
numares announces FDA 510(k) Submission of AXINON System[®], a NMR platform for metabolomics-based, AI-driven Diagnostics

Boston, USA/Regensburg, Germany – March 24, 2021. Leading NMR diagnostics company *numares AG* today announced that the company made a 510(k) submission to the U.S. Food and Drug Administration (FDA) for its *AXINON[®] IVD System*, a NMR-platform for AI-driven, metabolomics-based diagnostics. If cleared, *AXINON[®]* would become the first NMR-based clinical laboratory system using AI-evaluated metabolic data. Several multi-marker assays for *AXINON[®]* will cover numerous unmet medical needs, in order to prevent, diagnose and treat disease.

The clearance of *AXINON[®]* would bring a novel diagnostic approach to clinical laboratories, the combination of several metabolic biomarkers, so-called metabolite constellations, analyzed by advanced nuclear magnetic resonance (NMR) technology and evaluated by *numares'* proprietary, AI-driven *AXINON[®]* diagnostic software.

"This U.S. regulatory filing for its diagnostics platform is an important milestone for *numares*," said Winton Gibbons, President - US and co-Chief Executive Officer of *numares*. "After entering into collaborations on joint diagnostics development with analytical instrumentation and solution provider *Bruker Corporation* in January 2021, and with *Mayo Clinic Laboratories* in 2019, this FDA submission is the first step in our common endeavor to bring NMR diagnostics into routine clinical use, and make metabolomics-based diagnostics accessible to the patients."

numares is currently developing multi-marker algorithms for several diagnostic tests on the *AXINON[®] IVD System*. These include *AXINON[®] GFR_{NMR}* to reliably assess kidney function by improved determination of glomerular filtration rate (GFR). *numares* expects to submit this test to the FDA also in the first half 2021. The third assay *AXINON[®] renalTX-SCORE[®]* is intended to reliably identify early kidney rejection in post-transplant surveillance, and be submitted to the FDA in 2022. Further multi-marker tests are in development, e.g., for liver disease, cancer detection, and multiple sclerosis.

Dr. Maulik Shah, *numares'* Medical Director comments: "*AXINON[®]* provides clinical laboratories with a powerful technology that leverages the information-rich metabolome with artificial intelligence to give healthcare professionals new insights into disease diagnosis and management for improved patient outcomes. At the same time, automation capabilities, excellent precision, easy operability will allow easy adaption of the FDA-cleared system by clinical laboratories and will make *AXINON[®]* an indispensable routine diagnostic tool in precision medicine."

"The 510(k) submission of our *AXINON[®] System* is an important step and prerequisite to further strengthen commercialization of *numares'* products in the United States", concludes Dr. Volker Pfahlert, co-CEO of *numares* and chairman of the executive board. "Metabolic disorders

are a rapidly increasing problem and major challenge to today's healthcare systems. Patients will benefit from our approach to consider the patient's metabolome with sophisticated algorithms. Once cleared by the FDA, we believe AXINON® has the potential to meaningfully improve health outcomes and quality of life for millions of patients.”

The AXINON® System consists of AI-based AXINON® Software, ready-to-use AXINON® kits, and an advanced NMR technology, refined by *numares'* proprietary *Magnetic Group Signaling™* to ensure highly standardized and automated processing of serum or urine samples in high-throughput.

Media:



numares AXINON® IVD System: The AI-driven AXINON® Software, in combination with advanced NMR technology, refined by *numares'* proprietary *Magnetic Group Signaling™*, allows metabolomics-based precision diagnostics by implementation of various *numares'* tests, e.g. to identify early kidney rejection in post-transplant surveillance, assess kidney function by improved determination of glomerular filtration rate (GFR) and risk for cardiovascular disease (CVD).

About *numares*

numares AG, based in Regensburg, Germany, is an innovative diagnostics company that applies machine learning to metabolomics data to develop advanced analytical tests for high-throughput use in clinical diagnostics. The *AXINON*[®] *System* employs advanced nuclear magnetic resonance (NMR) spectroscopy to evaluate metabolic constellations. *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, kidney, liver, and neurological diseases. You will find more information at <https://www.numares.com/>

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