen* assays on our widely used QIAsymphony automation platform."

The *therascreen* PITX2 RGQ PCR Kit is a unique DNA methylation test which determines the percent methylation ratio (PMR) in promoter 2 of the pituitary homeobox transcription factor 2 (PITX2) gene as a novel biomarker. The clinical performance of the *therascreen* PITX2 assay was evaluated in a retrospective clinical study in lymph node-positive, estrogen receptor-positive and HER2-negative high-risk breast cancer patients treated with anthracycline-based chemotherapy. Patients with low PMRs demonstrated increased disease-free survival applying 10-year follow-up as primary study endpoint.

„We have several treatment options for high risk breast cancer patients and standard of care is anthracycline-based chemotherapy. For the first time, the determination of PITX2 DNA-methylation provides an excellent diagnostic tool to identify those patients who do benefit and those who have a lower probability to benefit. This novel test is a great step forward for us clinicians to further optimize patient treatment." commented Prof. Dr. Marion Kiechle, Chairman of the Department of Obstetrics & Gynecology and the Breast Cancer Center of The Technical University of Munich, Germany.

The assay is processed on QIAGEN's Rotor-Gene® Q MDx real-time cycler, part of the QIAsymphony family of instruments, with automated analysis and calculation of the PITX2 percent methylation ratio using the Rotor-Gene AssayManager® software. The simple, fast workflow from FFPE tissue samples to the PITX2 PMR as an easy readout can deliver multiple clinical results in less than two working days.

The *therascreen* PITX2 assay has been developed as part of a licensing and co-development agreement with Therawis Diagnostics GmbH, an oncology-focused company founded by clinicians and scientists at the Technical University of Munich. QIAGEN and Therawis entered a licensing and co-development agreement in 2016 to develop and commercialize predictive assays in oncology, and the *therascreen* PITX2 test is the initial project in that collaboration.

About Therawis Diagnostics

Therawis Diagnostics GmbH is a privately held oncology-focused company with offices located in Munich, Germany, and was founded together with clinicians and scientists of the Technical University of Munich in September 2015. Therawis Diagnostics GmbH develops and commercializes a comprehensive portfolio of predictive diagnostics to guide optimal therapy for cancer patients. Further information can be found at http://www.therawis.com.

About QIAGEN

QIAGEN N.V., a Netherlands-based holding company, is the leading global provider of Sample to Insight solutions that enable customers to gain valuable molecular insights from samples containing the building blocks of life. Our sample technologies isolate and process DNA, RNA and proteins from blood, tissue and other materials. Assay technologies make these biomolecules visible and ready for analysis. Bioinformatics software and knowledge bases interpret data to report relevant, actionable insights. Automation solutions tie these together in seamless and cost-effective workflows. QIAGEN provides solutions to more than 500,000 customers around the world in Molecular Diagnostics (human healthcare), Applied Testing (forensics, veterinary testing and food safety), Pharma (pharma and biotech companies) and Academia (life sciences research). As of December 31, 2017, QIAGEN employed approximately 4,600 people in over 35 locations worldwide. Further information can be found at http://www.qiagen.com.

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