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Patrys' multiple myeloma clinical trial progresses

August 12, 2013 | News | By BioSpectrum Bureau



Singapore: Patrys, a clinical stage biotechnology company, has received approval to progress its Phase I/IIa PAT-SM6 multiple myeloma trial to its fourth and final group of patients, based on positive safety data.

There were no significant adverse events reported from the third patient group, comprised of three patients who were treated with Patrys' lead antibody PAT-SM6. Patients in this group received four doses of PAT-SM6 at a dose level of 3 mg/kg.

The independent board monitoring the trial, which is underway at the Department of Haematology and Oncology, University Hospital of WÃ?Æ?Ã?Â¼rzburg in Germany - has given approval for the trial to progress to the fourth and final patient group.

Recruitment of this fourth group of three patients has commenced. These patients will initially receive four doses of PAT-SM6 at a dose level of 6 mg/kg, which is twice the amount received by the patients in the third cohort. This is more in line with dosing levels of other antibodies currently on the market.

The trial is an open-label multi-dose escalation trial in relapsed and multi-resistant patients with multiple myeloma who have failed all currently marketed drugs and have a very poor prognosis. Initially, twelve patients will be enrolled in four dosing groups and will receive a minimum of two cycles (four doses) of treatment.

If a patient shows a partial response to treatment with PAT-SM6 an additional cycle (two doses) of treatment will be offered. The primary objective of the study is to evaluate the safety and tolerability of escalating doses of PAT-SM6, and the secondary objective is to measure efficacy as determined by a series of well-established laboratory assays. As the trial is an open-label multi-dose escalation study, data will be released on an ongoing basis.

Professor Max Topp and Dr Leo Rasche, both from the University Hospital of WÃ?Æ?Ã?Â¼rzburg, are responsible for recruiting and treating patients in the trial. The specialist clinic is headed by Professor Dr Hermann Einsele who is also a Member of the Medical Advisory Board for the European Network of Myeloma Patient Groups, a non-profit network organisation of multiple myeloma patient groups dedicated to raising the awareness of multiple myeloma.

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