

ASX & Media Release

Planning for Patrys' Multiple Myeloma Trial Underway

- **Nuvisan Pharma Services appointed to assist with gaining trial approval in Germany**
- **Second indication for lead clinical candidate PAT-SM6**

Melbourne, Australia; 19 December, 2011: Patrys Limited (ASX: PAB; Company) is pleased to announce the details of its upcoming clinical trial program in multiple myeloma (MM) patients.

This trial will utilise lead clinical candidate PAT-SM6, which is currently in the final stages of a Phase I melanoma study in Australia. The initiation of this trial follows on from preclinical studies that have shown that PAT-SM6 is able to specifically target bone marrow cells sourced from MM patients (with either advanced or refractory disease), confirming the presence of the target on these cells. In addition, treatment of primary MM cells isolated from patients or cancer cells lines with PAT-SM6 caused significant cell death in all samples tested. Cell death was also increased by adding complement to the cell cultures resulting in significant complement dependent cytotoxicity (CDC), a well described mechanism of cell death in cancer cells.

A Phase I/IIa open-label multi dose escalation trial in relapsed and multi-resistant patients (N= 10-12 in 3-4 dosing groups) is planned to be undertaken at the University of Würzburg Phase I/II unit. The study is expected to commence in April 2012, and take approximately 12 months to complete. The design of the trial will allow continual rolling data to become available.

The primary objective of the study is to evaluate the safety and tolerability of escalating doses of PAT-SM6 in relapsed multiple myeloma patients. The secondary objective is to measure efficacy as determined by a series of well-established laboratory assays.

Each subject will receive several doses of PAT-SM6 in two cycles, except patients who show definite signs of progressive disease. If a patient shows a partial response, Patrys will likely discuss with the Data and Safety Monitoring Board at the University of Würzburg the possibility of patients receiving additional cycles of treatment.

German consultants Nuvisan Pharma Services have been engaged to assist with the ethics application to the *Paul-Ehrlich-Institut* (PEI), which oversees the regulatory approval for such trials in Germany.

The trial will be led by investigator Dr Leo Rasche at the Department of Hematology and Oncology, University Hospital of Würzburg, as part of an ongoing collaboration with Patrys. In addition, the trial will be supported by Professor Dr. Hermann Einsele, Director of the Department of Medicine II, University of Würzburg. Professor Dr. Einsele 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.

Professor Dr. 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."

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. At present several monoclonal antibodies are in development for multiple myeloma but none have been approved. It is likely any therapeutic would be used as part of a combination therapy.

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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 melanoma, PAT-SM6 has shown particularly strong promise. In October 2010, Patrys initiated a human clinical trial to evaluate PAT-SM6 as a therapy for melanoma. To date, the second group of patients has been treated and Patrys received approval to progress the clinical trial. Significantly, no safety issues have been observed or reported for any patients treated, to date, with PAT-SM6. Additionally, recent analysis of tumour samples from two patients treated with PAT-SM6 found that the antibody had penetrated into the tumour biopsies, even though the doses were substantially below the anticipated therapeutic levels. The clinical trial is taking place at the Royal Adelaide Hospital Cancer Centre and associated Pain and Anaesthesia Research Clinic and the Princess Alexandra Hospital, Brisbane. Patrys has filed patent applications to cover the PAT-SM6 antibody molecule, disease target, and the mechanism of action.

About Multiple Myeloma:

Of the approximately 1,200 Australians who are diagnosed with multiple myeloma each year, almost all are older than 40 years. Multiple myeloma is most common in people aged 60 years and older, and men are affected more often than women. In the United States, an estimated 20,520 adults will be diagnosed annually with multiple myeloma. It is estimated that 10,610 deaths from this disease will occur this year. The five-year survival rate (percentage of people who survive at least five years after the cancer is detected, excluding those who die from other diseases) of people with multiple myeloma is about 39%. However, several factors affect an individual's survival, such as the person's age and overall health.