



ASX & Media Release

## Patrys Releases Details of PAT-SM6 & Carfilzomib Clinical Trial

- **PAT-SM6 to be used in combination with carfilzomib and dexamethasone**
- **Phase Ib/IIa trial expected to commence end of 2014 and recruitment to take 15-18 months**
- **To be conducted at two leading University clinics in Germany**

**Melbourne, Australia; 25 August, 2014:** Patrys Limited (**ASX: PAB**), a clinical stage biotechnology company is pleased to release details of the planned PAT-SM6, carfilzomib and dexamethasone Phase Ib/IIa clinical trial.

The primary endpoint of the trial is to evaluate the safety and tolerability of PAT-SM6, given in combination with carfilzomib and dexamethasone in patients with multiple myeloma (MM) who are refractory and/or intolerant to bortezomib, a currently-marketed proteasome inhibitor. Secondary endpoints of the trial will include the overall response rate, duration of response, time to progression and a series of well-established laboratory assays will measure immunological and disease parameters.

The study will be a single-arm study with a two stage design: after testing the drug combination on nine patients in the first stage, the trial will be terminated if two or fewer patients respond (a partial response or better). If the trial goes to the second stage, a total of twenty four patients will be treated. This design will allow for statistical analyses to be made and a determination as to whether the combination of PAT-SM6, carfilzomib and dexamethasone is superior to carfilzomib and dexamethasone alone.

Each patient will be treated with up to four cycles of PAT-SM6 (6mg/kg/dose) in combination with carfilzomib (20-27mg/m<sup>2</sup>) and dexamethasone (40 mg). Each cycle will consist of three doses of PAT-SM6, six doses of carfilzomib and four doses of dexamethasone administered over a one month period. Patients will be followed up for a period of six months.

This phase Ib/IIa trial is expected to commence at the end of 2014 with all patients being recruited within 15-18 months. As with Patrys' previous and successful PAT-SM6 MM clinical trial, this study will be conducted under the leadership of Professor Hermann Einsele and Dr. Leo Rasche at the Department of Haematology and Oncology, University Hospital of Würzburg, Germany. In addition, the Technical University of Dresden, Germany will also be recruiting MM patients into the study.

Currently, the GMP manufacturing of PAT-SM6, required for this trial, is progressing well and discussions with Onyx (a subsidiary of Amgen) in relation to the trial are ongoing. The trial protocol has been approved by the Onyx Clinical Trial Review Committee (OCTRC) and Onyx remains committed to providing carfilzomib for the study. In addition, Patrys has submitted the required documents to the Paul Ehrlich Institut (PEI) in Germany for the first stage of the regulatory review process.

Professor Hermann Einsele said: "Here in Würzburg we are very excited to be, once again, leading Patrys' clinical trial programme. In our clinic, we see many patients with relapsed MM and new treatment strategies for these patients are urgently required. With support from Onyx, we have



designed a clinical trial that will enable us to test the unique combination of PAT-SM6 and carfilzomib. We are now all working hard together to complete the trial preparation and to get the study underway.”

Patrys’ CEO, Dr. Marie Roskrow added: “With several international parties involved, discussions and decisions around our next PAT-SM6 clinical trial have taken considerable time and effort. We are confident that we have designed a smart clinical trial and believe that the combination of PAT-SM6 and carfilzomib will yield some exciting results in this difficult-to-treat patient group.”

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**About Patrys Limited:**

Based in Melbourne, Australia, Patrys (ASX: PAB) is focused on the development of natural human antibodies as therapies for cancer and other major diseases. Patrys has a deep pipeline of anti-cancer natural human antibodies that enable both internal development and partnering opportunities. More information can be found at [www.patrys.com](http://www.patrys.com)

**About PAT-SM6:**

PAT-SM6 is a natural human IgM antibody which has been shown to have potent anti-cancer properties in a large number of laboratory and animal studies. More specifically, Patrys has 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, patient age, gender or disease stage. Patrys has filed patent applications to cover the PAT-SM6 antibody molecule, disease target and the mechanism of action. Patrys’ PAT-SM6 has shown convincing evidence of potential therapeutic benefit in the recently completed Phase I/IIa clinical trial in patients with relapsed and refractory multiple myeloma. PAT-SM6 has been granted orphan drug status in Europe and the USA for multiple myeloma. Patrys has also successfully completed a Phase I clinical trial to evaluate PAT-SM6 as a therapy for melanoma. Patrys is now preparing for the next clinical trial a combination study of PAT-SM6 and carfilzomib.

**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 220,000 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 Kyprolis (carfilzomib) with combined net sales greater than US\$8 Billion in 2013.