

Data from 1st Cohort of Patients in Multiple Myeloma Clinical Trial

- **First cohort of patients treated with multiple doses of PAT-SM6 in multiple myeloma clinical trial; no serious adverse events reported**
- **Early evidence that PAT-SM6 is active in patients with resistant, end-stage disease**
- **Second cohort of patients currently being recruited**

Melbourne, Australia; 7 March, 2013: Patrys Limited (ASX: PAB; “the Company”), a clinical stage biopharmaceutical company, is pleased to provide additional data from the first cohort of multiple myeloma patients treated with PAT-SM6 in the ongoing Phase I/IIa clinical trial.

All 3 patients (ages 67-71 years) in this first cohort had advanced multiple myeloma and had failed or were resistant to multiple courses of chemotherapy, including Velcade and Revlimid. Therapeutic options for such patients are usually limited to clinical trials. Each patient received a total of 4 doses of PAT-SM6 (each dose at 0.3mg/kg) given intravenously, over a 2 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 2 to commence. Patients in cohort 2 will each receive a minimum of 4 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 3 patients, between 80-100% 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, β 2-microglobulin) or changes noted on ECG. All 3 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 3 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.

Post inclusion in this trial, 2 out of the 3 patients went on to receive additional chemotherapy due to advancing disease. Both patients had an unexpectedly positive response to drugs that they had previously been resistant to. This may suggest that PAT-SM6 had an influence on the sensitivity of the malignant cells. It is known from the literature that cancer cells can be converted from resistant to sensitive when treated with agents that bind to the cancer-specific form of GRP78, as in the case of PAT-SM6.



The trial is being led by investigator Dr. Leo Rasche at the Department of Haematology and Oncology, University Hospital of Würzburg and is being supported by Professor Dr. Hermann Einsele, Director of the Department of Medicine II, University of Würzburg.

Commenting on the data, Dr. Rasche stated “We are very encouraged by these initial data from the first cohort of treated patients and are now aggressively recruiting the second group of 3 patients. The patients in this trial are extremely sick and to see early signs of antibody activity in the face of resistant disease is exciting and promising.”

Patrys CEO, Dr. Marie Roskrow, added “Our clinical trial is progressing as planned and we are very excited by this early data. Stimulating the immune system of patients with end-stage multiple myeloma is not easy and we look forward to treating patients with higher doses of PAT-SM6 in the hope that we will induce some positive clinical responses.”

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About Patrys Limited:

Based in Melbourne, Australia, Patrys (ASX: PAB) is focused on the development of natural human antibody therapies for cancer. More information can be found at www.patrys.com.

About PAT-SM6:

The natural human antibody PAT-SM6 has been shown to have potent anti-cancer properties in a large number of laboratory and animal studies. More specifically, Patrys has now screened PAT-SM6 against more than 200 tumours from individual patients with various cancers, and the product binds to over 90% of the tumours screened regardless of cancer type or patient age, gender or disease stage. With respect to multiple myeloma PAT-SM6 has shown particularly strong promise. Patrys has filed patent applications to cover the PAT-SM6 antibody molecule, disease target, and the mechanism of action. Patrys has successfully completed a Phase I clinical trial to evaluate PAT-SM6 as a therapy for melanoma.

About Multiple Myeloma:

Multiple myeloma is a type of bone marrow cancer arising from plasma cells, and new therapies are desperately needed to treat patients who become resistant to established chemotherapeutics. There is an estimated 200,000 cases worldwide and the incidence is increasing. The five-year survival of patients is approximately 40% (at 10 years ~20%). Despite new marketed therapies, multiple myeloma remains largely incurable and fatal. The multiple myeloma market is dominated by three major products: Revlimid, Velcade and Thalidomide with combined net sales greater than US\$3 Billion in 2010.