

Press Release

## Clinical data of Medigene's dendritic cell (DC) vaccines in AML presented at CIMT conference

**Martinsried/Munich, 11 May 2016.** [Medigene AG](#) (MDG1, Frankfurt, Prime Standard), a clinical stage immune-oncology company focusing on the development of T cell immunotherapies for the treatment of cancer, informs that the academic group of Prof. Gunnar Kvalheim at the Department of Cellular Therapy at the Oslo University Hospital, Norway, has presented clinical data on Compassionate Use<sup>1</sup> patients receiving dendritic cell (DC) vaccines for the treatment of acute myeloid leukaemia (AML) utilizing Medigene's DC vaccine technology at the 14<sup>th</sup> Cancer Immunotherapy Conference (CIMT) in Mainz, Germany. CIMT is Europe's largest meeting focused on cancer immunotherapy research and development.

The poster presentation of the Oslo University Hospital showed preliminary data from five AML patients receiving DC vaccines targeting the antigens Wilm's tumor-1 (WT-1) and preferentially expressed antigen in melanoma (PRAME) employing Medigene's new generation monocyte-derived fast dendritic cells. The poster is entitled "WT-1 and PRAME mRNA transfected TLR 7/8 polarized fast DCs vaccines in AML patients raise specific immune responses that correlate with clinical outcome".

AML is frequently diagnosed in elderly patients, who normally cannot tolerate intensive chemotherapy and/or stem cell transplantation, making curative treatment difficult and rates of early relapse high.

Results reported here are from five patients, where DC vaccination was started after hematopoietic recovery from first line chemotherapy treatment.

Data from the first four patients has already been reported at the 57th Annual Meeting of the American Society of Hematology (ASH) in December 2015. Those four patients have now been treated between 16 and 26 months.

**Prof. Gunnar Kvalheim, Head of Department of Cellular Therapy, Oslo University Hospital**, explains: "Altogether, these results show that fast TLR- polarized DCs can induce or enhance specific T cell responses with a patient individual pattern. Clinical responses are related to immune responses and can result in prolonged survival in AML patients not eligible for curative treatment."

**Prof. Dolores J. Schendel, CEO and CSO of Medigene AG**, adds: "These positive results encourage us in pursuing our proprietary DC vaccine development program for which we are currently conducting our own Phase I/II clinical AML trial, expanding the ongoing academic clinical studies."

The Oslo University Hospital has an agreement with Medigene for the use of Medigene's new generation DC vaccines for their ongoing academic clinical studies. Medigene's DC vaccines are produced according to GMP guidelines at the Department of Cellular Therapy at the Oslo University Hospital. Acute myeloid leukaemia is Medigene's lead indication in its DC vaccine program.

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<sup>1</sup> Compassionate Use: Prescription of as-yet unapproved drugs in particularly severe cases where there are no treatment alternatives

**About Medigene's DC vaccines:** The platform for the development of antigen-tailored DC vaccines is the most advanced platform of the highly innovative and complementary immunotherapy platforms of Medigene Immunotherapies. Currently, Medigene evaluates its DC vaccines in a company-sponsored Phase I/II clinical trial in acute myeloid leukaemia (AML). Further studies utilizing Medigene's DC vaccine technology include two ongoing clinical investigator-initiated trials (IITs): a clinical Phase I/II trial for treating acute myeloid leukaemia (AML) at Ludwig Maximilians University Hospital Grosshadern, Munich, and a clinical Phase II trial of a treatment for prostate cancer at Oslo University Hospital. Moreover, compassionate use patients are treated with DC vaccines at the Department of Cellular Therapy at Oslo University Hospital.

Dendritic cells (DCs) are the most potent antigen presenting cells of our immune system. Their task is to take up, process and present antigens on their cell surface, which enables them to activate antigen-specific T cells for maturation and proliferation. This way T cells can recognize and eliminate antigen-bearing tumor cells. Dendritic cells can also induce natural killer cells (NK cells) to attack tumor cells. The team of Medigene Immunotherapies GmbH's scientists has developed new, fast and efficient methods for generating dendritic cells ex-vivo, which have relevant characteristics to activate both T cells and NK cells. The DC vaccines are developed from autologous (patient-derived) precursor cells, isolated from the patient's blood, and can be loaded with tumor-specific antigens to treat different types of cancer. Medigene's DC vaccines are in development for the treatment of minimal residual disease or use in combination therapies.

Further audio-visual education about Medigene's DC-Vaccines at:  
<https://vimeo.com/123005832>

**Medigene AG** is a publicly listed (Frankfurt: MDG1, prime standard) biotechnology company headquartered in Martinsried near Munich, Germany. The company is developing highly innovative, complementary treatment platforms to target various types and stages of cancer with candidates in clinical and pre-clinical development. Medigene concentrates on the development of personalized T cell-based immunotherapies.

For more information, please visit [www.medigene.com](http://www.medigene.com)

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