

Princess Alexandra Hospital Joins PAT-SM6 Melanoma Trial

- Expansion of clinical trial program for PAT-SM6 to two active recruitment centres
- Ensures patient enrolment progress

Melbourne, Australia; 19 September, 2011: Patrys Limited (ASX: PAB; "the Company"), today announced the initiation of a second clinical centre, Princess Alexandra Hospital based in Queensland, in its Phase I clinical trial of anti-cancer antibody PAT-SM6 for the treatment of melanoma.

Princess Alexander Hospital joins the Royal Adelaide Hospital, which is currently recruiting the third group of patients. 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.

Dr Marie Roskrow, CEO said: "We have recently announced that the third cohort is open for recruitment, with an additional centre involved in the study this should enable us to advance the study quickly. As the trial progresses it is also important to have additional centres ready to assist in the next phase of testing for PAT-SM6."

Associate Professor Mark Smithers, lead investigator for the trial at Princess Alexandra Hospital added: "We are pleased to support this trial at Princess Alexandra Hospital and offer patients a trial that is investigating a new treatment for the very difficult problem of recurrent melanoma."

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.

- Ends -

For further information, please contact:

Patrys Limited: Dr. Marie Roskrow Chief Executive Officer P: +61 3 9670 3273 info@patrys.com Patrys IR: Rebecca Wilson Buchan Consulting P: 0417 382 391 rwilson@bcq.com.au Patrys Media: Tom Donovan Buchan Consulting P: +61 3 9866 4722 tdonovan@bcq.com.au

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 <u>www.patrys.com</u>.



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.

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

<u>Approval</u>: Approval for this trial was granted by the Human Ethics Committee of the Royal Adelaide Hospital on 30 July 2010 and by the Human Research Ethics Committee of the Princess Alexandra Hospital, Brisbane on 15 September 2011. Notification was given to the Australian regulatory body, the Drug and Safety Evaluation Branch of the Therapeutic Goods Administration (TGA). The trial has been conducted under the TGA's Clinical Trial Notification (CTN) scheme.

<u>Global Standards</u>: The trial has been 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.

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

<u>Primary Objectives:</u> 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

<u>Method</u>: 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.