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Patrys released myeloma trial data

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Singapore: Patrys released additional data from the first cohort of multiple myeloma patients treated with PAT-SM6 in the ongoing phase I/IIa clinical trial. All three patients in this first cohort had advanced multiple myeloma and had failed or were resistant to multiple courses of chemotherapy, including Velcade and Revlimid. The trial is being led by investigator Dr Leo Rasche at the Department of Haematology and Oncology, University Hospital of WÃ¼rzburg, Germany, and is being supported by Professor Dr Hermann Einsele, director of the Department of Medicine II, University of WÃ¼rzburg, Germany.

Therapeutic options for such patients are usually limited to clinical trials. Each patient received a total of four doses of PAT-SM6 (each dose at 0.3mg/kg) given intravenously, over a two week period as per the protocol. They were then followed up for 36 days. All of the doses of PAT-SM6 were well tolerated with no serious adverse events or dose-limiting toxicities noted in any patient. None of these patients have gone on to receive additional doses of PAT-SM6. On the basis of these positive safety data, the Data Safety Monitoring Board (DSMB) gave approval for cohort two to commence. Patients in cohort two will each receive a minimum of four doses of PAT-SM6, each dose being 1mg/kg.

Prior to treatment with PAT-SM6, multiple myeloma cells were extracted from the bone-marrow of the patients and tested, in vitro, for their ability to bind the antibody. In all three patients, between 80-to-100 percent of their cancer cells bound PAT-SM6 strongly and specifically. There was no binding of the antibody to the non-malignant cells confirming the absolute specificity of PAT-SM6 for cancer cells. This analysis was performed by both immunohistochemistry (IHC) and flow cytometry (FACS).

All patients had significantly reduced numbers of white blood cells, red blood cells and platelets prior to their inclusion in the trial. It was observed that, post treatment with PAT-SM6, these blood counts improved significantly and more rapidly than might have been expected in this group of very sick patients. There were no significant drug-related changes in clinical chemistry (CRP, uric acid, ÃŸ2-microglobulin) or changes noted on ECG. All three patients had rapidly progressive disease and this was confirmed by rising levels of serum M protein, serum free light chains and immunoglobulins.

As part of their follow-up post treatment, the overall status of the patient's immune system was monitored. It was noted that in all three patients, specialised T lymphocytes (T Regulatory cells and cytotoxic T cells), B cells and natural killer (NK) cells were transiently but positively stimulated. Although not conclusive, such changes clearly indicate that PAT-SM6 is active in patients and is stimulating the immune system.