

Patrys gets regulatory approval for Multiple Myeloma trial

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Singapore: Australia Patrys, a clinical stage biopharmaceutical company, has received approval to commence its planned Phase I/IIa multiple myeloma trial with lead product PAT-SM6.

The planned trial will be an open-label multi dose escalation trial in relapsed and multi-resistant patients. Twelve patients will be enrolled in four dosing groups and will receive a minimum of two cycles of treatment. If a patient shows a partial response to treatment with PAT-SM6 additional cycles of treatment will be offered.

Multiple myeloma is a type of bone marrow cancer arising from plasma cells, for which new therapies are desperately needed to treat patients who become resistant to established chemotherapeutics. There is an estimated 200,000 cases of myeloma worldwide with only 40% of patients survive over five years.

The patients in the Phase I/IIa trial set to take place in Germany have typically failed all currently marketed drugs and have a very poor prognosis. 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.

This trial is being strongly supported by Professor Dr. Hermann Einsele and his colleagues at the Department of Haematology and Oncology, University Hospital of Würzburg, as part of an ongoing collaboration with Patrys. Professor Dr. Einsele's clinical trials unit has considerable expertise in conducting phase I/IIa clinical trials in multiple myeloma patients and is considered a leading centre in Europe.

Professor Dr. Hermann Einsele said: "I am very excited to be supporting the PAT-SM6 clinical trial and helping to bring this novel treatment to multiple myeloma patients in Germany."

Dr Marie Roskrow, Patrys' CEO said: "The approval to commence this trial marks a major milestone for Patrys and we are delighted to be collaborating with a world leading centre in multiple myeloma. PEI undertook a very thorough and detailed review of PAT-SM6 and their approval gives us confidence that our development plan will pass the scrutiny of potential

licensing partners."

"A trial in patients with this disease is attractive from a development perspective as it is possible to determine very quickly whether the product is working by assessing routine blood counts and bone marrow samples."