

numares announces commercial launch of renalTX-SCORE®

Non-invasive urine-based test for kidney rejection diagnostics utilizes metabolic biomarker networks

Regensburg, Germany, 4 April 2017 – Fast-growing innovative diagnostics company numares AG today announced the commercial launch of its new non-invasive test renalTX-SCORE® for the diagnosis of kidney rejection. It is the first test available worldwide evaluating a metabolic biomarker network rather than single biomarkers or tissue biopsy for the diagnosis of an acute rejection reaction following a kidney transplant. renalTX-SCORE will be marketed in Europe as a CE-marked in-vitro diagnostic test (IVD).

numares' approach utilizes the effects of a disease on the dynamics of human metabolism. Those effects can be recognized as specific changes in a biomarker network, generated by changes in the metabolic machinery caused by the disease. The renalTX-SCORE test, which is available as part of numares' AXINON® IVD system, evaluates the status of a multimetabolite biomarker network rather than quantifying just one or a few biomarkers as with more traditional diagnostics. A urine sample is obtained from the patient, an NMR spectrum is created, then evaluated by the test. If the result indicates that a patient may be experiencing an acute rejection reaction then the patient would be referred for biopsy to confirm the result or even for therapeutic intervention.

The current diagnostic standard for acute rejection is biopsy of the kidney. This invasive intervention can damage the transplant, cause discomfort and stress in the patient and is relatively expensive. renalTX-SCORE, for the first time, enables a regular and close monitoring of the transplanted kidney without additional strain on the patient and the organ.

renalTX-SCORE was developed in collaboration with Professor Bernhard Banas, Head of the Transplant Center at the Regensburg University Hospital in Germany.

"This non-invasive diagnostic to identify organ rejection in kidney transplant patients, which we have successfully developed together with numares, can be used in outpatient follow-up care even before needle biopsy is performed," said Professor Banas. "renalTX-SCORE has the potential to reduce the number of biopsies, a procedure which reduces both patient discomfort and potential damage to the transplanted kidney. It can be performed more often due to being non-invasive and cost-effective.

Volker Pfahlert, chairman of the executive board of numares AG added, "With renalTX-SCORE, we are launching the first metabolomics test for our AXINON IVD system. We have developed a test that is not only the first to use a biomarker network from urine for kidney rejection diagnostics, but it can also be seamlessly integrated into clinical routine, is easy to handle and delivers fast results. It should therefore be part of the standard repertoire of follow-up checkups of every transplant center in Europe."

Further information about renalTX-SCORE can be found here.



About kidney transplantation

Kidney transplants are the most common organ transplantations worldwide. In 2014, more than 27,000 kidneys were transplanted in Europe and 2,100 kidneys in Germany alone. The annual worldwide number of transplanted kidneys is about 80,000. Around 10 percent of transplant patients are affected by rejection reactions within the first year. These can shorten the lifespan of the transplant and in the worst case lead to the loss of the organ. Meaning there is a great need for early detection and rapid therapy of transplant rejection.

About biomarker networks

The innovative approach to use biomarker networks for diagnostic purposes becomes increasingly relevant for several further medical questions, which can be not be addressed by appropriate diagnostic solutions so far. It is numares' mission to fulfill those unmet diagnostic needs by developing products for its NMR-based AXINON® IVD system. It is reflected by the company's product pipeline. To achieve its mission, numares developed its proprietary Magnetic Group Signaling® (MGS®) technology as a prerequisite.

About Magnetic Group Signaling® (MGS®)

Nuclear Magnetic Resonance (NMR) has long been used as a research tool, in particular for determining the structure of chemical compounds. In the past, this technology was too complex to be used in metabolomics-based medical research or diagnostics due to several technical limitations.

numares developed its proprietary Magnetic Group Signaling® (MGS®) technology to enable NMR to answer demanding questions in metabolomics. With MGS®, important prerequisites like standardization and qualification can be fulfilled through technical processes and procedures. For the first time systematic processing and use of diagnostic information from the metabolism is possible. Thanks to MGS®, numares' in vitro diagnostic system (IVD) AXINON® is able to generate reliable and reproducible data of highest quality – independent of the NMR device or the user. This enables fully automated analysis of patient samples without any human intervention.

About numares

numares AG is a fast-growing innovative diagnostics company that develops and markets software-based test systems for high-throughput use in clinical diagnostics and life science research. The *AXINON®* IVD system and its diagnostic tests employ nuclear magnetic resonance (NMR) spectroscopy creating a numeric spectrum with which to evaluate metabolomic networks. The output of these analyses provide physicians with valuable information on the disease status of patients. numares developed its proprietary *Magnetic Group Signaling®* (*MGS®*) technology to enable NMR for highly standardized and rapid throughput testing, making it a cost-efficient new solution for diagnostic purposes. The



metabolomics tests address unmet medical needs in the indication fields of cardiovascular diseases, nephrology, oncology and neurology, shaping another important pillar in precision medicine. numares AG is headquartered in Regensburg, Germany, with offices in Boston and Singapore.

You will find more information at www.numares.com.

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