

## **Data from 2nd and 3rd Cohorts of Patients in Multiple Myeloma Clinical Trial**

- **Convincing evidence that PAT-SM6 is active in patients with end-stage disease who are resistant to other marketed therapies**
- **Two multi-resistant patients experienced stable disease post treatment with PAT-SM6**
- **PAT-SM6 seems to prolong the time to the next therapy and this is deemed clinically significant**
- **No serious adverse events reported**
- **Final (4th) cohort of patients currently being recruited**

**Melbourne, Australia; 13 August, 2013:** Patrys Limited (ASX: PAB; “the Company”), a clinical stage biotechnology company, is pleased to release additional clinical data for six multiple myeloma patients treated with PAT-SM6 in the Phase I/IIa clinical trial.

The six patients were involved in the 2<sup>nd</sup> and 3<sup>rd</sup> cohorts of the ongoing trial (three in each cohort), and their positive clinical outcomes supported the trial progressing to its 4<sup>th</sup> and final patient cohort. Recruitment of these patients is currently underway.

The six patients (5 male and 1 female aged 65-75 years) had end-stage, multi-resistant multiple myeloma. On average, they had received five prior lines of therapy including autologous stem cell transplantation and other novel marketed compounds including Velcade and Revlimid. Therapeutic options for such patients are usually limited to clinical trials and their median overall survival is about nine months.

Each patient in the 2<sup>nd</sup> cohort received four doses of PAT-SM6 (each dose at 1mg/kg/dose) given intravenously, over a two week period as per the protocol. Patients in the 3<sup>rd</sup> cohort received four doses at 3mg/kg/dose. All patients were then followed up for 36 days.

All of the six patients treated in these cohorts tolerated PAT-SM6 very well. There were no drug-related serious adverse events and no dose-limiting toxicities. On the basis of these safety data, the independent Drug Safety Monitoring Board (DSMB) gave approval for the 4<sup>th</sup> and final cohort to commence. Patients in this final cohort will receive a minimum of four doses of PAT-SM6, each dose being at 6mg/kg/dose. This is more in line with dosing levels of other antibodies currently on the market.

Of these six patients treated with PAT-SM6, two have shown stable disease. The first of these (from the 2<sup>nd</sup> cohort) was a 73 year-old man who had previously received six lines of therapy including a stem cell transplant. At the time of entry into the trial he was resistant to all-available therapies and had rapidly advancing disease. At day +36 after treatment with four doses of PAT-SM6, he showed evidence of stable disease according to the International Myeloma Working Group criteria.

The second responder was a 75 year-old man (from the 3<sup>rd</sup> cohort) who had previously received four lines of therapy and showed significant progression of his disease. Like the first responder, he showed evidence of stable disease after treatment with PAT-SM6 and currently (now day +82 post treatment) his disease remains stable and he has not gone on to receive any other treatment.



Post inclusion in the trial, five out of six patients went on to receive additional chemotherapy due to advancing disease. Interestingly, two out of those five patients responded very positively to drugs that they had previously been resistant to. This suggests that PAT-SM6 is having a positive influence on the cancer cells by converting them from resistant to sensitive. Overall, there was a median time to next therapy of 42 days and this is certainly considered to be clinically significant.

As part of the overall assessment of these treated patients, the status of their immune systems was closely monitored. Of significant importance were the changes in a specific type of T cell, called a Natural Killer (NK) cell. These white blood cells play a major role in the rejection of tumours and virally-infected cells. Specifically, in one of the patients who showed stable disease post treatment with PAT-SM6, their levels of NK cells were significantly increased perhaps suggesting that these cells played a role in the control of tumour growth. Analyses of these complex data are currently ongoing.

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

“Our trial with PAT-SM6 is producing some very exciting data and it is particularly encouraging to see two patients, with end-stage multiple myeloma, respond so positively to treatment with this novel antibody,” commented Patrys’ CEO, Dr. Marie Roskrow. “All of the patients being recruited into this trial are resistant to the currently marketed drugs and PAT-SM6 is inducing strong and sustained immunological responses.”

“As we move into the final cohort of this trial, Patrys is beginning to attract the attention of potential new investors and commercial partners. We are delighted with the progress of the trial and are most grateful to Dr. Rasche and his colleagues for their continuing clinical support,” Dr. Roskrow said.

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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](http://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 30% (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\$6 Billion in 2012.