

Press release

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Improved safety for leukaemia patients after allogeneic hematopoietic stem cell transplantation

A perilous threat for hematopoietic stem cell recipients is the acute Graft-versus-Host Disease – The Hannover Medical School developed together with the mosaiques diagnostics & therapeutics AG an early diagnosis of this momentous disease.

Hannover - 12.000 people are diagnosed with leukaemia every year in Germany. Allogeneic hematopoietic stem cell transplantation (aHSCT) is the only curative treatment for leukaemia in adult patients, but carries the risk of severe, even lethal complications. The mosaiques diagnostics & therapeutics AG, together with a consortium of international experts led by Prof. Dr. Eva Weissinger of the Hannover Medical School, developed technology that enables early diagnosis of severe complications during aHSCT. The researchers thoroughly validated their approach in an international, blinded, multicenter clinical study including 141 patients, and demonstrated the high value of their method based on clinical proteomics.

In more than the half of aHSCTs the immune cells of the transplant (graft) recognize the recipient (host) as *foreign* and mount an immunologic attack, resulting in Graft-versus-host Disease (GvHD). The fast initiation of therapeutic measures is crucial to survival of the patient. The innovative technique enables the early detection and prevention of GvHD, on an average of seven days in advance compared to standard diagnostic methods. This is an inestimable gain of time for treatment of patients, a lifesaving advantage. Furthermore, the success of therapy can be monitored during the time of treatment.

The study outcome is published in the leading journal BLOOD (Issue April 2007), entitled: *Proteomic patterns predict acute graft-versus-host disease after allogeneic hematopoietic stem cell transplantation*. The presentation of the study results on the international congress *Chronic Graft-versus-Host Disease: Implementation of the NIH*

Consensus Criteria for Clinical Trials has been appreciated with great tribute. Prof. Pavletic, director of the consensus conference for diagnose and therapy of the chronic form of this complication, emphasises, that an investigator independent, verifiable diagnostic method in the field of chronic GvHD diagnosis, has an immediate significance, reported Prof. Weissinger, head of the *transplantation biology* unit on the Hannover Medical School. The study has been funded by the German José Carreras Leukaemia Foundation and the federal state of Lower Saxony.

The costs of aHSCT amounts up to 150.000 Euro per patient. In the case of complications, the costs may double or triple. In the opinion of the *Institute of Quality and Efficiency in Health Care (IQWiG)* the compulsory health insurances should not bear the treatment expenses in the upcoming future due to the high costs mainly of complications, hence the life saving aHSCT would become unaffordable for most patients. The now available diagnostic method of rapid and early diagnosis of GvHD enables the decision for an appropriate therapy in the case of complications at an early stage and will eliminate a large portion of the complication-associated costs. It is to be hoped that the beneficial cost effects will change the opinion of IQWiG and the life saving sHSCT therapy can be available for all patients, not only the wealthy.

About mosaiques diagnostics & therapeutics AG

The mosaiques diagnostics & therapeutics AG was founded in 2002 in Hanover (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 are involved in these processes, forming a distinct pattern, which changes with disease. 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 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.