

ASX & Media Release

## Patrys Progresses PAT-SM6 Melanoma Trial

- **Patrys recruiting final patient treatment group**
- **No safety issues reported in any patients treated to date**

**Melbourne, Australia; 25 July, 2011:** Patrys Limited (ASX: PAB; “the Company”), a clinical stage biopharmaceutical company, is pleased to provide an update on the progress of its PAT-SM6 melanoma clinical trial. This trial is designed to assess the safety and tolerability of the antibody treatment.

The Royal Adelaide Hospital (RAH) is currently recruiting the third and final group of patients. Significantly, no safety issues have been observed or reported for any patients treated, to date, with PAT-SM6.

“We are now confident in recruiting the final patients quickly to enable completion of the clinical trial. With no major adverse safety events reported to date, this final phase is an exciting step for the company,” said Patrys CEO, Dr Marie Roskrow.

Under the trial design three different dosages will be evaluated in three groups of patients. The trial targets patients with a particular form of the disease called “in-transit” melanoma. This cancer is limited to a single limb and has usually undergone multiple treatments prior to the PAT-SM6 trial.

By recruiting patients with in-transit disease, Patrys can collect tissue samples to study the effects of PAT-SM6 on the tumours, although in line with standard industry practice the primary aim of this study is to measure the safety and tolerability of the drug.

As a secondary objective, the trial will also examine multiple secondary endpoints aimed at preliminary measuring of the anti-tumour activity of PAT-SM6, which will be examined comprehensively in later stage trials.

PAT-SM6 is a natural human antibody that has shown promise as a potential treatment for multiple types of cancer including melanoma. It is the first reported clinical product to target an important protein on the surface of cancer cells called GRP78 that plays a number of key roles in cancer cell survival, growth and metastasis.

Melanoma is a very serious global medical problem, with an expected doubling of incidence every 15 years. Australia has the highest rate of melanoma in the world, where nearly 10,000 cases are diagnosed each year. Current treatments for metastatic melanoma are largely ineffective, resulting in a five year survival rate of just 16%.

- Ends -

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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. Patrys has a deep pipeline of internal development candidates and additional products that are the subject of a collaboration agreement with a larger industry partner. 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 melanoma, 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. In October 2010, Patrys initiated a human clinical trial to evaluate PAT-SM6 as a therapy for melanoma. To date, the first group of patients has been treated and Patrys received approval to progress the clinical trial. The clinical trial is taking place at the Royal Adelaide Hospital (RAH) Cancer Centre and associated Pain and Anaesthesia Research Clinic.

**About GRP78:**

Patrys clinical candidate PAT-SM6 binds to a form of Glucose-regulated protein 78 (GRP78), which is expressed on the surface of cancer cells but not detected on the surface of healthy cells. Once bound, the PAT-SM6/GRP78 complex is then internalised into cancer cells inducing apoptosis and cell death. The potential of GRP78 as a target for cancer therapy is supported by extensive third party literature that has reported several roles played by GRP78 with respect to promoting tumour proliferation, tumour survival, metastases and resistance to a wide variety of existing anti-cancer therapies. As a result, GRP78 expression has been correlated with an adverse prognosis in melanoma, breast, lung, gastric, hepatocellular and prostate cancer, and drug resistance in breast cancer. Given GRP78's reported roles with respect to several cancers, a molecule such as PAT-SM6 presents a promising anti-cancer treatment to the extent it interferes with the function of GRP78 in cancer.

### **Appendix: PAT-SM6 Human Clinical Trial - Melanoma**

**Approval:** Approval for this trial was granted by the Human Ethics Committee of the Royal Adelaide Hospital on 30 July 2010 and notification given to the Australian regulatory body, the Drug and Safety Evaluation Branch of the Therapeutic Goods Administration (TGA). The trial will be conducted under the TGA's Clinical Trial Notification (CTN) scheme.

**Global Standards:** The trial will be conducted in accordance with the principles of the International Conference on Harmonization (ICH), which incorporate standards of conduct for clinical trials that are essentially uniform for all the major regulatory agencies world-wide, including the United States FDA and Australia's TGA.

**Trial Title:** A Single Dose, Dose Escalating, Phase I Clinical Trial of PAT-SM6 Monoclonal Antibody in Patients with Recurrent In-Transit Cutaneous Melanoma

**Primary Objectives:** Establish the safety profile of a single dose of the anti-GRP78 monoclonal antibody PAT-SM6 in patients with recurrent in-transit cutaneous melanoma

**Major Secondary Objectives:**

- Describe the pharmacokinetics of PAT-SM6
- Screen for the development of patient antibodies against PAT-SM6 (immunogenicity)
- Explore the anti-tumour activity of PAT-SM6
- Assess the pharmacodynamic effect(s) of PAT-SM6 in patient tumour samples
- Identify potential predictors (biomarkers) of therapeutic efficacy and/or safety

**Method:** This trial is a multicentre, open-label, dose-escalation, Phase I study. Patients will receive a single dose of PAT-SM6 intravenously, followed 96 hours later by collection of cutaneous tumour tissue.