

ASX & Media Release

## Clinical Trial Successfully Completed in PAT-SM6 for Melanoma

- **Highest dose levels shown to be safe**
- **Full trial results on track to be reported by end 1Q 2012**
- **Supports the continued clinical development of PAT-SM6**

**Melbourne, Australia; 9 February, 2012:** Patrys Limited (ASX: PAB; “the Company”), a clinical stage biopharmaceutical company, is pleased to advise that the treatment of patients has now been completed in the Phase I trial of the Company’s PAT-SM6 anti-cancer antibody for the treatment of melanoma.

The primary trial objective was to establish safety and tolerability. No significant safety issues were observed or reported for any patients treated with PAT-SM6.

The secondary trial objective is to examine multiple secondary endpoints aimed at measuring the anti-tumour activity of PAT-SM6. Patrys expects the full trial data to be available by the end of March.

In August 2011, Patrys reported that 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.

“We look forward to reporting, in detail, a complete data set from all of the treated patients by the end of the first quarter of 2012. The fact that we have hit the primary endpoint of the trial is very encouraging with our novel PAT-SM6 anti-cancer antibody and we are now able to move forward confidently with planning of our next PAT-SM6 clinical trial for patients with the blood cancer, multiple myeloma,” said Dr Marie Roskrow, Patrys’ Chief Executive Officer.

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 -**

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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 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. The clinical trial took place at the Royal Adelaide Hospital Cancer Centre and associated Pain and Anaesthesia Research Clinic and the Princess Alexandra Hospital in Queensland and was completed in February 2012.

**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 was conducted under the TGA's Clinical Trial Notification (CTN) scheme.

Global Standards: The trial was 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.