

Therawis Diagnostics

Therawis Diagnostics and QIAGEN enter into a development and commercialization agreement on predictive biomarkers in oncology

Munich, Germany, May 26, 2016 – Therawis Diagnostics GmbH today announced that the company has entered into a licensing and co-development agreement with QIAGEN N.V. to develop and commercialize predictive assays in oncology. An initial project will be to develop and market PITX2 as a marker to predict effectiveness of anthracycline treatment in triple negative and other high-risk breast cancer patients.

Prof. Dr. med. Olaf G. Wilhelm, co-founder and Chief Executive Officer of Therawis Diagnostics GmbH, an oncology-focused company founded by clinicians and scientists at the Technical University of Munich commented: “Partnering with QIAGEN will make our PITX2 test widely available in standardized workflows for routine diagnostics and to benefit breast cancer patients globally. We look forward to co-developing and commercializing additional tests. Therawis Diagnostics is uniquely focused on bringing to market predictive diagnostics to guide the optimal therapy for breast cancer patients.”

“We are pleased to partner with Therawis Diagnostics, which developed the PITX2 assay and achieved initial clinical validation”, said Kai te Kaat, Head of QIAGEN’s Oncology Franchise. “The test addresses high unmet needs in breast cancer, the most common malignancy among women, and will add to our expanding portfolio that covers a range of Sample to Insight solutions to further advance personalized healthcare in this and other cancer indications.”

Under current clinical guidelines, the standard of care in high-risk breast cancer includes anthracycline-based chemotherapy, which produces a response rate of up to 50% in patients and has side effects that can be as severe as congestive heart failure or leukemia. The PITX2 test licensed by QIAGEN predicts which individuals will benefit from these chemotherapeutic drugs. It potentially could enable clinicians to make decisions on whether to use standard drugs or provide other treatments to patients who are unlikely to benefit from anthracycline-based chemotherapy. The PITX2 biomarker also has potential value for a companion diagnostic to guide the use of novel targeted therapies under development.

About 1.7 million new breast cancer cases are reported each year, making it the most common cancer among women and second-most common overall, according to the World Health Organization (WHO). Annual deaths due to breast cancer are estimated at more than 500,000. As with other cancers, the disease varies greatly among individuals, as do outcomes, based on many different factors.

For example, triple-negative breast cancer (TNBC) makes up about 15% of cases, about 120,000 a year in Europe and the U.S., with a poor prognosis and low overall survival rate. The standard of care for TNBC is a diagnostic core biopsy followed by neo adjuvant anthracycline-based chemotherapy and surgery. Only about 35% of TNBC patients respond to the chemotherapy, and 65% do not. So the value of a reliable predictive test to guide treatment decisions would be significant. To date, the PITX2 biomarker has demonstrated unprecedented predictive value in triple-negative and other high-risk breast cancers.

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 aims at to commercialize 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 March 31, 2016, 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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