

Press release

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MOSAIQUES and U.S. FDA describe detection of drug-induced side effects in early phase animal models

MOSAIQUES' CE/MS technology paves the way for early assessment of drug-induced side effects and helps ensuring patient's safety from the very beginning of preclinical research.

Rockville/Hannover - Drug-induced toxicity represents a significant problem in health care delivery: Over 100,000 people die per year from adverse effects of medications in the U.S. (*Starfield, JAMA 2000, 284: 483-485*). This has led to an intense awareness of drug-induced side effects, which may hamper the development of new therapeutic agents. Initial assessment of possible side effects in animal models is certainly preferred over discovering side effects in a clinical study - if not worse after approval - in human.

Now mosaiques diagnostics demonstrated the enormous capability of its proprietary CE/MS technology by the early and reliable assessment of drug-induced side effects in animal models. The data clearly indicate that CE/MS analysis is able to display drug-induced changes in the urinary proteome. To reveal drug-induced alterations (or the absence thereof) with high statistical significance opens an avenue towards screening for potential side effects with limited or reasonable effort during preclinical research.

Prof. Dr. Dr. Harald Mischak, mosaiques' founder and CSO, said: "We are aiming to reduce or even prevent adverse effects of drugs by implementing our technology in (pre)clinical testing. This project with the U.S. FDA underlines the relevance of our technology for modern medicine and appropriate treatment." CEO and co-founder of mosaiques, Joachim Conrads, adds: "Interest from pharmaceutical companies to implement our technology in their (pre)clinical research programs is steadily increasing and we have initiated several collaborations, which show that industry is convinced by the benefits of the CE/MS technology."

The results also indicate that the number of individuals required for statistically sound results is by far less in laboratory animals in comparison to human. Furthermore, the found similarity to human beings, strongly

supports the notion that urinary proteome analysis is a very valuable tool not limited to assessing drug toxicity and unwanted side-effects in preclinical investigations, but also to reduce the risk for appearance of such side effects later in clinical studies, or even after approval.

This study is accepted for publication in **PROTEOMICS - Clinical Applications**, entitled: *Profiling of rat urinary proteomic patterns associated with drug-induced nephrotoxicity using capillary electrophoresis coupled with mass spectrometry as a potential model for detection of drug-induced adverse effects.*

The project was funded in part by grants of the *Federal Ministry of Education and Research (BMBF)* and the *European Union*.

About mosaïques diagnostics & therapeutics AG

mosaïques diagnostics & therapeutics AG is based in Hannover, Germany. The company's core competence is the early and reliable detection of diseases, thus facilitating personalized medicine and significant improvements in drug development. The company utilizes diagnostic polypeptide patterns (DiaPat) derived from the fast and accurate analysis of proteins and polypeptides in body fluids (e.g. urine and cerebrospinal fluid) via capillary electrophoresis coupled mass spectrometry (CE/MS). Early detection of diseases, differential diagnosis, therapy control, and cost saving within the national and international health care systems are the primary concerns of mosaïques. During the recent years, mosaïques developed numerous diagnostics test, such as assessment of diabetic nephropathy up to 3 to 5 years in advance and risk estimation for myocardial infarction and stroke by detection of vulnerable plaques. Altogether, diagnostic tests for bladder and prostate cancer, chronic renal diseases, diabetic nephropathy, graft-versus-host disease, ureteropelvic junction obstruction in newborns, and myocardial infarction are already marketed in Germany through the subsidiary DiaPat GmbH. mosaïques' polypeptide pattern technology has been proven in over 30 blinded and partly prospective clinical studies together with over 220 clinicians and scientist at over 55 academic and industrial institutions around the world. By now over 20,000 qualified patient samples from different pathological alterations have been analysed and annotated in mosaïques' proprietary database.