

## Press release

February 20th, 2009

### Further information

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### **MOSAIQUES and U.S. Food and Drug Administration (FDA) sign contract for collaboration in discovery and validation of biomarkers for assessment of drug toxicity**

**Rockville/Hannover** - mosaiques diagnostics and therapeutics AG, a global leading proteomics innovations company, announces the signing of a collaborative agreement with the U.S. Food and Drug Administration.

The aim of this collaborative project is the identification and validation of protein- and peptide biomarkers for drug toxicity in urine. Based on preliminary experiments, it is anticipated that toxic effects of drugs will result in indicative changes in the proteome of bodyfluids, before gross pathological changes become apparent. The U.S. Food and Drug Administration will contribute know how on drugs, expected drug toxicities, as well as conduction animals studies. mosaiques diagnostics will contribute know how on proteome analysis (especially preparation of urine and capillary electrophoresis coupled mass spectrometry) and on data evaluation, calibration and multivariate statistics. It is anticipated that these biomarkers, once validated, will enable a more accurate assessment of potential drug toxicity, consequently identification of potentially serious side effects of therapeutics at an early stage of development and before actual pathological changes.

CEO and co-founder of mosaiques, Joachim Conrads, said: "One of the key issues to reduce toxicity of drugs is being able to quickly and accurately access severe side effects in early developmental phases. This is no simple matter and the available testing methods simply take too long. mosaiques' groundbreaking technology speeds up this process and lays the foundation for safer drugs and personalized medicine."

mosaiques' founder and CSO, Prof. Dr. Dr. Harald Mischak adds: "Our progress over the last five years has been remarkable. Our method is unlike any other currently available. We are aiming to reduce or even prevent adverse effects of drugs by implementing our technology in (pre)clinical testing. This agreement with the FDA underlines the potential of the protein pattern technology for modern medicine and appropriate treatment."

## **About mosaiques diagnostics & therapeutics AG**

mosaiques 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 mosaiques. During the recent years, mosaiques 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. mosaiques' 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 mosaiques' proprietary database.

PUBLIC HEALTH SERVICE  
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

SUMMARY PAGE

EITHER PARTY MAY, WITHOUT FURTHER CONSULTATION OR PERMISSION,  
RELEASE THIS SUMMARY PAGE TO THE PUBLIC.

TITLE OF CRADA: Identification and validation for Urinary Biomarkers for Drug  
Toxicity

PHS [FDA] Component: Center for Drug Evaluation & Res.  
FDA Principal Investigator: Joseph Hanig, Ph.D.  
Collaborator: Mosaiques Diagnostics & Therapeutics AG  
Collaborator Principal Investigator: Eric Schiffer, Ph.D.  
TERM OF CRADA: 3 years from the Effective Date.

ABSTRACT OF THE RESEARCH PLAN:

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