Press release

Medigene: Promising data from Phase I/II IIT and Compassionate Use Programme with dendritic cell vaccines in AML presented at ASH Annual Meeting 2015

- Early results from an ongoing Phase I/II IIT and a Compassionate Use Programme presented on two posters by academic partners
- High success rate for GMP generation of DC vaccines from elderly patients, heavily pretreated with chemotherapy
- Excellent safety profile of the DC vaccines
- Detectable immune responses to the selected antigens were observed in patients under treatment with the next generation DC vaccines

Martinsried/Munich, 8 December 2015. Medigene AG (MDG1, Frankfurt, Prime Standard) announces that early data from two independent clinical programmes in patient groups with acute myeloid leukaemia (AML) receiving dendritic cell (DC) vaccines, prepared according to technologies licensed and developed by Medigene, show an excellent safety profile and the capacity to induce T cell responses in elderly patients unable to undergo stem cell transplantation.

Two posters were presented at the 57th Annual Meeting of the American Society of Hematology (ASH) in Orlando, FL, USA, detailing early clinical results of patients with acute myeloid leukaemia (AML) treated with these next-generation DC vaccines. One poster, entitled "Next-Generation Dendritic Cell Vaccination in Postremission Therapy of AML: Results of a Clinical Phase I Trial", included data from an ongoing Phase I/II investigator initiated trial (IIT) under the direction of Prof. Marion Subklewe of the Ludwig-Maximilians-Universität (LMU) in Munich, Germany. In particular, results were presented regarding the six patients included in a Phase I proof-of-concept study who have completed vaccination lasting up to 26 weeks. The second poster entitled "AML Patients in Minimal Residual Disease Vaccinated with a Novel Generation of Fast Dendritic Cells Expressing WT-1 and PRAME Mount Specific Immune Responses That Relate to Clinical Outcome" included results from four patients treated with DCs from 5 to 16 months so far in an ongoing Compassionate Use Programme under the direction of Prof. Gunnar Kvalheim at Oslo University Hospital (OUH) in Norway.

Links to the poster abstracts:
Phase I/II IIT of LMU: https://ash.confex.com/ash/2015/webprogram/Paper85287.html
Compassionate Use Programme of OUH: https://ash.confex.com/ash/2015/webprogram/Paper84590.html

Prof. Marion Subklewe, Professor of Internal Medicine with special Focus on Cellular Immunotherapy at the Ludwig-Maximilian University Großhadern, Munich, explains: “Upon completion of our Phase I trial, we have obtained the first evidence that use of WT-1 and PRAME as vaccine antigens can be validated through detection of T cell responses in various patients analysed to date”.

1 Compassionate Use: Prescription of as-yet unapproved drugs in particularly severe cases where there are no treatment alternatives
Prof. Gunnar Kvalheim, Head of Department of Cellular Therapy at the Oslo University Hospital comments on his findings so far: “We are optimistic that these results pave the way for DC vaccines as a new therapy option for patients that have high risk for disease relapse and do not qualify for stem cell transplantation. The feasibility to make good quality DC vaccines from heavily pretreated patients and the capacity of our patients to make T cell responses to one or both antigens are important early findings.”

Prof. Dolores J. Schendel, Chief Scientific Officer of Medigene AG, summarizes the findings from the two ASH reports: “We are pleased with the new information that could be derived from the preliminary assessments of the ten AML patients receiving next-generation DC vaccines in these ongoing independent studies. It was feasible to manufacture high quality DCs according to our technology that led to detectable immune responses in different patients to one or both leukaemia-associated antigens. The rapidity with which T cell responses were detected in some patients speaks to the good immunizing capacity of the DCs. These observations support the approach implemented in our own company-sponsored DC vaccine trial that was launched in March of this year at OUH.”

About Medigene’s DC vaccines: The platform for the development of antigen-tailored DC vaccines is the most advanced platform of the three 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: a clinical phase I/II trial in AML at the Ludwig-Maximilian University Hospital Großhadern, Munich, and a clinical phase II trial in prostate cancer at Oslo University Hospital. Moreover, a compassionate use programme is being conducted 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 recognise and eliminate antigen-bearing tumour cells. Dendritic cells can also induce natural killer cells (NK cells) to attack tumour 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-specific) 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 DCs 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.

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