



numares initiates pan-European multicenter study of AXINON® renalTX-SCORE® on kidney allograft rejection

PARASOL multicenter study to continue building clinical case for non-invasive renal allograft rejection testing with AXINON® renalTX-SCORE®

UMBRELLA results to be presented at upcoming transplant conferences: ATC and TTS 2018

Regensburg, Germany, May 18, 2018 – numares AG today announced the initiation of PARASOL, a European multicenter study, to continue building upon the clinical case from the results of the UMBRELLA study. AXINON® renalTX-SCORE® is a non-invasive, urine-based CE-marked *in-vitro* diagnostic test (IVD) for the diagnosis of kidney transplant rejection. It was launched in Europe in 2017 and is the first test available worldwide to evaluate a metabolic constellation rather than single biomarkers for the diagnosis of an acute rejection after transplantation.

“AXINON® renalTX-SCORE® has the potential to support a physician’s diagnosis and therefore to reduce the number of unnecessary biopsies,” said Volker Pfahlert, chairman of the executive board of numares AG. “The original UMBRELLA study, which will be presented at two upcoming conferences, The American Transplant Congress (ATC) in May in Seattle, WA, and the 27th International Congress of The Transplantation Society (TTS) in July in Madrid, generated the data that led to its CE-mark. PARASOL will build on this initial study to generate stronger health economic and clinical use case data that will be helpful in discussions with health systems. First results of this study are expected in 3Q18, and initiation of a similar trial in the U.S. is expected toward the end of 2018.”

The randomized, multi-center study will enroll approximately 600 patients at five sites located in Regensburg, Germany, Vienna, Austria, Prague, Czech Republic, Grenoble, France and Barcelona, Spain. It will evaluate the use of the four-biomarker metabolic constellation for the detection of acute kidney allograft rejection of urine samples from patients at least 14 days after transplantation who are scheduled for renal allograft biopsy.

numares’ approach utilizes the effects of a disease on the dynamics of human metabolism. These effects can be recognized as specific changes in metabolites caused by readjustments of the metabolic machinery due to the disease. The AXINON® renalTX-SCORE® test evaluates the status of a metabolite constellation, rather than quantifying just one or a few biomarkers as with more traditional diagnostics. The metabolic constellation is deciphered by employing machine learning tools to evaluate a large number of metabolites for inclusion in the constellation consisting of a small number of metabolites.



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

About kidney transplantation

Kidney transplants are the most common organ transplantations worldwide. In 2016, roughly 80,000 kidney transplants were carried out worldwide, 19,000 in the U.S. and 2,100 in Germany. 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, result in graft-loss. Accordingly, there is a great need for early detection and rapid therapy of transplant rejection.

About numares

numares AG, based in Regensburg, Germany, is a fast-growing innovative diagnostics company that applies machine learning to metabolics data to develop advanced analytical test tests for high-throughput use in clinical diagnostics and life science research. The *AXINON®* in-vitro diagnostics (IVD) system employs nuclear magnetic resonance (NMR) spectroscopy to create a “numaric” spectrum to evaluate metabolic constellations. The IVDs based on this metabolic network provide physicians with valuable insights on patient disease status. *Magnetic Group Signaling (MGS®)* is a proprietary technology that enables NMR for highly standardized and rapid throughput testing. Metabolic tests stand as an important pillar in precision medicine to address unmet needs in cardiovascular diseases, nephrology, oncology and neurology. You will find more information at www.numares-health.com.

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