
numares AG achieves key milestone: identifies candidate metabolomic network for bladder cancer diagnostics

Completes enrollment of prospective study (BLADE) to advance second software-based AXINON® IVD test

Regensburg, Germany, 13 July 2017 – numares AG obtained promising results from a retrospective study that provides initial evidence that evaluation of metabolomic biomarker networks can be used as a non-invasive diagnostic for bladder cancer. Based on these results, the company enrolled patients in a prospective study to confirm and further refine the metabolomic network. The test is intended to be launched as a CE-marked *in-vitro* diagnostics (IVD) in Europe in the second half of 2018.

Bladder cancer can be challenging to diagnose. Available urine-based tests are often not reliable if there are traces of blood in the urine sample (called microhematuria), which is also associated with bladder cancer. However, even persistent microhematuria is a poor prognostic indicator, because only two to five percent of patients with microhematuria are diagnosed with bladder cancer. As a result, the majority of patients presenting with microhematuria undergo cystoscopy to rule out bladder cancer as a cause of the symptom. Cystoscopy is an invasive procedure that causes risks as well as pain for the patient. Thus, there is a significant need for a non-invasive bladder cancer screening test to reduce the number of cystoscopies.

To address this need, numares initiated a project to develop a non-invasive bladder cancer IVD test that would be run on AXINON®, a fully-integrated laboratory system based on nuclear magnetic resonance (NMR) spectroscopy. The first step in the project was to evaluate approximately 300 urine samples from patients with and without bladder cancer with the objective of identifying metabolites that could be developed into a bladder cancer-specific metabolomic network.

“Based on this analysis, we have initiated and are currently finishing the recruitment phase of our prospective validation study, BLADE (Bladder Cancer Detection using Metabolomic Evaluation of Urine and Blood), to confirm our initial findings,” said Dr. Philipp Pagel, chief medical officer of numares. “We collected urine samples from patients with persistent microhematuria who are scheduled for cystoscopy. With this program, numares pursues the European Association of Urology’s (EAU) appeal to evaluate new biomarkers in urine for avoiding cystoscopies.”

“The positive results of our retrospective analysis were an important milestone for numares as the bladder cancer test has now advanced into the next phase,” said Volker Pfahlert, chairman of the executive board of numares. “When launched, the bladder cancer test will be our second metabolomic network-based diagnostic. The first, the recently-launched renalTX-SCORE®, uses a metabolomic biomarker network to diagnose kidney transplant rejection in

urine samples. Along with renalTX-SCORE, the bladder cancer project further illustrates the power of the metabolomic biomarker network approach.”

About bladder cancer

Urinary bladder carcinoma is among the most common types of cancer with approximately 350,000 new cases per year. Men are significantly more often (3.8 times) affected than women. In Europe about 118,000 new cases were discovered in 2012. In the US there is an estimation of 80,000 new cases and 17,000 deaths by bladder cancer in 2017.

Bladder cancer is mostly associated with quite unspecific signs and symptoms, such as blood in the urine. If medical anamnesis and ultrasonic examination do not reveal the cause of the hematuria, as a next step a cystoscopy is recommended.

About biomarker networks

The innovative approach to use biomarker networks for diagnostic purposes becomes increasingly relevant for several further medical questions, which cannot 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 and employs machine learning techniques (also known as artificial intelligence) to process the large amount of data and to identify metabolomic biomarker networks.

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 “numaric” 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 <http://www.numares.com>.

For further information please contact:

numares AG
Dipl.-Biol. Christiane Proll, MBA
Tel.: +49 941 2809 49-14
E-Mail: christiane.proll@numares.com

IRA WÜLFING KOMMUNIKATION GmbH
Dr. Reinhard Saller
Tel.: +49 89 2000 30-30
E-Mail: reinhard.saller@wuefing-kommunikation.de

U.S.A.
The Ruth Group
Investors:
Robert Flamm, Ph.D.
Tel.: 1-646-536-7017
E-Mail: rflamm@theruthgroup.com

Media:
Kirsten Thomas/Cari Randall
Tel: 1-508-280-6592/1-646-536-7002
E-Mail: kthomas@theruthgroup.com/crandall@theruthgroup.com