

## Press release

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### Further information

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### Grand Rounds in Proteomics at the FDA

*A pilot process for biomarker qualification at the FDA should elucidate the potential of proteomic data for the drug development and evaluation process.*

**Silver Spring/Hannover** - The *U.S. Food and Drug Administration* (FDA) is aiming to assess the value of novel biomarkers in the drug development and evaluation process. Especially biomarkers which are capable to reduce time and costs as well as showing adverse events at an early state are of interest. Therefore, the FDA invited for Grand Rounds in proteomics on April 3rd for the first time. A group of leading scientists and representatives of the pharmaceutical industry (e.g. Amgen, Bristol-Myers Squibb, Pfizer and Roche) met at the *Center for Drug Evaluation and Research* in Silver Spring (MD, USA) to present the state of the art in biomarker discovery and application.

Among the invited speakers was Prof. Dr. Harald Mischak of mosaiques diagnostics & therapeutics AG. He reported on the benefits and advancements of mosaiques's proteomics platform, pinpointing the advantages of high-resolution protein/peptide patterns for diagnostics and clinical research. Mosaiques accomplishes diagnosis of diseases and evaluation of therapy and therapeutics by analysing urine or other body fluids. Prof. Mischak pointed out the value of proteome analysis in the non-invasive monitoring of patients, enabling advancements in clinical trials and drug development.

The FDA intends to encourage voluntary proteomic data submissions to assess the readiness of proteomic platforms in drug development and regulatory review. Within this process, mosaiques

diagnostics & therapeutics AG will provide proteomic data from ongoing and upcoming clinical studies to point out the potential of their proprietary technology. Notably, voluntary submissions in genomics have been transformed into regulatory submissions and the FDA reviewers will elucidate if something similar can be expected in proteomics.

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

The mosaiques diagnostics & therapeutics AG was founded in 2002 in Hannover (Germany). The company's core competence is the early and reliable detection of diseases based on fast and accurate analysis of proteins and polypeptides in urine utilising **diagnostic patterns** (DiaPat). Proteins are indispensable for the function of cells and organs, as well as for all communication inside the body. They catalyse chemical reactions and protect the body against pathogens. Thousands of proteins and peptides are involved in these processes, forming a distinct pattern, which changes with disease. Mosaiques identifies up to 6,000 of such proteins and peptides and generates disease specific patterns. This huge amount of information improves accurate diagnosis of diseases. Diagnosis of bladder and prostate cancer, chronic renal diseases, diabetic nephropathy, Graft-versus-Host Disease, ureteropelvic junction obstruction in newborn and infarct risk is already marketed in Europe through the subsidiary DiaPat GmbH. The mosaiques diagnostics & therapeutics AG also performs clinical trials with the pharmaceutical industry that enable improvement of therapy and therapeutics, based on the individual molecular polypeptide signature.